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Federal Register

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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 161

[Docket No. APHIS–2017–0065]

RIN 0579–AE40

National Veterinary Accreditation Program; Correction

AGENCY: Animal and Plant Health Inspection Service, Agriculture (USDA).

ACTION: Correcting amendment.

SUMMARY: In a final rule that was published in the *Federal Register* on February 25, 2020, and effective on March 26, 2020, we amended the regulations governing the National Veterinary Accreditation Program by, among other things, replacing all instances of the term “Veterinarian-in-Charge” with the term “Veterinary Official.” However, we inadvertently left two instances of the term “Veterinarian-in-Charge” in the regulations. This document corrects that oversight in the final rule.

DATES: Effective July 13, 2020.

FOR FURTHER INFORMATION CONTACT: Dr. Todd Behre, Coordinator, National Veterinary Accreditation Program; National Animal Disease Traceability and Veterinary Accreditation Center, APHIS Veterinary Services; (518) 281–2157; todd.h.behre@usda.gov.

SUPPLEMENTARY INFORMATION: On February 25, 2020, we published in the *Federal Register* (85 FR 10562–10565, Docket No. APHIS–2017–0065) a final rule that amended the National Veterinary Accreditation Program regulations in 9 CFR parts 160, 161, and 162. Among other changes to these regulations, we replaced the term “Veterinarian-in-Charge” with the term “Veterinary Official” throughout. However, in § 161.1(e)(4), we inadvertently left two instances of

“Veterinarian-in-Charge” unchanged. This document corrects that error.

List of Subjects in 9 CFR Part 161

Reporting and recordkeeping requirements, Veterinarians.

Accordingly, we are amending 9 CFR part 161 as follows:

PART 161—REQUIREMENTS AND STANDARDS FOR ACCREDITED VETERINARIANS AND SUSPENSION OR REVOCATION OF SUCH ACCREDITATION

■ 1. The authority citation for part 161 continues to read as follows:

Authority: 7 U.S.C. 8301–8317; 15 U.S.C. 1828; 7 CFR 2.22, 2.80, and 371.4.

§ 161.1 [Amended]

■ 2. In § 161.1, paragraph (e)(4) introductory text is amended by removing the words “Veterinarian-in-Charge” both times they appear and adding the words “Veterinary Official” in their place.

Done in Washington, DC, this 22nd day of June 2020.

Mark Davidson,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2020–13920 Filed 7–10–20; 8:45 am]

BILLING CODE 3410–34–P

BUREAU OF CONSUMER FINANCIAL PROTECTION

12 CFR Part 1041

Payday, Vehicle Title, and Certain High-Cost Installment Loans; Ratification of Payment Provisions

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Ratification.

SUMMARY: The Bureau of Consumer Financial Protection (Bureau), through its Director, is ratifying certain provisions of its November 17, 2017 rule regarding payday, vehicle title, and certain high-cost installment loans.

DATES: This ratification is issued on July 13, 2020 and relates back to the Rule published on November 17, 2017.

FOR FURTHER INFORMATION CONTACT: Christopher Shelton, Counsel, Legal Division, at 202–435–7700. If you require this document in an alternative

electronic format, please contact *CFPB_Accessibility@cfpb.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

The Bureau was established by the Consumer Financial Protection Act of 2010 (CFPA).¹ Section 1011(c)(3) of the CFPA provided that the President may remove the Director of the Bureau only for inefficiency, neglect of duty, or malfeasance in office.²

The Bureau’s rule regarding Payday, Vehicle Title, and Certain High-Cost Loan Installments (2017 Final Rule or Rule)³ contained two primary components: (1) Mandatory underwriting provisions requiring lenders to assess borrowers’ ability to repay before making covered loans;⁴ and (2) payments provisions governing lenders’ withdrawing payments for covered loans from consumers’ bank accounts.⁵

On June 29, 2020, the Supreme Court held in *Seila Law LLC v. CFPB* that the CFPA’s removal provision violates the separation of powers.⁶ The Court further held that “the CFPB Director’s removal protection is severable from the other statutory provisions bearing on the CFPB’s authority. The agency may therefore continue to operate, but its Director, in light of our decision, must be removable by the President at will.”⁷ “The only constitutional defect we have identified in the CFPB’s structure is the Director’s insulation from removal.”⁸

The Bureau is separately issuing a rule that rescinds the mandatory underwriting provisions of the 2017 Final Rule. That rule does not affect the separate payments provisions, and this ratification is independent of that rule.

II. Ratification

The Bureau, through its Director, hereby affirms and ratifies the payment provisions⁹ of the 2017 Final Rule.

¹ Public Law 111–203, title X, 124 Stat. 1376, 1955–2113 (2010).

² 12 U.S.C. 5491(c)(3).

³ 82 FR 54472 (Nov. 17, 2017).

⁴ 12 CFR 1041.4–1041.6, 1041.10, 1041.11, 1041.12(b)(1)–(3).

⁵ 12 CFR 1041.2, 1041.3, 1041.7–1041.9, 1041.12(a), (b) introductory text, (b)(4)–(5), 1041.13.

⁶ 591 U.S.—(2020) (slip op.).

⁷ *Id.* at 3.

⁸ *Id.* at 32.

⁹ 12 CFR 1041.2, 1041.3, 1041.7–1041.9, 1041.12(a), (b) introductory text, (b)(4)–(5), 1041.13.

The Bureau's Director is familiar with the payment provisions and has also conducted a further evaluation of them for purposes of this ratification. Based on the Director's evaluation of the payment provisions, it is the Director's considered judgment that they should be ratified.¹⁰

Dated: July 7, 2020.

Kathleen L. Kraninger,

Director, Bureau of Consumer Financial Protection.

[FR Doc. 2020-14937 Filed 7-10-20; 8:45 am]

BILLING CODE 4810-AM-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2018-0180; Project Identifier 2017-CE-043-AD; Amendment 39-21146; AD 2020-13-01]

RIN 2120-AA64

Airworthiness Directives; Daher Aircraft Design, LLC (Type Certificate Previously Held by Quest Aircraft Design, LLC), Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all Daher Aircraft Design, LLC (type certificate previously held by Quest Aircraft Design, LLC), Model KODIAK 100 airplanes. This AD was prompted by reports of cracks found in certain nose landing gear (NLG) forks. This AD requires a one-time inspection to determine if an affected NLG fork is installed, repetitive inspections of the affected NLG fork for cracks, repetitive inspections of the shimmy damper bracket for looseness, and of the shimmy damper system for damaged components if an affected NLG fork is installed, and rework/replacement of parts as necessary. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective August 17, 2020.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of August 17, 2020.

¹⁰In ratifying the payment provisions, the Bureau ratifies the procedural steps that were necessary to issue the payment provisions, including the decision to propose the payment provisions for public comment. See 81 FR 47863 (proposed July 22, 2016).

ADDRESSES: For service information identified in this final rule, contact Kodiak Aircraft Company, Inc., 1200 Turbine Drive, Sandpoint, Idaho 83864; phone: (208) 263-1111 or 1 (866) 263-1112; email: KodiakCare@daher.com; internet: <http://Kodiak.aero/support>. You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call 816-329-4148. It is also available on the internet at <https://www.regulations.gov> by searching for and locating Docket No. FAA-2018-0180.

Examining the AD Docket

You may examine the AD docket on the internet at <https://www.regulations.gov> by searching for and locating Docket No. FAA-2018-0180; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the regulatory evaluation, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT:

Wade Sullivan, Aerospace Engineer, Airframe Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206-231-3530; email: Wade.Sullivan@faa.gov.

SUPPLEMENTARY INFORMATION:

Discussion

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all Quest Aircraft Design, LLC (type certificate now held by Daher Aircraft Design, LLC), Model KODIAK 100 airplanes. The NPRM published in the **Federal Register** on March 8, 2018 (83 FR 9820). The NPRM was prompted by reports of cracks on the NLG fork on Model KODIAK 100 airplanes. The NPRM proposed to require a one-time inspection to determine if an affected NLG fork is installed, repetitive inspections of the affected NLG fork for cracks, repetitive inspections of the shimmy damper bracket for looseness if an affected NLG fork is installed, and rework/replacement of parts as necessary. The FAA is issuing this AD to prevent separation of the NLG fork and consequent reduced control on landing. If the NLG fork separates on an

unimproved surface, the risk of the NLG digging in and the airplane overturning on the ground increases.

Since the FAA issued the NPRM, the type certificate holder for the Model KODIAK 100 airplane changed from Quest Aircraft Design, LLC (Quest), to Daher Aircraft Design, LLC. This final rule reflects that change and updates the contact information to obtain service documentation.

Comments

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

Request To Revise Proposed AD To Lessen Economic Impact

Quest requested numerous changes to paragraphs (h), (i), and (j) of the proposed AD. In support, Quest stated that these changes would address all sources of shimmy and lessen the economic impact to operators in international locations where nondestructive testing (NDT) inspection methods are less accessible.

First, Quest requested that the FAA change paragraphs (h)(1) and (i)(1) of the proposed AD to require the initial inspections only if there is shimmy. Quest stated that its analysis and review of the NLG fork determined that extended shimmy with the existing design (type A NLG fork) could result in fatigue cracks at the locations reported.

The FAA disagrees with this request because there is no regulatory requirement for all pilots to report a nosewheel shimmy event. If the initial inspections were conditional on reported shimmy events, the unsafe condition would go unaddressed each time a pilot forgot or neglected to report an event.

Quest also requested that the FAA revise the service information that would be required throughout the proposed AD to allow later revisions.

The FAA disagrees with this request. Requiring the use of a service document that does not yet exist at the time an AD is published violates 1 CFR 51.1(f), regarding approval by the Director of the Federal Register of a publication incorporated by reference. In order for operators to use later revisions of a referenced document (issued after the publication of the AD), either the AD must be revised to reference the specific later revisions, or operators must request approval to use a later revision as an alternative method of compliance (AMOC) using the procedures in paragraph (l) of this AD.

Quest requested that the FAA revise paragraph (h)(2) of the proposed AD to remove the identification of the replacement part so that replacement of a cracked NLG fork is not limited to NLG fork P/N 100-410-7013 (type B).

The FAA disagrees. The type B NLG fork, P/N 100-410-7013, is the only replacement option that has been shown to address the unsafe condition. The FAA disagrees with relying solely on the repetitive inspections without requiring replacement with the type B NLG fork if a crack is found. If a different option provides an acceptable level of safety, an operator may request an AMOC using the procedures in paragraph (l) of this AD.

Quest requested that the FAA revise paragraph (i)(1) of the proposed AD to change the requirement to inspect the shimmy damper bracket for looseness using revision 21 of the maintenance manual to a requirement to perform the nosewheel shimmy system troubleshooting procedure in revision 24 (or later) of the maintenance manual. In support of this request, Quest stated that shimmy can result from a wide range of factors, and thus a less focused procedure is more appropriate.

The FAA disagrees with this request. The FAA has determined that the procedures to inspect the shimmy damper bracket and replace damaged components adequately address the unsafe condition. Performing the entire nosewheel shimmy system troubleshooting procedure in Revision 24 goes beyond what is required and is not necessary to address the unsafe condition.

Quest further requested that the FAA revise paragraph (j) of the proposed AD to require replacement of the NLG fork using the procedures in the maintenance manual, instead of the procedures in Quest Field Service Instruction FSI-147.

The FAA partially agrees. Replacing an NLG fork with a type B NLG fork may be accomplished using the Quest maintenance manual or other standard maintenance practices. The FAA has changed paragraph (j) of this AD accordingly.

Request To Extend the Repetitive Inspection Intervals

Quest, New Tribes Mission (Papua New Guinea) Ltd (New Tribes Mission), and SIL Aviation requested that the FAA extend the repetitive inspection intervals for the NDT inspection of the NLG fork. In the NPRM, the FAA proposed a 100-hour TIS interval; the commenters requested an interval ranging from 200 to 1,000 hours TIS. According to New Tribes Mission,

extending the repetitive interval would align with other scheduled Kodiak inspection items and still provide a measure of assurance that no cracks are forming, while reducing labor time and costs and increasing aircraft availability for operators. Quest stated that the 30-second duration of a severe shimmy occurrence used in its original analysis was extraordinarily long, and suggested that half that duration would still provide a reasonable and conservative number for analysis and allow increasing the repetitive inspection interval to 200 hours TIS.

The FAA agrees with the analysis supporting an increase in the repetitive inspection intervals to 200 hours TIS and has revised paragraphs (h)(1) and (i)(1) of this AD accordingly. The FAA has determined there is insufficient data to support increasing the repetitive inspection intervals beyond 200 hours TIS. The FAA will consider a further extension of this repetitive interval, via further rulemaking or approval of an AMOC, if analysis of the nosewheel shimmy and the effect of the NLG gravel deflectors shows that safety would be ensured by a longer interval.

Request To Extend Repetitive Interval Based on Shimmy Documentation

Quest requested that the FAA allow a longer repetitive inspection interval of 800 hours TIS for operators that implement a shimmy-occurrence documentation procedure and where no severe shimmy (longer than 3 seconds per landing) occurs. The commenter suggested that it was important for international operators to include this option in the AD instead of through an AMOC because of the various international regulations and associated complexities in obtaining approvals.

The FAA disagrees with this request. Although the engineering analysis provided by Quest suggests that cracks are more likely to develop in airplanes that experience nosewheel shimmy, there is no regulatory requirement for all pilots to report or record a shimmy event. Even if an operator were to adopt and implement a procedure, there is no reliable way to determine if an airplane has experienced a previous shimmy event. A new owner of an airplane would have no way of determining if the airplane had experienced a shimmy event with the previous owner based on a review of the maintenance records. The FAA has not changed this AD based on this comment.

Request To Limit Applicability to Airplanes With NLG Gravel Deflector

New Tribes Mission and SIL Aviation requested that the FAA limit the

applicability of the proposed AD to airplanes with a supplemental type certificate (STC) for an NLG gravel deflector installed. The commenters stated that the four instances of cracking on the NLG fork were limited to airplanes of the same operator, operated in the same location, with an STC for an NLG gravel deflector installed. New Tribes Mission noted that the extra weight of the gravel deflector could exacerbate the effects of the shimmy. Both commenters stated that other operators in similar locations and conditions, with airplanes that had accumulated more hours TIS and landings but without the gravel deflector installed, have not reported any signs of cracking on airplanes.

The FAA does not agree with this request. Although Quest's analysis suggests that nosewheel shimmy contributes to the cracking, there is insufficient data to make that conclusion specifically for airplanes with the gravel deflector installed. Should Quest complete a shimmy analysis of the effect of the NLG gravel deflectors, the FAA will determine whether to take further rulemaking action.

The FAA has not changed this AD based on this comment.

Request To Allow Credit for Inspections Already Completed

Quest requested that the FAA provide relief from the initial requirement to perform an NDT inspection within 25 hours if an operator has previously complied with the inspection. Quest stated that such operators should not be required to perform another "initial" inspection.

Paragraph (f) of this AD requires compliance unless already done. Thus, the AD already allows operators to take credit for the initial NDT inspection if it is done before the effective date of the AD. Operators must then repeat the inspection at intervals not to exceed 200 hours TIS. No changes to this AD are necessary based on this comment.

Comments Regarding the Type of Inspection

SIL Aviation and New Tribes Mission stated that the NDT inspection methods required by the AD are not readily available and/or are cost prohibitive. SIL Aviation noted that the type of inspection would be very costly to its operation. The FAA infers that these commenters would like the AD to allow the inspection using a different method.

The FAA acknowledges the commenters' concerns about the costs associated with this AD. However, the FAA has determined that the required

actions in this AD are necessary to address the unsafe condition. The FAA considered several possible NDT methods and determined that the inspection options (fluorescent penetrant, dye penetrant, or eddy current inspection) for the inspection required by this AD are the most cost effective and simple to perform in the field while still providing an adequate level of safety. The dye penetrant kits are available from several sources. Under the provisions of paragraph (l) of this AD, operators may request approval of an AMOC for a different inspection method if that method provides the same or higher level of crack detection.

Other Changes to the Proposed AD

In the NPRM, the FAA proposed that paragraph (h)(2) require replacing a cracked NLG fork by following section 5. Instructions in Quest Aircraft Field Service Instruction FSI-147, Revision 00 (not dated), and paragraph (i)(3) require replacing damaged components by following pages 32_110 and 32_111, section 3252, Shimmy Damper, in Chapter 32, Landing Gear, of Quest Aircraft Company Kodiak 100 Maintenance Manual, Revision No. 21, dated February 15, 2017. The FAA has revised paragraphs (h)(2) and (i)(3) in this AD to remove the incorporation by reference of the specified service information to allow the actions to be done using standard maintenance practices.

The FAA has also clarified the proposed requirements in paragraph (i). Paragraph (i)(1) of the proposed AD specified inspecting the shimmy damper bracket for looseness by following pages 32_110 and 32_111, section 3252, Shimmy Damper, found in Chapter 32, Landing Gear, of Quest Aircraft Company Kodiak 100 Maintenance Manual, Revision No. 21, dated February 15, 2017. Section 3252 contains a broader inspection procedure of the shimmy damper system and not only an inspection of the bracket for looseness. Paragraph (i)(3) of the proposed AD then specified corrective action for damaged components in the shimmy damper system as a result of the inspection in paragraph (i)(1). The FAA has revised paragraph (i)(1) in this AD to clarify that the entire inspection of the shimmy damper system is required.

Conclusion

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

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

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

Related Service Information Under 1 CFR Part 51

The FAA reviewed Quest Aircraft Field Service Instruction FSI-147, Revision 00, Release Date January 29, 2018, which provides instructions for inspection and, if necessary, replacement of the NLG fork. The FAA reviewed pages 32_110 and 32_111, section 3252, Shimmy Damper, in Chapter 32, Landing Gear, of Quest Aircraft Company Kodiak 100 Maintenance Manual, Revision No. 21, dated February 15, 2017, which contains procedures for inspecting the shimmy damper system. The FAA also reviewed Quest Aircraft Field Service Instruction FSI-146, Revision 00, Release Date April 18, 2017, which provides instructions for modifying the shimmy damper attach bracket. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the ADDRESSES section.

Costs of Compliance

The FAA estimates that this AD affects 116 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Determine if type A or type B NLG fork is installed.	1 work-hour × \$85 per hour = \$85	Not applicable	\$85	\$9,860

The FAA estimates the following costs to do any necessary additional inspections, replacements, and modifications that would be required

based on the results of the NLG fork type determination. The FAA has no way of determining the number of airplanes that might need these

inspections, replacements, and modifications:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Inspection of the NLG fork for cracks	4 work-hours × \$85 per hour = \$340	Not applicable	\$340 per inspection cycle.
Replacement of the NLG fork	4 work-hours × \$85 per hour = \$340	\$7,002.36	\$7,342.36.
Inspection of the shimmy damper system including the bracket.	1 work-hour × \$85 per hour = \$85	Not applicable	\$85 per inspection cycle.
Rework of the shimmy damper bracket	4 work-hours × \$85 per hour = \$340	\$127.33	\$467.33.

The FAA has received no definitive data that would enable the agency to provide cost estimates for replacing damaged components specified in this AD.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I,

section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

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

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

- (1) Is not a “significant regulatory action” under Executive Order 12866,
- (2) Will not affect intrastate aviation in Alaska, and
- (3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

- 2. The FAA amends § 39.13 by adding the following new airworthiness directive:

2020–13–01 Quest Aircraft Design, LLC:
Amendment 39–21146; Docket No. FAA–2018–0180; Project Identifier 2017–CE–043–AD.

(a) Effective Date

This airworthiness directive (AD) is effective August 17, 2020.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Daher Aircraft Design, LLC (type certificate previously held by Quest Aircraft Design, LLC), Model KODIAK 100 airplanes, all serial numbers, certificated in any category.

(d) Subject

Joint Aircraft System Component (JASC)/ Air Transport Association (ATA) of America Code 32, Landing Gear.

(e) Unsafe Condition

This AD was prompted by reports from the manufacturer of fatigue cracks on the nose landing gear (NLG) fork. The FAA is issuing this AD to detect and prevent fatigue cracking of the NLG fork. The unsafe condition, if not corrected, could result in separation of the NLG fork with consequent reduced control on landing. If the NLG fork separates on an unimproved surface, the risk of the NLG digging in and the airplane overturning on the ground increases.

(f) Compliance

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

(g) Inspection for Type of NLG Fork

Within 25 hours time-in-service (TIS) after August 17, 2020 (the effective date of this AD), inspect the airplane to determine if an NLG fork part number (P/N) 100–410–7001 (type A) or an NLG fork P/N 100–410–7013 (type B) is installed. If you determine that an NLG fork P/N 100–410–7013 (type B) is installed during the inspection, no further action is required by this AD. If a review of the maintenance records can identify the P/N NLG fork that is installed, you may use a maintenance records review in lieu of inspecting the airplane to determine if an NLG fork P/N 100–410–7001 (type A) or an NLG fork P/N 100–410–7013 (type B) is installed.

(h) Inspection of the NLG Fork for Cracks

(1) If you determine that an NLG fork P/N 100–410–7001 (type A) is installed during the inspection required by paragraph (g) of this AD, within 25 hours TIS after August 17, 2020 (the effective date of this AD) and thereafter at intervals not to exceed 200 hours TIS, do a fluorescent penetrant, dye penetrant, or open-hole eddy current inspection of the NLG fork for cracks by following section 5. Instructions in Quest Aircraft Field Service Instruction FSI–147, Revision 00, Release Date January 29, 2018.

(2) If you find any cracks of the NLG fork during any inspection required by paragraph (h)(1) of this AD, before further flight, replace the NLG fork with an NLG fork P/N 100–410–7013 (type B). Replacement of the NLG fork with an NLG fork P/N 100–410–7013 (type B) terminates the repetitive inspections required by paragraphs (h)(1) and (i)(1) of this AD.

(i) Inspection of the Shimmy Damper Bracket

(1) If you have not replaced an NLG fork P/N 100–410–7001 (type A) per the initial

inspection and replacement requirements in paragraph (h) of this AD, then within 25 hours TIS after August 17, 2020 (the effective date of this AD) and thereafter at intervals not to exceed 200 hours TIS (until the NLG fork is replaced with a P/N 100–410–7013 (type B) fork), inspect the shimmy damper bracket for looseness, and inspect the shimmy damper system for damaged (loose, leaking, corroded, or worn) components, by following pages 32_110 and 32_111, section 3252, Shimmy Damper, found in Chapter 32, Landing Gear, of Quest Aircraft Company Kodiak 100 Maintenance Manual, Revision No. 21, dated February 15, 2017.

(2) If a loose shimmy damper bracket is found during any inspection required by paragraph (i)(1) of this AD, rework the shimmy damper bracket with interference-fit bolts by following Quest Aircraft Field Service Instruction FSI–146, Revision 00, Release Date April 18, 2017. Reworking the shimmy damper bracket with the interference-fit bolts terminates the repetitive inspections required by paragraph (i)(1) of this AD.

(3) If any other damaged components are found in the shimmy damper system during any inspection required by paragraph (i)(1) of this AD, before further flight, replace the damaged components.

(j) Optional Terminating Action

In lieu of the NLG fork and shimmy damper bracket inspections required by paragraphs (h)(1) and (i)(1) of this AD, you may replace the NLG fork P/N 100–410–7001 (type A) with an NLG fork P/N 100–410–7013 (type B). This replacement terminates the inspection requirements of this AD, and no further actions are required.

(k) Restriction of NLG Fork P/N 100–410–7001 (Type A) Installation

Once an NLG fork P/N 100–410–7013 (type B) is installed on an airplane, do not install an NLG fork P/N 100–410–7001 (type A). If an NLG fork P/N 100–410–7013 (type B) is removed from the airplane for any reason (for example, to install floats), you must reinstall an NLG fork P/N 100–410–7013 (type B) when operating with wheels.

(l) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (m) of this AD. Information may also be emailed to: 9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/ certificate holding district office.

(m) Related Information

For more information about this AD, contact Wade Sullivan, Aerospace Engineer, Aerospace Engineer, Airframe Section, FAA,

Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206-231-3530; email: Wade.Sullivan@faa.gov.

(n) Material Incorporated by Reference

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

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

(i) Pages 32_110 and 32_111, section 3252, Shimmy Damper, Chapter 32, Landing Gear, of Quest Aircraft Company Kodiak 100 Maintenance Manual, Revision No. 21, dated February 15, 2017.

(ii) Quest Aircraft Field Service Instruction FSI-146, Revision 00, Release Date April 18, 2017.

Note 1 to paragraph (n)(2)(ii) of this AD: The Release Date is a pen-and-ink addition that appears only on the Revision Notice transmitted with FSI-146.

(iii) Quest Aircraft Field Service Instruction FSI-147, Revision 00, Release Date January 29, 2018.

Note 2 to paragraph (n)(2)(iii) of this AD: The Release Date is a pen-and-ink addition that appears only on the Revision Notice transmitted with FSI-147.

(3) For service information identified in this AD, contact Kodiak Aircraft Company, Inc., 1200 Turbine Drive, Sandpoint, Idaho 83864; phone: (208) 263-1111 or 1 (866) 263-1112; email: KodiakCare@daher.com; internet: <http://Kodiak.aero/support>.

(4) You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329-4148.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email fedreg.legal@nara.gov, or go to <https://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued on June 9, 2020.

Ross Landes,

Deputy Director for Regulatory Operations, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2020-14886 Filed 7-10-20; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2019-1099; Product Identifier 2018-SW-026-AD; Amendment 39-21164; AD 2020-15-01]

RIN 2120-AA64

Airworthiness Directives; Airbus Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for Airbus Helicopters Model EC 155B and EC155B1 helicopters. This AD requires modifying the wiring of the attitude and heading reference system (AHRS) connector. This AD was prompted by a report of wiring of the AHRS contrary to approved design specifications. The actions of this AD are intended to address an unsafe condition on these products.

DATES: This AD is effective August 17, 2020.

The Director of the Federal Register approved the incorporation by reference of certain documents listed in this AD as of August 17, 2020.

ADDRESSES: For service information identified in this final rule, contact Airbus Helicopters, 2701 N Forum Drive, Grand Prairie, TX 75052; telephone 972-641-0000 or 800-232-0323; fax 972-641-3775; or at <https://www.airbus.com/helicopters/services/technical-support.html>. You may view the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N-321, Fort Worth, TX 76177. It is also available on the internet at <https://www.regulations.gov> by searching for and locating Docket No. FAA-2019-1099.

Examining the AD Docket

You may examine the AD docket on the internet at <https://www.regulations.gov> by searching for and locating Docket No. FAA-2019-1099; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the European Aviation Safety Agency (now European Union Aviation Safety Agency) (EASA) AD, any service information that is incorporated by reference, any comments received, and other information. The street address for Docket Operations is U.S. Department of

Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT:

George Schwab, Aviation Safety Engineer, Safety Management Section, Rotorcraft Standards Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone 817-222-5110; email george.schwab@faa.gov.

SUPPLEMENTARY INFORMATION:

Discussion

On February 28, 2020, at 85 FR 11879, the FAA published a notice of proposed rulemaking (NPRM) in the **Federal Register**, which proposed to amend 14 CFR part 39 by adding an AD that would apply to Airbus Helicopters Model EC 155B and EC155B1 helicopters. The NPRM proposed to require modifying the wiring at connector 11 ALPHA based on the helicopter configuration and in accordance with specified portions of the applicable service information. The proposed requirements were intended to correct the AHRS wiring, and prevent the display of misleading attitude and vertical speed information and subsequent loss of control of the helicopter in instrument meteorological conditions (IMC).

The NPRM was prompted by EASA AD No. 2018-0069, dated March 26, 2018, issued by EASA, which is the Technical Agent for the Member States of the European Union, to correct an unsafe condition for Airbus Helicopters Model EC 155 B and EC 155 B1 helicopters. EASA advises that the AHRS1 and AHRS2 on Model EC 155-series helicopters use the same flight/ground signal contrary to the approved design specification, which requires the AHRS1 and AHRS2 to use independent signals to ensure redundancy. EASA states that if AHRS1 and AHRS2 both receive an incorrect "ground" status due to a single failure while in flight, it will generate an error in the computation of the attitude and vertical speed and, as a result, an incorrect display of these indications to the flight crew. EASA advises that this condition, if not corrected, could lead to erroneous attitude and vertical speed indications, resulting in increased workload for the flight crew and reduced control of the helicopter during flight in IMC.

Accordingly, the EASA AD requires modifying the connection of connector 11 ALPHA, and based on the helicopter configuration, also modifying the wiring to connector 11 ALPHA.

Comments

The FAA gave the public the opportunity to participate in developing this final rule. The FAA received comments from one commenter. The commenter commented in support of the NPRM.

FAA's Determination

The FAA has reviewed the relevant information and determined that an unsafe condition exists and is likely to exist or develop on other helicopters of these same type designs and that air safety and the public interest require adopting the AD requirements as proposed.

Differences Between This AD and the EASA AD

The compliance time for the EASA AD is within 7 or 12 months depending on helicopter configuration. The compliance time for this AD is before further flight in IMC or within 660 hours time-in-service, whichever occurs first.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Airbus Helicopters Alert Service Bulletin (ASB) No. EC155–34A033, Revision 2, dated January 30, 2018. This service information specifies re-allocating the electronic board output connections by modifying the wiring of connector 11 ALPHA for helicopters with modification (MOD) 0722B51 installed and modifying the wiring to connector 11 ALPHA for those helicopters that also have a combined voice and flight data recording system (MOD 0731B89) installed.

The FAA also reviewed Airbus Helicopters ASB No. EC155–34A037, Revision 0, dated February 19, 2018. This service information specifies installing MOD 0722B51 by modifying the wiring of connector 11 ALPHA to separate the flight/ground information so the left-hand landing gear flight information is also used by the automatic pilot system as well as but separately from the right-hand landing gear flight information. This service information also specifies re-allocating the electronic board output connections by modifying the wiring of connector 11 ALPHA.

This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Other Related Service Information

The FAA also reviewed Airbus Helicopters ASB No. EC155–34A033, Revision 0, dated July 19, 2017, and

Airbus Helicopters ASB No. EC155–34A033, Revision 1, dated October 9, 2017. Revisions 0 and 1 of this service information contain the same procedures for modifying the wiring as Revision 2. However, Revision 1 clarifies the applicable helicopter configurations and updates the post-modification testing procedures, and Revision 2 clarifies the post-modification test procedures and updates a figure.

Costs of Compliance

The FAA estimates that this AD affects 17 helicopters of U.S. Registry. The FAA estimates that operators may incur the following costs in order to comply with this AD. Labor costs are estimated at \$85 per work-hour.

Modifying the wiring takes about 4 work-hours and parts cost about \$20 for an estimated cost of \$360 per helicopter and \$6,120 for the U.S. fleet.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on helicopters identified in this rulemaking action.

Regulatory Findings

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

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

1. Is not a "significant regulatory action" under Executive Order 12866,
2. Will not affect intrastate aviation in Alaska, and
3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities

under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2020–15–01 Airbus Helicopters:

Amendment 39–21164; Docket No. FAA–2019–1099; Product Identifier 2018–SW–026–AD.

(a) Applicability

This AD applies to Airbus Helicopters Model EC 155B and EC155B1 helicopters, certificated in any category.

(b) Unsafe Condition

This AD defines the unsafe condition as incorrect wiring of an attitude and heading reference system (AHRS). This condition could result in the display of misleading attitude and vertical speed information, and subsequent loss of control of the helicopter in instrument meteorological conditions (IMC).

(c) Effective Date

This AD becomes effective August 17, 2020.

(d) Compliance

You are responsible for performing each action required by this AD within the specified compliance time unless it has already been accomplished prior to that time.

(e) Required Actions

Before further flight in IMC or within 660 hours time-in-service, whichever occurs first:

(1) For helicopters with wiring change modification (MOD) 0722B51 installed, modify the wiring of connector 11 ALPHA as depicted in Figure 1 of Airbus Helicopters Alert Service Bulletin (ASB) No. EC155–34A033, Revision 2, dated January 30, 2018 (ASB EC155–34A033). If a combined voice and flight data recording system (MOD 0731B89) is installed, also modify the wiring to connector 11 ALPHA as depicted in Figure 2 of ASB EC155–34A033.

(2) For helicopters without wiring change MOD 0722B51 installed, modify the wiring of connector 11 ALPHA as depicted in Figure 1 and Figure 2 of Airbus Helicopters ASB No. EC155–34A037, Revision 0, dated February 19, 2018.

(f) Special Flight Permits

A special flight permit may be issued for operation under visual flight rules only.

(g) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Rotorcraft Standards Branch, FAA, may approve AMOCs for this AD. Send your proposal to: George Schwab, Aviation Safety Engineer, Safety Management Section, Rotorcraft Standards Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone 817-222-5110; email 9-ASW-FTW-AMOC-Requests@faa.gov.

(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, the FAA suggests that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office, before operating any aircraft complying with this AD through an AMOC.

(h) Additional Information

(1) Airbus Helicopters Alert Service Bulletin (ASB) No. EC155-34A033, Revision 0, dated July 19, 2017, and Airbus Helicopters ASB No. EC155-34A033, Revision 1, dated October 9, 2017, which are not incorporated by reference, contain additional information about the subject of this AD. For service information identified in this AD, contact Airbus Helicopters, 2701 N Forum Drive, Grand Prairie, TX 75052; telephone 972-641-0000 or 800-232-0323; fax 972-641-3775; or at <https://www.airbus.com/helicopters/services/technical-support.html>. You may view a copy of the service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N-321, Fort Worth, TX 76177.

(2) The subject of this AD is addressed in European Aviation Safety Agency (now European Union Aviation Safety Agency) (EASA) No. 2018-0069, dated March 26, 2018. You may view the EASA AD on the internet at <https://www.regulations.gov> in Docket No. FAA-2019-1099.

(i) Subject

Joint Aircraft Service Component (JASC) Code: 3420, Attitude and Direction Data System.

(j) Material Incorporated by Reference

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

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

(i) Airbus Helicopters Alert Service Bulletin (ASB) No. EC155-34A033, Revision 2, dated January 30, 2018.

(ii) Airbus Helicopters ASB No. EC155-34A037, Revision 0, dated February 19, 2018.

(3) For Airbus Helicopters service information identified in this AD, contact Airbus Helicopters, 2701 N Forum Drive, Grand Prairie, TX 75052; telephone 972-641-0000 or 800-232-0323; fax 972-641-3775; or at <https://www.airbus.com/helicopters/services/technical-support.html>.

(4) You may view this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N-321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call 817-222-5110.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email fedreg.legal@nara.gov, or go to: <https://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued on July 7, 2020.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2020-14940 Filed 7-10-20; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 97**

[Docket No. 31319 Amdt. No. 3911]

Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This rule establishes, amends, suspends, or removes Standard Instrument Approach Procedures (SIAPs) and associated Takeoff Minimums and Obstacle Departure Procedures (ODPs) for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective July 13, 2020. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of July 13, 2020.

ADDRESSES: Availability of matters incorporated by reference in the amendment is as follows:

For Examination

1. U.S. Department of Transportation, Docket Ops-M30, 1200 New Jersey Avenue SE, West Bldg., Ground Floor, Washington, DC 20590-0001.

2. The FAA Air Traffic Organization Service Area in which the affected airport is located;

3. The office of Aeronautical Navigation Products, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or,

4. The National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email fedreg.legal@nara.gov or go to: <https://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Availability

All SIAPs and Takeoff Minimums and ODPs are available online free of charge. Visit the National Flight Data Center at nfdc.faa.gov to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from the FAA Air Traffic Organization Service Area in which the affected airport is located.

FOR FURTHER INFORMATION CONTACT:

Thomas J. Nichols, Flight Procedures and Airspace Group, Flight Technologies and Procedures Division, Flight Standards Service, Federal Aviation Administration. Mailing Address: FAA Mike Monroney Aeronautical Center, Flight Procedures and Airspace Group, 6500 South MacArthur Blvd., Registry Bldg. 29, Room 104, Oklahoma City, OK 73169. Telephone: (405) 954-4164.

SUPPLEMENTARY INFORMATION: This rule amends Title 14 of the Code of Federal Regulations, Part 97 (14 CFR part 97), by establishing, amending, suspending, or removes SIAPs, Takeoff Minimums and/or ODPs. The complete regulatory description of each SIAP and its associated Takeoff Minimums or ODP for an identified airport is listed on FAA form documents which are incorporated by reference in this amendment under 5 U.S.C. 552(a), 1 CFR part 51, and 14 CFR part 97.20. The applicable FAA forms are FAA Forms 8260-3, 8260-4, 8260-5, 8260-15A, and 8260-15B when required by an entry on 8260-15A.

The large number of SIAPs, Takeoff Minimums and ODPs, their complex nature, and the need for a special format make publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, Takeoff Minimums or ODPs, but instead refer to their graphic depiction on charts printed by publishers of aeronautical

materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP, Takeoff Minimums and ODP listed on FAA form documents is unnecessary. This amendment provides the affected CFR sections and specifies the types of SIAPs, Takeoff Minimums and ODPs with their applicable effective dates. This amendment also identifies the airport and its location, the procedure, and the amendment number.

Availability and Summary of Material Incorporated by Reference

The material incorporated by reference is publicly available as listed in the **ADDRESSES** section.

The material incorporated by reference describes SIAPs, Takeoff Minimums and/or ODPS as identified in the amendatory language for part 97 of this final rule.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP, Takeoff Minimums and ODP as Amended in the transmittal. Some SIAP and Takeoff Minimums and textual ODP amendments may have been issued previously by the FAA in a Flight Data Center (FDC) Notice to Airmen (NOTAM) as an emergency action of immediate flight safety relating directly to published aeronautical charts.

The circumstances that created the need for some SIAP and Takeoff Minimums and ODP amendments may require making them effective in less than 30 days. For the remaining SIAPs and Takeoff Minimums and ODPs, an effective date at least 30 days after publication is provided.

Further, the SIAPs and Takeoff Minimums and ODPs contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these SIAPs and Takeoff Minimums and ODPs, the TERPS criteria were applied to the conditions existing or anticipated at the affected airports. Because of the close and immediate relationship between these SIAPs, Takeoff Minimums and ODPs, and safety in air commerce, I find that notice and public procedure under 5 U.S.C. 553(b) are impracticable and contrary to the public interest and, where applicable, under 5 U.S.C 553(d), good cause exists for making some SIAPs effective in less than 30 days.

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 so minimal.

For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air Traffic Control, Airports, Incorporation by reference, Navigation (Air).

Issued in Washington, DC on June 26, 2020.

Robert C. Carty

Executive Deputy Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, Title 14, Code of Federal Regulations, Part 97 (14 CFR part 97) is amended by establishing, amending, suspending, or removing Standard Instrument Approach Procedures and/or Takeoff Minimums and Obstacle Departure Procedures effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

Effective 13 August 2020

West Memphis, AR, West Memphis Muni, VOR/DME–A, Amdt 6, CANCELLED
Sulphur, LA, Southland Field, VOR/DME–A, Amdt 2, CANCELLED
Norridgewock, ME, Central Maine ARPT of Norridgewock, VOR/DME RWY 3, Amdt 3, CANCELLED
Rockland, ME, Knox County Rgnl, NDB RWY 3, Orig-B, CANCELLED
Rockland, ME, Knox County Rgnl, NDB RWY 31, Orig-E, CANCELLED
South Haven, MI, South Haven Area Rgnl, VOR RWY 23, Amdt 11B, CANCELLED
Siler City, NC, Siler City Muni, VOR–A, Amdt 3, CANCELLED
Bennettsville, SC, Marlboro County Jetport-H E Avent Field, NDB RWY 7, Amdt 5A, CANCELLED
Greenwood, SC, Greenwood County, NDB RWY 27, Amdt 2, CANCELLED

Pickens, SC, Pickens County, VOR/DME–A, Amdt 1, CANCELLED
Burlington/Mount Vernon, WA, Skagit Rgnl, NDB RWY 11, Amdt 5A, CANCELLED
Juneau, WI, Dodge County, NDB RWY 2, Orig, CANCELLED
Madison, WI, Dane County Rgnl-Truax Field, VOR RWY 18, Amdt 1D, CANCELLED
Madison, WI, Dane County Rgnl-Truax Field, VOR RWY 21, Orig-A, CANCELLED
Madison, WI, Dane County Rgnl-Truax Field, VOR RWY 36, Orig-B, CANCELLED
Reedsburg, WI, Reedsburg Muni, VOR–A, Amdt 6, CANCELLED

Effective 10 September 2020

Aniak, AK, Aniak, NDB/DME RWY 29. Amdt 4, CANCELLED
Aniak, AK, Aniak, RNAV (GPS) RWY 29, Amdt 3
Deadhorse, AK, Deadhorse, ILS OR LOC RWY 6, Amdt 4
Deadhorse, AK, Deadhorse, LOC BC RWY 24, Orig
Port Heiden, AK, Port Heiden, ITAWU TWO, Graphic DP
Hollister, CA, Hollister Muni, RNAV (GPS) RWY 31, Amdt 1
Livermore, CA, Livermore Muni, ILS RWY 25R, Amdt 9A
Marina, CA, Marina Muni, RNAV (GPS) RWY 11, Amdt 2
Marina, CA, Marina Muni, RNAV (GPS) RWY 29, Amdt 2
Marina, CA, Marina Muni, VOR RWY 11, Amdt 2A, CANCELLED
Marina, CA, Marina Muni, VOR/DME RWY 29, Amdt 2C, CANCELLED
Monterey, CA, Monterey Rgnl, ILS OR LOC RWY 10R, Amdt 29A
Monterey, CA, Monterey Rgnl, RNAV (GPS) RWY 10R, Amdt 1A
San Jose, CA, Norman Y Mineta San Jose Intl, ILS OR LOC RWY 30L, ILS RYW 30L (SA CAT I), ILS RWY 30L (SA CAT II), Amdt 26
Hayden, CO, Yampa Valley, ILS OR LOC RWY 10, Orig-A
Boca Raton, FL, Boca Raton, RNAV (GPS) Y RWY 23, Amdt 1D
Bloomington/Normal, IL, Central IL Rgnl Arpt At Bloomington-Normal, ILS OR LOC RWY 2, Orig-D
Centralia, IL, Centralia Muni, RNAV (GPS) RWY 36, Amdt 1C
Chicago, IL, Chicago Midway Intl, Takeoff Minimums and Obstacle DP, Amdt 12A
Winnfield, LA, David G Joyce, RNAV (GPS) RWY 9, Orig-C
Baudette, MN, Baudette Intl, ILS OR LOC RWY 30, Amdt 1
Minneapolis, MN, Minneapolis-St Paul Intl/Wold-Chamberlain, LOC RWY 22, Amdt 1C
Minneapolis, MN, Minneapolis-St Paul Intl/Wold-Chamberlain, RNAV (GPS) RWY 22, Amdt 1C
Rush City, MN, Rush City Rgnl, NDB RWY 34, Orig-B
Rush City, MN, Rush City Rgnl, RNAV (GPS) RWY 34, Amdt 1
Thief River Falls, MN, Thief River Falls Rgnl, RNAV (GPS) RWY 4, Orig-A
Warroad, MN, Warroad Intl Memorial, ILS OR LOC RWY 31, Amdt 2
Warroad, MN, Warroad Intl Memorial, NDB RWY 31, Amdt 2A, CANCELLED

Warroad, MN, Warroad Intl Memorial, RNAV (GPS) RWY 13, Amdt 1A
 Warroad, MN, Warroad Intl Memorial, RNAV (GPS) RWY 31, Orig-B
 Ainsworth, NE, Ainsworth Rgnl, RNAV (GPS) RWY 13, Amdt 1
 Ainsworth, NE, Ainsworth Rgnl, RNAV (GPS) RWY 17, Amdt 3
 Ainsworth, NE, Ainsworth Rgnl, RNAV (GPS) RWY 31, Amdt 1
 Ainsworth, NE, Ainsworth Rgnl, RNAV (GPS) RWY 35, Amdt 3
 Jaffrey, NH, Jaffrey Airfield-Silver Ranch, Takeoff Minimums and Obstacle DP, Amdt 1A
 Caldwell, NJ, Essex County, LOC RWY 22, Amdt 4B
 Caldwell, NJ, Essex County, RNAV (GPS) RWY 22, Amdt 2B
 New York, NY, John F Kennedy Intl, RNAV (GPS) Y RWY 13R, Orig-A, CANCELLED
 Penn Yan, NY, Penn Yan, NDB RWY 28, Amdt 6E, CANCELLED
 Guymon, OK, Guymon Muni, Takeoff Minimums and Obstacle DP, Amdt 1A
 Bradford, PA, Bradford Rgnl, VOR RWY 14, Amdt 1, CANCELLED
 Bradford, PA, Bradford Rgnl, VOR/DME RWY 14, Amdt 10, CANCELLED
 Harrisburg, PA, Harrisburg/Capital City, Takeoff Minimums and Obstacle DP, Amdt 5
 Isla De Vieques, PR, Antonio Rivera Rodriguez, Takeoff Minimums and Obstacle DP, Amdt 2A
 Sumter, SC, Sumter, ILS OR LOC RWY 23, Amdt 1A
 Sumter, SC, Sumter, RNAV (GPS) RWY 23, Amdt 1A
 Gladewater, TX, Gladewater Muni, RNAV (GPS) RWY 14, Orig-C
 Kenedy, TX, Kenedy Rgnl, VOR-A, Amdt 7A, CANCELLED
 Blacksburg, VA, Virginia Tech/Montgomery Executive, LOC RWY 13, Amdt 2
 Blacksburg, VA, Virginia Tech/Montgomery Executive, RNAV (GPS) RWY 13, Amdt 3
 Blacksburg, VA, Virginia Tech/Montgomery Executive, RNAV (GPS) RWY 31, Amdt 1
 Blacksburg, VA, Virginia Tech/Montgomery Executive, Takeoff Minimums and Obstacle DP, Amdt 6
 Waynesboro, VA, Eagle's Nest, RNAV (GPS) RWY 6, Amdt 1A
 Waynesboro, VA, Eagle's Nest, RNAV (GPS) RWY 24, Amdt 1A
 Chetek, WI, Chetek Muni-Southworth, RNAV (GPS) RWY 17, Orig-F
 Medford, WI, Taylor County, RNAV (GPS) RWY 27, Orig-A
 Merrill, WI, Merrill Muni, RNAV (GPS) RWY 7, Amdt 1B
 Merrill, WI, Merrill Muni, RNAV (GPS) RWY 25, Amdt 1A
 Rice Lake, WI, Rice Lake Rgnl—Carl's Field, ILS OR LOC RWY 1, Orig-B
 Shell Lake, WI, Shell Lake Muni, RNAV (GPS) RWY 14, Orig-B
 Shell Lake, WI, Shell Lake Muni, RNAV (GPS) RWY 32, Orig-B
 Bluefield, WV, Mercer County, RNAV (GPS) RWY 5, Orig-B
 Wheeling, WV, Wheeling Ohio Co, RNAV (GPS) RWY 3, Amdt 1A

[FR Doc. 2020-15003 Filed 7-10-20; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 31320; Amdt. No. 3912]

Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This rule amends, suspends, or removes Standard Instrument Approach Procedures (SIAPs) and associated Takeoff Minimums and Obstacle Departure Procedures for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide for the safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective July 13, 2020. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of July 13, 2020.

ADDRESSES: Availability of matter incorporated by reference in the amendment is as follows:

For Examination

1. U.S. Department of Transportation, Docket Ops-M30, 1200 New Jersey Avenue SE, West Bldg., Ground Floor, Washington, DC 20590-0001;

2. The FAA Air Traffic Organization Service Area in which the affected airport is located;

3. The office of Aeronautical Navigation Products, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or,

4. The National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email fedreg.legal@nara.gov or go to: <https://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Availability

All SIAPs and Takeoff Minimums and ODPs are available online free of charge. Visit the National Flight Data Center online at nfdc.faa.gov to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from the FAA Air Traffic Organization Service Area in which the affected airport is located.

FOR FURTHER INFORMATION CONTACT:

Thomas J. Nichols, Flight Procedures and Airspace Group, Flight Technologies and Procedures Division, Flight Standards Service, Federal Aviation Administration, Mailing Address: FAA Mike Monroney Aeronautical Center, Flight Procedures and Airspace Group, 6500 South MacArthur Blvd., Registry Bldg. 29, Room 104, Oklahoma City, OK 73169. Telephone: (405) 954-4164.

SUPPLEMENTARY INFORMATION: This rule amends Title 14, Code of Federal Regulations, Part 97 (14 CFR part 97) by amending the referenced SIAPs.

The complete regulatory description of each SIAP is listed on the appropriate FAA Form 8260, as modified by the National Flight Data Center (NFDC)/Permanent Notice to Airmen (P-NOTAM), and is incorporated by reference under 5 U.S.C. 552(a), 1 CFR part 51, and 14 CFR 97.20. The large number of SIAPs, their complex nature, and the need for a special format make their verbatim publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, but refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP contained on FAA form documents is unnecessary. This amendment provides the affected CFR sections, and specifies the SIAPs and Takeoff Minimums and ODPs with their applicable effective dates. This amendment also identifies the airport and its location, the procedure and the amendment number.

Availability and Summary of Material Incorporated by Reference

The material incorporated by reference is publicly available as listed in the **ADDRESSES** section.

The material incorporated by reference describes SIAPs, Takeoff Minimums and ODPs as identified in the amendatory language for part 97 of this final rule.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP and Takeoff Minimums and ODP as amended in the transmittal. For safety and timeliness of change considerations, this amendment incorporates only specific changes contained for each SIAP and Takeoff Minimums and ODP as modified by FDC permanent NOTAMs.

The SIAPs and Takeoff Minimums and ODPs, as modified by FDC permanent NOTAM, and contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these changes to SIAPs and Takeoff Minimums and ODPs, the TERPS criteria were applied only to specific conditions existing at the affected airports. All SIAP amendments in this rule have been previously issued by the FAA in a FDC NOTAM as an emergency action of immediate flight safety relating directly to published aeronautical charts.

The circumstances that created the need for these SIAP and Takeoff Minimums and ODP amendments require making them effective in less than 30 days.

Because of the close and immediate relationship between these SIAPs, Takeoff Minimums and ODPs, and safety in air commerce, I find that notice and public procedure under 5 U.S.C.

553(b) are impracticable and contrary to the public interest and, where applicable, under 5 U.S.C. 553(d), good cause exists for making these SIAPs effective in less than 30 days.

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 so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air Traffic Control, Airports, Incorporation by reference, Navigation (Air).

Issued in Washington, DC, on June 26, 2020.

Robert C. Carty,

Executive Deputy Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, Title 14,

Code of Federal regulations, part 97, (14 CFR part 97), is amended by amending Standard Instrument Approach Procedures and Takeoff Minimums and ODPs, effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

§§ 97.23, 97.25, 97.27, 97.29, 97.31, 97.33, 97.35 [Amended]

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, MLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, Identified as follows:

* * * *Effective Upon Publication*

AIRAC date	State	City	Airport	FDC No.	FDC date	Subject
13-Aug-20 ..	MN	Grand Rapids	Grand Rapids/Itasca Co-Gordon Newstrom Fld.	0/1450	6/22/20	ILS OR LOC RWY 34, Amdt 2B.
13-Aug-20 ..	SC	Georgetown	Georgetown County	0/2329	6/5/20	RNAV (GPS) RWY 5, Orig-B.
13-Aug-20 ..	SC	Georgetown	Georgetown County	0/2330	6/5/20	RNAV (GPS) RWY 23, Amdt 2B.
13-Aug-20 ..	IL	Springfield	Abraham Lincoln Capital	0/8240	6/11/20	RNAV (GPS) RWY 4, Orig-C.
13-Aug-20 ..	IL	Springfield	Abraham Lincoln Capital	0/8242	6/11/20	RNAV (GPS) RWY 22, Orig-B.
13-Aug-20 ..	IL	Springfield	Abraham Lincoln Capital	0/8243	6/11/20	RNAV (GPS) RWY 31, Orig.
13-Aug-20 ..	IL	Springfield	Abraham Lincoln Capital	0/8244	6/11/20	VOR/DME RWY 13, Orig-B.
13-Aug-20 ..	IL	Springfield	Abraham Lincoln Capital	0/8245	6/11/20	VOR/DME RWY 22, Orig-C.
13-Aug-20 ..	MI	Alpena	Alpena County Rgnl	0/8275	6/11/20	RNAV (GPS) RWY 1, Orig-C.
13-Aug-20 ..	TX	El Paso	El Paso Intl	0/8673	6/12/20	LOC/DME RWY 4, Amdt 3A.
13-Aug-20 ..	TX	El Paso	El Paso Intl	0/8674	6/12/20	RNAV (GPS) X RWY 4, Orig-C.
13-Aug-20 ..	TX	El Paso	El Paso Intl	0/8675	6/12/20	RNAV (GPS) Y RWY 22, Orig-D.
13-Aug-20 ..	NY	Albany	Albany Intl	0/9742	6/16/20	VOR RWY 28, Orig-D.
13-Aug-20 ..	NY	Albany	Albany Intl	0/9744	6/16/20	RNAV (GPS) Y RWY 1, Amdt 1B.
13-Aug-20 ..	NY	Albany	Albany Intl	0/9745	6/16/20	RNAV (GPS) RWY 10, Orig-B.
13-Aug-20 ..	NY	Albany	Albany Intl	0/9746	6/16/20	RNAV (GPS) RWY 28, Orig-C.
13-Aug-20 ..	NY	Albany	Albany Intl	0/9747	6/16/20	ILS OR LOC RWY 1, ILS RWY 1 (SA CAT II), Amdt 11B.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. FDA-2018-F-3230]

Food Additives Permitted for Direct Addition to Food for Human Consumption; Vitamin D₂ Mushroom Powder

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the food additive regulations to provide for the safe use of vitamin D₂ mushroom powder as a nutrient supplement in specific food categories. This action is in response to a petition filed by Oakshire Naturals, LP.

DATES: This rule is effective July 13, 2020. See section VII for further information on the filing of objections. Submit either electronic or written objections and requests for a hearing on the final rule by August 12, 2020.

ADDRESSES: You may submit objections and requests for a hearing as follows. Please note that late, untimely filed objections will not be considered. Electronic objections must be submitted on or before August 12, 2020. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 12, 2020. Objections 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 objections in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Objections submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your objection will be made public, you are solely responsible for ensuring that your objection 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 objection, that information will be posted on <https://www.regulations.gov>.

- If you want to submit an objection with confidential information that you do not wish to be made available to the public, submit the objection 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 objections submitted to the Dockets Management Staff, FDA will post your objection, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2018-F-3230 for "Food Additives Permitted for Direct Addition to Food for Human Consumption; Vitamin D₂ Mushroom Powder." Received objections, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit an objection with confidential information that you do not wish to be made publicly available, submit your objections 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." We will review this copy, including the claimed confidential information, in our 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: Lauren VieBrock, Center for Food Safety and Applied Nutrition (HFS-255), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740-3835, 301-796-7454.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 18, 2018 (83 FR 47118), we announced that we filed a food additive petition (FAP 8A4821) submitted by Oakshire Naturals LP (Oakshire), 295 Thompson Road, P.O. Box 388, Kennett Square, PA 19348. The petition proposes that we amend our food additive regulations in part 172 (21 CFR part 172) *Food Additives Permitted for Direct Addition to Food for Human Consumption* to provide for the safe use of vitamin D₂ mushroom powder, produced by exposing homogenized edible mushrooms to ultraviolet (UV) light, as a nutrient supplement in: (1) Foods to which vitamin D₂, vitamin D₃, and vitamin D₂ bakers yeast are currently allowed to be added under §§ 184.1950, 172.379, 172.380, and 172.381 (21 CFR 184.1950, 172.379, 172.380, and 172.381) (excluding cheese and cheese products, foods represented for use as a sole source of nutrition for enteral feeding, infant formula, milk and milk products, and margarine); (2) fruit smoothies; (3) vegetable juices; (4) extruded vegetable snacks; (5) soups and soup mixes (except for those containing meat or poultry that are subject to regulation by the U.S. Department of Agriculture under the Federal Meat Inspection Act or the Poultry Products Inspection Act); and (6) plant protein products as defined in 21 CFR 170.3(n)(33).

Vitamin D is essential for human health. The major function of vitamin D is the maintenance of blood serum concentrations of calcium and

phosphorus by enhancing the absorption of these minerals in the small intestine. Vitamin D deficiency can lead to abnormalities in calcium and bone metabolism, such as rickets in children or osteomalacia in adults. Excessive intake of vitamin D elevates blood plasma calcium levels by increased intestinal absorption or mobilization from the bone that can lead to vascular and tissue calcification, with subsequent damage to the heart, blood vessels, and kidneys (Ref. 1).

To ensure that vitamin D is not added to the U.S. food supply at levels that could raise safety concerns, we affirmed vitamin D as generally recognized as safe (GRAS) with specific limitations as listed in § 184.1950. Under § 184.1(b)(2), an ingredient affirmed as GRAS with specific limitations may be used in food only within such limitations, including the category of food, functional use, and level of use. Any addition of vitamin D to food beyond those limitations requires a food additive regulation.

Vitamin D comprises a group of fat-soluble seco-sterols and comes in many forms. The two major physiologically relevant forms are vitamin D₂ and vitamin D₃. "Vitamin D," without a subscript, represents vitamin D₂, vitamin D₃, or both. Vitamin D is affirmed as GRAS under § 184.1950 for use in food as a nutrient supplement. In accordance with 21 CFR 184.1(b)(2), and as specified in § 184.1950(c)(1), vitamins D₂ and D₃ may be used in food as the sole source of added vitamin D only within the following specific limitations:

Category of food	Maximum levels in food (as served)
Breakfast cereals	350 international units (IU)/100 grams (g).
Grain products and pasta.	90 IU/100 g.
Milk	42 IU/100 g.
Milk products	89 IU/100 g.

Additionally, under § 184.1950(c)(2) and (3), vitamin D is affirmed as GRAS for use in infant formulas and margarine, respectively. Under § 172.379, vitamin D₂ is an approved food additive for use as a nutrient supplement in edible plant-based beverages intended as milk alternatives, edible plant-based yogurt alternatives, soy beverage products, soy-based butter substitute spreads, and soy-based cheese substitutes and soy-based cheese substitute products. Under § 172.380, vitamin D₃ is an approved food additive for use as a nutrient supplement in certain calcium-fortified fruit juices and fruit juice drinks; soy-protein based meal replacement beverages; meal

replacement bars and other-type bars represented for special dietary use in reducing or maintaining body weight; some cheese and cheese products; meal replacement beverages not intended for special dietary use in reducing or maintaining body weight; foods represented as a sole source of nutrition for enteral feeding; and some milk. Under § 172.381, vitamin D₂ bakers yeast may be used in foods as a source of vitamin D₂ and as a leavening agent in yeast-leavened baked goods and baking mixes and yeast-leavened baked snack foods.

Vitamin D₂, also known as ergocalciferol, is the chemical 9,10-seco(5Z,7E,22E)-5,7,10(19),22-ergostatetraen-3-ol. The additive that is the subject of this petition is vitamin D₂ mushroom powder that is produced by exposing a mushroom homogenate to UV light, resulting in increased conversion of endogenous ergosterol to ergocalciferol. Under section 402(a)(7) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), sources of irradiation, such as UV light, must be used in accordance with a regulation or exemption in effect pursuant to section 409 of the FD&C Act.

To support their petition, Oakshire submitted dietary exposure estimates of vitamin D from the proposed uses of vitamin D₂ mushroom powder, as well as from naturally occurring dietary sources of vitamin D, uses in accordance with our approved food additive regulations (§§ 172.379, 172.380, and 172.381) and our GRAS affirmation regulation (§ 184.1950), and from dietary supplements. Oakshire compared their dietary exposure estimates to the Tolerable Upper Intake Level (UL) for vitamin D established by the Institute of Medicine (IOM) of the National Academies. Oakshire also submitted a number of publications pertaining to human clinical studies on vitamin D. Oakshire included analyses to determine the presence of lumisterol, tachysterol, and vitamin D₄ that are formed as a result of the UV treatment of the mushroom homogenate. Based on this information, Oakshire concluded that the proposed uses of vitamin D₂ mushroom powder are safe.

II. Evaluation of Safety

To establish with reasonable certainty that a food additive is not harmful under its intended conditions of use, we consider the projected human dietary intake of the additive, the additive's toxicological data, and other relevant information (such as published literature) available to us. We compare an individual's estimated daily intake (EDI) of the additive from all food

sources, including dietary supplements, to an acceptable intake level established by toxicological data. The EDI is determined by projections based on the amount of the additive proposed for use in particular foods and on data regarding the amount consumed from all food sources of the additive. We use the EDI for the 90th percentile consumer of a food additive as a measure of high chronic dietary intake.

A. UV Light Treatment Used To Produce Vitamin D₂ Mushroom Powder

To support the safety of UV treatment to produce vitamin D₂ mushroom powder, Oakshire provided information on the effects of UV light on biological molecules, the safety of UV light for treatment of food, and studies evaluating the bioavailability and safety of vitamin D from the consumption of vitamin D₂ mushroom powder (Ref. 1). Oakshire describes the source of UV radiation as a medium pressure mercury vapor lamp emitting broad-spectrum light (at wavelengths of 250–600 nm), with major intensity peaks in the UVB (280–315 nm) and UVA ranges (315–400 nm). Oakshire also analyzed extracts of mushroom powders from both UV-treated and untreated mushroom homogenate and identified the substances present in the mushroom powders. Oakshire identified tachysterol (a photoisomer resulting from UV light treatment of the vitamin D₂ precursor, previtamin D₂) and lumisterol (typically formed from UV light treatment of previtamin D₂) as present in the mushroom powders derived from UV-treated mushroom homogenate. Oakshire discussed the safety of these substances and we agree that the presence of small amounts of tachysterol and lumisterol do not pose a toxicological concern (Ref. 1).

Agaricus bisporus mushrooms, which Oakshire uses to produce its vitamin D₂ mushroom powder, also contain low levels of 22,23-dihydroergosterol. When treated with UV light, 22,23-dihydroergosterol forms vitamin D₄ ((5Z,7E)-(3S)-9,10-seco-5,7,10(19)-ergostatrien-3-ol). Oakshire analyzed powders from UV-treated mushroom homogenate and found it to contain vitamin D₄ at levels approximately 10 percent of vitamin D₂ levels. Studies have shown that vitamin D₄ that is structurally similar to vitamin D₃ has significantly less biological potency than vitamin D₃ (Ref. 1). We included the contribution of vitamin D₄ in the dietary exposure estimate for vitamin D₂ mushroom powder by presuming that vitamin D₄ was present at a level of 10 percent of vitamin D₂ levels in the vitamin D₂ mushroom powder, and that

vitamin D₄ had equivalent potency to vitamin D₂ (Ref. 2). Oakshire discussed the safety of vitamin D₄, and we agree that the presence of vitamin D₄ in Vitamin D₂ mushroom powder does not pose a toxicological concern (Ref. 1).

B. Acceptable Intake Level for Vitamin D

The IOM considers the UL as the highest daily intake level of a nutrient that poses no risk of adverse effects with chronic consumption of the nutrient (Ref. 3). The UL is determined using a risk assessment model developed specifically for nutrients. The dose-response assessment, which concludes with an estimate of the UL, is built upon three toxicological concepts commonly used in assessing the risk of exposures to chemical substances: No-observed-adverse-effect level, lowest-observed-effect level, and application of an uncertainty factor (Ref. 3).

In 2011, the Standing Committee on the Scientific Evaluation of Dietary Reference Intakes of the Food and Nutrition Board at the IOM conducted an extensive review of relevant published scientific literature on vitamin D to update the nutrient's dietary reference intakes and ULs. Based on this information, the IOM revised the ULs for vitamin D and developed a report on their findings (Ref. 3). The IOM established the following ULs:

- 1,000 IU per person per day (IU/p/d) for infants 0 months to 6 months of age;
- 1,500 IU/p/d for infants 6 months to 12 months of age;
- 2,500 IU/p/d for children 1 year to 3 years of age;
- 3,000 IU/p/d for children 4 years to 8 years of age; and
- 4,000 IU/p/d for children 9 years to 18 years of age and adults.

We considered the ULs established by the IOM relative to the intake estimates as the primary basis for assessing the safety of the petitioned uses of vitamin D₂ mushroom powder. We also reviewed published studies on the safety of vitamin D submitted in the petition, as well as other relevant published studies available to us (Ref. 1).

C. Estimated Daily Intake for Vitamin D

Oakshire provided mean and 90th percentile vitamin D exposure estimates for consumers of foods from the: (1) Proposed food uses of vitamin D₂ mushroom powder; (2) current food uses of vitamin D (including authorized uses as a food ingredient, naturally occurring sources of vitamin D, and dietary supplements); and (3) combined current and proposed food uses.

Oakshire provided exposure estimates for the overall U.S. population (including infants under 1 year of age) and fourteen population subgroups (Ref. 2).

The exposure estimates provided by Oakshire are appropriate. However, they did not employ the conservative assumptions that we typically use in pre-market exposure estimates. For pre-market exposure estimates, we conservatively assume that all foods for which the use of the additive is approved will contain the additive at the maximum level permitted. In the case of vitamin D exposure estimates presented in the most recent food additive approval for a new use of vitamin D (FAP 3A4801, 81 FR 46578, July 18, 2016), we also included exposure to the vitamin D metabolite 25-hydroxyvitamin D (25(OH)D). For these reasons, we calculated our own exposure estimate for vitamin D₂ mushroom powder, as well as a cumulative exposure estimate for vitamin D from all background sources (approved food uses, dietary supplements, and naturally occurring sources, including 25(OH)D) and the petitioned uses for vitamin D₂ mushroom powder (Ref. 2).

For the overall U.S. population 1 year of age and older, we estimated the cumulative exposure at the 90th percentile from all food sources of vitamin D, including the proposed uses and background sources, to be 2,240 IU/p/d. We estimated the cumulative exposure for infants 0 to 6 months of age and infants 6 to 12 months of age to be 948 IU/p/d and 960 IU/p/d, respectively, for the 90th percentile consumer (Ref. 2).

D. Safety of the Petitioned Uses of Vitamin D₂ Mushroom Powder

We reviewed and evaluated the information submitted by Oakshire regarding the safety of vitamin D₂ mushroom powder, including the safety of using UV light treatment to produce it, and conclude that the use of vitamin D₂ mushroom powder does not pose a safety concern (see section II.A). We also reviewed and evaluated the information submitted by Oakshire regarding the safety of dietary intake of vitamin D₂ from the proposed uses of the vitamin D₂ mushroom powder. Oakshire submitted reports of scientific studies published since our last evaluation of published scientific data in support of safety of the use of vitamin D and issuance of the final rule amending our food additive regulations to allow certain uses of vitamins D₂ and D₃ (81 FR 46578). Oakshire concluded that these studies support a conclusion

that the proposed uses of vitamin D₂ mushroom powder are safe.

We reviewed the studies submitted by Oakshire, as well as other relevant published studies available to us since our previous evaluations of food additive petitions for fortifying a variety of foods with vitamin D (81 FR 46578, July 18, 2016; 79 FR 46993, August 12, 2014; 77 FR 52228, August 29, 2012; 74 FR 11019, March 16, 2009; 70 FR 69435, November 16, 2005; 70 FR 37255, June 29, 2005; 70 FR 36021, June 22, 2005; 68 FR 9000, February 27, 2003). These studies did not raise any safety concerns regarding the current or proposed uses of vitamin D. The most recent food additive petition for a new use of vitamin D resulted in our amendment of the food additive regulations in §§ 172.379 and 172.380 to allow for the safe use of vitamin D₂ as a nutrient supplement in edible plant-based beverages intended for use as milk alternatives and in edible plant-based yogurt alternatives, and of vitamin D₃ as a nutrient supplement in milk (81 FR 46578). The earlier food additive petitions also resulted in amendments of the food additive regulations to allow for the safe use of vitamin D as a nutrient supplement in certain foods.

We considered the ULs established by the IOM relative to the intake estimates as the primary basis for assessing the safety of the petitioned uses of vitamin D. Depending on the age group, the IOM UL for vitamin D for the U.S. population 1 year of age and older ranges from 2,500 IU/p/d to 4,000 IU/p/d (Ref. 3). The estimated dietary exposure to vitamin D from all food sources, including the proposed uses, at the 90th percentile for the U.S. population 1 year of age and older is estimated to be 2,240 IU/p/d, which is below the lowest IOM UL of 2,500 IU/p/d in the range of ULs for the overall U.S. population 1 year of age and older. Estimated exposure to vitamin D from all food sources, including the proposed uses, for infants 0 months to 6 months of age at the 90th percentile is 948 IU/p/d; for infants 6 months to 12 months of age, estimated exposure to vitamin D is 960 IU/p/d. Both of these estimates are below the IOM UL of 1,000 IU/p/d for infants 0 months to 6 months of age and 1,500 IU/p/d for infants 6 months to 12 months of age. Because the 90th percentile cumulative EDI of vitamin D from all food sources of vitamin D, including the proposed uses and background sources, for each population group is less than the corresponding IOM UL for that population group, we conclude that dietary intake of vitamin D₂ mushroom powder from the proposed uses is safe (Ref. 1).

III. Conclusion

Based on all data relevant to vitamin D₂ mushroom powder we reviewed, we conclude that there is a reasonable certainty that no harm will result from the uses of vitamin D₂ mushroom powder, produced using UV light treatment, as a source of vitamin D₂ in: (1) Foods to which vitamin D₂, vitamin D₃, and vitamin D₂ bakers yeast are allowed under §§ 184.1950, 172.379, 172.380, and 172.381 (excluding cheese and cheese products, foods represented for use as a sole source of nutrition for enteral feeding, infant formula, milk and milk products, and margarine); (2) fruit smoothies; (3) vegetable juices; (4) extruded vegetable snacks; (5) soups and soup mixes (except for those containing meat or poultry that are subject to regulation by the U.S. Department of Agriculture under the Federal Meat Inspection Act or the Poultry Products Inspection Act); and (6) plant protein products as defined in 21 CFR 170.3(n)(33). Thus, we are amending our food additive regulations as set forth in this document.

IV. Public Disclosure

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that we considered and relied upon in reaching our decision to approve the petition will be made available for public disclosure (see **ADDRESSES**). As provided in § 171.1(h), we will delete from the documents any materials that are not available for public disclosure.

V. Analysis of Environmental Impacts

As stated in the September 18, 2018 **Federal Register** notification of petition for FAP 8A4821 (83 FR 47118), the petitioners claimed a categorical exclusion from preparing an environmental assessment or environmental impact statement under § 25.32(k) (21 CFR 25.32(k)) because vitamin D₂ mushroom powder is intended to remain in food through ingestion by consumers and is not intended to replace macronutrients in food. We further stated that if FDA determines a categorical exclusion applies, neither an environmental assessment nor an environmental impact statement is required. We have not received any new information or comments regarding this claim of categorical exclusion. We have considered the petitioner's claim of categorical exclusion and have determined that this action is categorically excluded under § 25.32(k). Therefore, neither an environmental

assessment nor an environmental impact statement is required.

VI. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VII. Objections

If you will be adversely affected by one or more provisions of this regulation, you may file with the Dockets Management Staff (see **ADDRESSES**) either electronic or written objections. You must separately number each objection, and within each numbered objection you must specify with particularity the provision(s) to which you object, and the grounds for your objection. Within each numbered objection, you must specifically state whether you are requesting a hearing on the particular provision that you specify in that numbered objection. If you do not request a hearing for any particular objection, you waive the right to a hearing on that objection. If you request a hearing, your objection must include a detailed description and analysis of the specific factual information you intend to present in support of the objection in the event that a hearing is held. If you do not include such a description and analysis for any particular objection, you waive the right to a hearing on the objection.

Any objections received in response to the regulation may be seen in the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <https://www.regulations.gov>.

VIII. Section 301(ll) of the FD&C Act

Our review of this petition was limited to section 409 of the FD&C Act (21 U.S.C. 348). This final rule is not a statement regarding compliance with other sections of the FD&C Act. For example, section 301(ll) of the FD&C Act (21 U.S.C. 331(ll)) prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FD&C Act (21 U.S.C. 355), a biological product licensed under section 351 of the Public Health Service Act (42 U.S.C. 262), or a drug or biological product for which substantial clinical investigations have been instituted and their existence has been made public, unless one of the exemptions in section 301(ll)(1) to (4) of the FD&C Act applies. In our review of this petition, FDA did not consider whether section 301(ll) of the FD&C Act or any of its exemptions apply to food

containing this additive. Accordingly, this final rule should not be construed to be a statement that a food containing this additive, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll) of the FD&C Act. Furthermore, this language is included in all food additive final rules and therefore should not be construed to be a statement of the likelihood that section 301(ll) of the FD&C Act applies.

IX. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at <https://www.regulations.gov>. References without asterisks are not on public display at <https://www.regulations.gov> because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. FDA Memorandum from A. Khan, Toxicology Review Branch, Division of Food Ingredients, to L. VieBrock, Regulatory Review Branch, Division of Food Ingredients, March 18, 2020.*
2. FDA Memorandum from D. Folmer, Safety Assurance Team, Division of Science and Technology, to L. VieBrock, Regulatory Review Branch, Division of Food Ingredients, March 18, 2020.*
3. Committee to Review Dietary Reference Intakes for Vitamin D and Calcium, Food and Nutrition Board, Institute of Medicine, "Dietary Reference Intakes for Calcium and Vitamin D," National Academies Press, Washington, DC, 2011. Available at <https://www.nap.edu/read/13050/chapter/1> (accessed November 11, 2019).

List of Subjects in 21 CFR Part 172

Food additives, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 172 is amended as follows:

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

■ 1. The authority citation for part 172 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 348, 371, 379e.

■ 2. Add § 172.382 to subpart D to read as follows:

§ 172.382 Vitamin D₂ mushroom powder.

Vitamin D₂ mushroom powder may be used safely in foods as a source of vitamin D₂ in accordance with the following prescribed conditions:

(a) Vitamin D₂ mushroom powder is the substance produced by exposing an aqueous homogenate of edible cultivars of *Agaricus bisporus* mushrooms to ultraviolet (UV) light, resulting in the photochemical conversion of

endogenous ergosterol in the mushrooms to vitamin D₂ (also known as ergocalciferol or [9,10-Seco(5Z,7E,22E)-5,7,10(19),22-ergostatetraen-3-ol]).

(b) The total dose of UV light applied to the mushroom homogenate shall not exceed 12 Joules/square centimeter (J/cm²).

(c) Vitamin D₂ mushroom powder meets the following specifications:

(1) Moisture, not more than 10 percent.

(2) Negative for *Salmonella*, *Staphylococcus aureus*, and *Listeria monocytogenes*, and any other recognized microbial pathogen or any harmful microbial toxin.

(3) Standard plate count, not more than 5,000 colony forming units per gram (CFU/g).

(4) Yeasts and molds, not more than 100 CFU/g.

(5) Lead, not more than 0.5 milligrams per kilogram (mg/kg).

(6) Arsenic, not more than 0.3 mg/kg.

(d) To assure safe use of the additive, the label or labeling of the food additive container shall bear, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act, adequate directions for use to provide a final product that complies with the limitations prescribed in paragraph (f) of this section.

(e) Labels of manufactured food products containing the additive shall bear, in the ingredient statement, the name of the additive “vitamin D₂ mushroom powder,” in the proper order of decreasing predominance in the finished food.

(f) Vitamin D₂ mushroom powder may be used as a source of vitamin D₂ in food as follows:

TABLE 1 TO PARAGRAPH (f)

Category of food	Maximum level of vitamin D ₂
Breakfast cereals	350 IU/100 g.
Edible plant-based beverages marketed as milk alternatives	84 IU/100 g.
Edible plant-based products marketed as yogurt alternatives	89 IU/100 g.
Extruded vegetable snacks	80 IU/28 g.
Fruit smoothies	100 IU/240 mL.
100% fruit juices that are fortified with greater than or equal to 330 mg of calcium per 240 mL, excluding fruit juices that are specially formulated or processed for infants.	100 IU/240 mL.
Fruit juice drinks that are fortified with greater than or equal to 100 mg of calcium per 240 mL, excluding fruit juice drinks that are specially formulated or processed for infants.	100 IU/240 mL.
Grain products and pastas	90 IU/100 g.
Meal replacement bars or other-type bars that are represented for special dietary use in reducing or maintaining body weight.	100 IU/40 g.
Meal replacement beverages that are not intended for special dietary use in reducing or maintaining body weight and that are represented for use such that the total amount of Vitamin D provided by the product does not exceed 1,000 IU per day.	500 IU/240 mL.
Plant protein products	80 IU/85 g.
Soups and soup mixes, except for soup and soup mixes containing meat or poultry that are subject to regulation by the U.S. Department of Agriculture under the Federal Meat Inspection Act or the Poultry Products Inspection Act.	100 IU/245 mL.
Soy-based spreads marketed as butter alternatives	330 IU/100 g.
Soy-based products marketed as cheese and cheese-product alternatives	270 IU/100 g.
Soy beverage products	89 IU/100 g.
Soy-protein based meal replacement beverages (powder or liquid) that are represented for special dietary use in reducing or maintaining body weight.	140 IU/240 mL.
Vegetable juices	100 IU/240 mL.
Yeast-leavened baked goods and baking mixes and yeast-leavened baked snack foods	400 IU/100 g.

Dated: June 22, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020-13822 Filed 7-10-20; 8:45 am]

BILLING CODE 4164-01-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R01-OAR-2020-0150; FRL-10011-22-Region 1]

Air Plan Approval; New Hampshire; Negative Declaration for the Oil and Gas Industry

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 State of New Hampshire. The revision provides the State’s determination, via a negative declaration, that there are no facilities within its borders subject to EPA’s 2016 Control Technique Guideline (CTG) for the oil and gas industry. The intended effect of this action is to approve this item into the New Hampshire SIP. This action is being taken under the Clean Air Act.

DATES: This rule is effective on August 12, 2020.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA-R01-OAR-2020-0150. All documents in the docket are listed on the <https://www.regulations.gov> website. Although listed in the index, some information is not publicly available, *i.e.*, CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available at <https://www.regulations.gov>, or at the U.S. Environmental Protection Agency, EPA Region 1 Regional Office, Air and Radiation Division, 5 Post Office Square—Suite 100, Boston, MA. EPA requests that if at all possible, you contact the contact listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding legal holidays and facility closures due to COVID-19.

FOR FURTHER INFORMATION CONTACT: Bob McConnell, Environmental Engineer, Air and Radiation Division (Mail Code 05-2), U.S. Environmental Protection Agency, Region 1, 5 Post Office Square, Suite 100, Boston, Massachusetts 02109-3912; (617) 918-1046.

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

Table of Contents

- I. Background and Purpose
- II. Response to Comment
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I. Background and Purpose

On April 6, 2020, EPA published a Notice of Proposed Rulemaking (NPRM; see 85 FR 19116) with an associated Direct Final Rule (DFR; see 85 FR 19087) for the State of New Hampshire. The DFR approved a negative declaration for New Hampshire for EPA's 2016 Control Technique Guideline (CTG) for the oil and gas industry. We received one, relevant adverse comment on the NPRM, and so withdrew the DFR via a Withdrawal Notice published on June 5, 2020. See 85 FR 34524. Other specific requirements of the State's submittal and the rationale for EPA's proposed action are explained in the NPRM and will not be restated here. Our response to the adverse comment on the NPRM

is summarized and responded to in section II below.

II. Response to Comment

We received one, relevant adverse comment on the NPRM. A summary of the comment, and our response, follows.

Comment: Did EPA even do any independent review to see if sources exist within New Hampshire? EPA seems to make a categorical conclusion about New Hampshire's SIP based simply on where EPA “believes” sources are located. EPA should withdraw this illogical conclusion and affirmatively determine whether the state has sources subject to the CTG based on a review of the State's SIP and an independent review of EPA's databases.

Response: First, we note that the commenter does not provide any information to contradict New Hampshire's finding that no sources subject to EPA's 2016 CTG for the oil and gas industry exist within the State. EPA is not aware of any information indicating that a facility subject to the 2016 oil and gas CTG exists within the State of New Hampshire. Additionally, we note that EPA has historically allowed states to submit a negative declaration for a particular CTG category if the state finds that no sources exist in the state which would be subject to that CTG. EPA has addressed the idea of negative declarations numerous times and for various NAAQS including in the General Preamble to the 1990 Amendments,¹ the 2006 RACT Q&A Memo,² and the 2008 Ozone Implementation Rule.³ In each of these documents, EPA asserted that if no sources exist in the nonattainment area for a particular CTG category, the state would be allowed to submit a negative declaration SIP revision. This principle also applies to states in the ozone transport region.

Second, we note that New Hampshire's finding is consistent with information contained within EPA data resources of industrial activity within the United States, such as the National Emissions Inventory (NEI) database of sources of air pollution, which is available at: [https://www.epa.gov/air-emissions-inventories/national-](https://www.epa.gov/air-emissions-inventories/national-emissions-inventory-nei)

¹“State Implementation Plans; General Preamble for the Implementation of Title I of the Clean Air Act Amendments of 1990,” (57 FR 13498 at 13512 (April 16, 1992)).

²“RACT Q's and A's—Reasonably Available Control Technology RACT: Questions and Answers” Memorandum from William T. Harnett, May 18, 2006.

³“Implementation of the 2008 National Ambient Air Quality Standards for Ozone: State Implementation Plan Requirements,” (80 FR 12263 at 12278 (March 6, 2015)).

emissions-inventory-nei. And last, we note that EPA Region 1 worked with New Hampshire, and EPA headquarters' technical experts on the CTG, to review the applicability criteria of EPA's 2016 oil and gas CTG to assist the State with its determination.

III. Final Action

We are approving a negative declaration for EPA's 2016 CTG entitled “Control Techniques Guidelines for the Oil and Natural Gas Industry” into the New Hampshire SIP.

IV. Statutory and Executive Order Reviews

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

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Is not an Executive Order 13771 regulatory action because this action is not significant under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National

Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and

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

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

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. Section 804,

however, exempts from section 801 the following types of rules: Rules of particular applicability; rules relating to agency management or personnel; and rules of agency organization, procedure, or practice that do not substantially affect the rights or obligations of non-agency parties. 5 U.S.C. 804(3). Because this is a rule of particular applicability, EPA is not required to submit a rule report regarding this action under section 801.

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 September 11, 2020. 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, Incorporation by

NEW HAMPSHIRE NONREGULATORY

reference, Ozone, Volatile organic compounds.

Dated: June 18, 2020.

Dennis Deziel,

Regional Administrator, EPA Region 1.

For the reasons stated in the preamble, EPA amends Part 52 of chapter I, title 40 of the Code of Federal Regulations as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart EE—New Hampshire

■ 2. In § 52.1520, amend paragraph (e) by adding an entry in the table for “Negative declaration for the 2016 Control Techniques Guideline for the Oil and Natural Gas Industry” at the end of the table, to read as follows:

§ 52.1520 Identification of plan.

* * * * *
(e) * * *

Name of nonregulatory SIP provision	Applicable geographic or nonattainment area	State submittal date/ effective date	EPA approved date ³	Explanations
Negative declaration for the 2016 Control Techniques Guidelines for the Oil and Natural Gas Industry.	Statewide	12/20/2019	7/13/2020 [Insert Federal Register citation].	Negative declaration.

³ In order to determine the EPA effective date for a specific provision listed in this table, consult the **Federal Register** notice cited in this column for the particular provision.

[FR Doc. 2020–13635 Filed 7–10–20; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2019–0291; FRL–10010–73–Region 9]

Air Plan Approval; California; Mariposa County Air Pollution Control District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to

approve a revision to the Mariposa County Air Pollution Control District (MCAPCD) portion of the California State Implementation Plan (SIP). This revision concerns reporting of emissions of volatile organic compounds (VOCs) and oxides of nitrogen (NO_x) in nonattainment areas. We are approving a local rule to require submittal of emissions statements under the Clean Air Act (CAA or the Act).

DATES: This rule will be effective on August 12, 2020.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R09–OAR–2019–0291. 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 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: Nancy Levin, EPA Region IX, 75 Hawthorne St., San Francisco, CA 94105. By phone: (415) 972–3848 or by email at levin.nancy@epa.gov.

SUPPLEMENTARY INFORMATION:

Throughout this document, “we,” “us” and “our” refer to the EPA.

Table of Contents

- I. Proposed Action
- II. Public Comments and EPA Responses

- III. EPA Action
- IV. Incorporation by Reference
- V. Statutory and Executive Order Reviews

I. Proposed Action

Table 1 lists the rule addressed by this final action with the dates that it was

adopted by the local air agency and submitted to the EPA by the California Air Resources Board. On March 16, 2020 (85 FR 14845), the EPA proposed to approve the rule into the California SIP.

TABLE 1—SUBMITTED RULE

Local agency	Rule No.	Rule title	Revised	Submitted
MCAPCD	513	Emissions Statements	05/15/18	04/30/19

We proposed to approve Rule 513 because we determined that it complies with the relevant CAA requirements. Our proposed action contains more information on the rule and our evaluation.

II. Public Comments and EPA Responses

The EPA’s proposed action provided a 30-day public comment period. During this period, we received no comments.

III. EPA Action

No comments were submitted. Therefore, as authorized in section 110(k)(3) of the Act, the EPA is fully approving this rule into the California SIP.

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 the MCAPCD rule described in the amendments to 40 CFR part 52 set forth below. The EPA has made, and will continue to make, these documents available through www.regulations.gov and at the EPA Region IX Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

V. Statutory and Executive Order Reviews

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

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because SIP approvals are exempted under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the 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. 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 September 11, 2020. 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, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: June 23, 2020.

John Busterud,
Regional Administrator, Region IX.

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 F—California

■ 2. Section 52.220 is amended by adding paragraphs (c)(26)(viii)(F) and (c)(534) to read as follows:

§ 52.220 Identification of plan-in part.

* * * * *

(c) * * *
(26) * * *
(viii) * * *

(F) Previously approved on August 22, 1977 in paragraph (c)(26)(viii)(A) of this section, and now deleted with replacement by Rule 513, “Emission Statements” in paragraph (c)(534)(i)(A)(1) of this section, Rule 408, “Source Recordkeeping and Reporting.”

* * * * *

(534) A new regulation for the following APCD was submitted on April 30, 2019 by the Governor’s designee.

(i) *Incorporation by reference.* (A) Mariposa County Air Pollution Control District.

(1) Rule 513, “Emissions Statements,” Adopted on May 15, 2018.

(2) [Reserved]
(B) [Reserved]
(ii) [Reserved]

[FR Doc. 2020–13863 Filed 7–10–20; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R01–OAR–2020–0132; FRL–10011–52–Region 1]

Air Plan Approval and Air Quality Designation; Connecticut; Determination of Clean Data for the 2008 8-Hour Ozone Standard for the Greater Connecticut Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final action.

SUMMARY: The Environmental Protection Agency (EPA) is finalizing a clean data

determination for the Greater Connecticut Serious 8-hour ozone nonattainment area, concluding that the area has monitored attainment of the 2008 8-hour National Ambient Air Quality Standard (NAAQS) for ozone, based upon certified 2016–2018 ozone data. This action suspends the requirements for this area to submit an attainment demonstration, a reasonable further progress plan, contingency measures, and other planning State Implementation Plan (SIP) revisions related to attainment of the 2008 8-hour ozone NAAQS on the condition that the area continues to attain the 2008 8-hour ozone NAAQS. This action is being taken in accordance with the Clean Air Act.

DATES: This final action is effective on August 12, 2020.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA–R01–OAR–2020–0132. All documents in the docket are listed on the <https://www.regulations.gov> website. Although listed in the index, some information is not publicly available, *i.e.*, CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available at <https://www.regulations.gov> or at the U.S. Environmental Protection Agency, EPA Region 1 Regional Office, Air and Radiation Division, 5 Post Office Square—Suite 100, Boston, MA. EPA requests that if at all possible, you contact the contact listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office’s official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding legal holidays and facility closures due to COVID–19.

FOR FURTHER INFORMATION CONTACT: Elizabeth Townsend, Air Quality Branch, U.S. Environmental Protection Agency, Region 1, 5 Post Office Square—Suite 100, (Mail code 05–2), Boston, MA 02109–3912, tel. (617) 918–1614, email townsend.elizabeth@epa.gov.

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

Table of Contents

- I. Background and Purpose
- II. Final Action
- III. Statutory and Executive Order Reviews

I. Background and Purpose

On March 27, 2020 (85 FR 17301), EPA published a notice of proposed rulemaking (NPRM) for the State of Connecticut. The NPRM proposed to determine that the Greater Connecticut Serious 8-hour ozone nonattainment area has attained the 2008 8-hour NAAQS for ozone, based on 2016–2018 ozone data. Since the NPRM was published, EPA has finalized and published the design values for 2019, based on 2017–2019 ozone data. These data support the conclusion that the Greater Connecticut area attains the 2008 8-hour NAAQS for ozone.

On April 20, 2020 (85 FR 21796), EPA published a correction to the proposed rule which corrected information, displayed in Table 1, of the 2016 fourth-high 8-hour ozone average concentration values for the Abington, Cornwall, and East Hartford monitors. Although incorrect values were displayed in the original version of the proposed rule, the correct values were utilized in the calculation of the design values and in the analysis for the clean data determination and therefore did not change our analysis or conclusions. EPA proposed to determine that the obligation for Connecticut to make submissions to meet certain CAA requirements related to attainment of the NAAQS for this area is not applicable for as long as the area continues to attain the NAAQS. The rationale for EPA’s proposed action is explained in the NPRM and will not be restated here. No public comments were received on the NPRM.

II. Final Action

For the reasons stated in the proposed action, EPA is finalizing a clean data determination for the Greater Connecticut Serious 8-hour ozone nonattainment area based on the area’s current attainment of the 2008 8-hour ozone standard. Pursuant to 40 CFR 51.1118, this action suspends the requirements for this area to submit State Implementation Plan (SIP) revisions related to attainment of the 2008 8-hour ozone NAAQS on the condition that the area continues to attain the 2008 8-hour ozone NAAQS. In particular, as discussed in the proposed action (85 FR 17301), the obligation for Connecticut to submit attainment demonstrations and associated reasonably available control measures, reasonable further progress plans, contingency measures for failure to attain or make reasonable progress and other planning SIPs related to attainment of the 2008 ozone NAAQS shall be suspended until such time as:

(1) The area is redesignated to attainment for the 2008 8-hour ozone NAAQS, at which time the requirements no longer apply; or (2) EPA determines that the area has violated the 2008 8-hour ozone NAAQS, at which time the area is again required to submit such plans.

III. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act.

Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

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

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

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the action 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 September 11, 2020. Filing a petition for reconsideration by the Administrator of this final action 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, Incorporation by reference, Ozone, Reporting and recordkeeping requirements.

Dated: June 22, 2020.

Dennis Deziel,

Regional Administrator, EPA Region 1.

[FR Doc. 2020-13787 Filed 7-10-20; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 81

[EPA-R03-OAR-2019-0577; FRL-10010-63-Region 3]

Air Plan Approval; West Virginia; Redesignation and Maintenance Plan for the West Virginia Portion of the Steubenville Sulfur Dioxide Nonattainment Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving the request from the State of West Virginia to redesignate to attainment its respective portion of the Steubenville, Ohio-West Virginia multi-state sulfur dioxide (SO₂) nonattainment area (referred to as the "Steubenville Nonattainment Area" or the "Area") for the 2010 1-hour SO₂ primary national ambient air quality standard (NAAQS) (also referred to as the "2010 SO₂ NAAQS"). EPA is also approving, as a revision to the West Virginia state implementation plan (SIP), West Virginia's maintenance plan for its portion of the Steubenville Nonattainment Area. Emissions of SO₂ in the Area have been reduced, and monitored ambient SO₂ readings in the nonattainment area are currently well below the 2010 SO₂ NAAQS.

DATES: This final rule is effective on August 12, 2020.

ADDRESSES: EPA has established a docket for this action under Docket ID Number EPA-R03-OAR-2019-0577. 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: Sara Calcinore, Planning & Implementation Branch (3AD30), Air & Radiation Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. The telephone number is (215) 814-2043. Ms. Calcinore can also be reached via

electronic mail at calcinore.sara@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The Steubenville Nonattainment Area is comprised of a portion of Jefferson County, Ohio and a portion of Brooke County, West Virginia.¹ On October 22, 2019 (84 FR 56385), EPA approved the attainment plans for the Steubenville Nonattainment Area as well as new emissions limits for the primary SO₂ sources in the Area. These sources include: (1) The American Electric Power (AEP) Cardinal Power Plant (referred to as “Cardinal Power Plant”) located in Brilliant, Ohio; (2) the JSW Steel USA Ohio facility (JSW Steel) in Mingo Junction, Ohio; (3) the Mingo Junction Energy Center, also in Mingo Junction, Ohio; and (4) Mountain State Carbon (MSC) in Follansbee, West Virginia.² EPA redesignated the Ohio portion of the Steubenville Nonattainment Area to attainment on November 29, 2019 (84 FR 65683).

On August 22, 2019, West Virginia submitted a request to redesignate the West Virginia portion of the Steubenville Nonattainment Area. On March 20, 2020 (85 FR 16038), EPA published a notice of proposed rulemaking (NPRM) for the State of West Virginia. In the NPRM, EPA proposed approval of West Virginia’s request to redesignate to attainment its portion of the Steubenville Nonattainment Area as well as West Virginia’s corresponding maintenance plan for the Area.

II. Summary of SIP Revision and EPA Analysis

EPA reviewed West Virginia’s redesignation request and found that West Virginia’s portion of the Steubenville Nonattainment Area satisfies the Clean Air Act (CAA) section

¹ The Ohio portion of the nonattainment area included Cross Creek Township, Steubenville Township, Warren Township, Wells Township, and Steubenville City in Jefferson County. 40 CFR 81.336. The West Virginia portion of the nonattainment area is the Cross Creek Tax District in Brooke County. 40 CFR 81.349.

² The attainment plan for the Steubenville Nonattainment Area included dispersion modeling demonstrating that the Steubenville Nonattainment Area had attained the 2010 SO₂ NAAQS based on the allowable emissions from Cardinal Power Plant, JSW Steel, Mingo Junction Energy Center, and MSC. The emissions limits for Cardinal Power Plant, JSW Steel, and Mingo Junction Energy Center are approved into the Ohio SIP under Chapter 3745–18. See 40 CFR 52.1870(c). The emissions limits for MSC are included in a consent order dated September 29, 2017 (Consent Order Number CO–SIP–C–2017–9), which is approved into the West Virginia SIP. 84 FR 56385 (October 22, 2019); 40 CFR 52.2520(d). The emissions limits for all four facilities are permanent and Federally enforceable.

107(d)(3)(E) requirements for redesignation. EPA also found that West Virginia’s maintenance plan for the Area satisfies the requirements of CAA section 175A. EPA’s rationale for this action can be found in the March 20, 2020 NPRM.

EPA received one adverse comment on the proposal. As discussed in section III in this final rule’s preamble, EPA concludes that West Virginia has satisfied the relevant requirements of CAA section 107(d)(3)(E) for the redesignation of its portion of the Steubenville Nonattainment Area. Therefore, EPA is redesignating West Virginia’s portion of the Steubenville Nonattainment Area to attainment for the 2010 SO₂ NAAQS and is approving, as a revision to the West Virginia SIP, the corresponding maintenance plan for the Area.

III. Public Comments and EPA Response

EPA received one comment on the March 20, 2020 NPRM. The comment and EPA’s response are discussed below. The comment is included in the docket for this action, available online at www.regulations.gov. Docket ID: EPA–R03–OAR–2019–0577.

Comment: On April 20, 2020, EPA received an anonymous comment on the NPRM. The commenter questioned how West Virginia can confirm the current compliance of the modeled facilities (*i.e.*, Cardinal Power Plant, JSW Steel, Mingo Junction Energy Center, and MSC) in the Steubenville Nonattainment Area when three of the four facilities are not within West Virginia’s jurisdiction. The commenter requests that EPA independently determine whether all four facilities are currently in compliance with their modeled limits.

EPA Response: States generally have the best information on the compliance status of sources within their jurisdiction. Therefore, EPA is primarily relying on Ohio to provide information on the compliance status of the Ohio sources and West Virginia to provide information on the compliance status of the West Virginia source. Ohio Environmental Protection Agency (OEPA)’s request for redesignation confirmed that the modeled facilities located in its portion of the Area (*i.e.*, Cardinal Power Plant, JSW Steel, and Mingo Junction Energy Center) are in full compliance with their emission limits.³ EPA accepted and concurred

³ See also Appendix D of West Virginia’s August 22, 2019 submittal included in the docket for this rulemaking action, available online at <https://www.regulations.gov>. Docket ID: EPA–R03–OAR–2019–0577.

with this statement regarding compliance by Ohio sources explicitly in its September 20, 2019 NPRM proposing approval of Ohio’s redesignation request and implicitly in its November 29, 2019 final rulemaking notice (FRN). See 84 FR 49492 and 84 FR 65683.

West Virginia has provided adequate assurance that MSC, the only primary SO₂ source within West Virginia’s portion of the Steubenville Nonattainment Area, is in compliance with its emissions limits as well as other conditions of the September 29, 2017 consent order (Consent Order Number CO–SIP–C–2017–9).⁴ Appendix C of West Virginia’s August 22, 2019 submittal includes documentation of MSC’s compliance with the consent order, including an August 9, 2016 letter from MSC confirming the disconnection of the coke oven gas (COG) pipeline to Mingo Junction Energy Center and a February 1, 2017 letter verifying that the data acquisition and monitoring system required by the consent order is operational.⁵ In the February 1, 2017 letter, MSC also commits to submitting the quarterly reports required by the consent order. EPA has reviewed the quarterly reports submitted by MSC to the WVDEP from October 1, 2017 to March 31, 2020,⁶ and finds that MSC is complying with the emissions limits, in accordance with the SIP-approved consent order, that were used in the modeling demonstration for the Steubenville Nonattainment Area.⁷

⁴ As stated previously, the emissions limits in the September 29, 2017 consent order were used for the modeling included in the attainment demonstration for the Steubenville Nonattainment Area. The consent order is approved in the West Virginia SIP and is permanent and Federally enforceable.

⁵ The September 29, 2017 consent order (Consent Order Number CO–SIP–C–2017–9) supersedes and replaces a previous consent order (Consent Order Number CO–SIP–2015–14). Consent Order Number CO–SIP–2015–14 required MSC to physically disconnect the COG pipeline leading to Mingo Junction Energy Center by January 1, 2017. It also required MSC to install, operate, and maintain a continuous monitoring system (CMS) and submit quarterly reports to the West Virginia Department of Environmental Protection (WVDEP) beginning with the January 1 through March 31, 2017 quarter. MSC submitted the August 9, 2016 and February 1, 2017 letters to WVDEP in order to demonstrate compliance with these requirements of Consent Order Number CO–SIP–2015–14. These requirements are also included in the September 29, 2017 consent order that replaced Consent Order Number CO–SIP–2015–14 and was approved into the West Virginia SIP. 84 FR 56385 (October 22, 2019); 40 CFR 52.2520(d).

⁶ Consent Order Number CO–SIP–C–2017–9 was effective September 29, 2017. Therefore, the applicable period for determining compliance with the emissions limits contained in the September 29, 2017 consent order is October 1, 2017 to March 31, 2020, which is the most recent completed quarter.

⁷ The quarterly reports are included in the docket for this rulemaking, available online at <https://www.regulations.gov>.

As mentioned previously, the emissions limits on Cardinal Power Plant, JSW Steel, Mingo Junction Energy Center, and MSC are all permanent and federally enforceable. These four sources are all subject to monitoring, testing, recordkeeping, and reporting requirements to assure compliance with the SO₂ emissions limits. WVDEP and OEPA have comprehensive programs to identify sources of violations of the SO₂ NAAQS and approved compliance and enforcement programs to address violations. WVDEP has committed to continuing the enforcement of all rules related to SO₂ emissions in the Steubenville Nonattainment Area and has verified that it has the legal authority and necessary resources to actively enforce any violations of its rules or permit provisions.

EPA finds that MSC is complying with the emissions limits set forth in the September 29, 2017 consent order. EPA also continues to believe that the sources in the Ohio portion of the area are complying with limits in the approved attainment plan, which West Virginia and EPA rely upon in concluding that West Virginia's portion of the area is attaining the standard. EPA continues to find that West Virginia's August 22, 2019 submittal satisfies the CAA section 107(d)(3)(E) requirements for the redesignation of the West Virginia portion of the Steubenville Nonattainment Area. Therefore, EPA is finalizing the redesignation of the West Virginia portion of the Steubenville Nonattainment Area for the 2010 SO₂ NAAQS.

IV. Final Action

EPA is approving the redesignation of the West Virginia portion of the Steubenville Nonattainment Area (*i.e.*, Cross Creek Tax District in Brooke County) from nonattainment to attainment of the 2010 SO₂ NAAQS. EPA is also approving, as a revision to the West Virginia SIP, West Virginia's maintenance plan for the Steubenville Nonattainment Area. EPA has found that the maintenance plan demonstrates maintenance of the SO₂ NAAQS through 2030 in the Steubenville Nonattainment Area and satisfies the requirements of CAA section 175A.

V. Statutory and Executive Order Reviews

A. General Requirements

Under the CAA, redesignation of an area to attainment and the accompanying approval of the

maintenance plan under CAA section 107(d)(3)(E) are actions that affect the status of a geographical area and do not impose any additional regulatory requirements on sources beyond those required by state law. A redesignation to attainment does not in and of itself impose any new requirements, but rather results in the application of requirements contained in the CAA for areas that have been redesignated to attainment. Moreover, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

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

health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

The SIP is not approved to apply on any Indian reservation land as defined in 18 U.S.C. 1151 or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

B. Submission to Congress and the Comptroller General

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

C. Petitions for Judicial Review

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 11, 2020. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action approving the redesignation of the Steubenville Nonattainment Area and associated maintenance plan 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, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Particulate matter,

Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

40 CFR Part 81

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

Dated: June 16, 2020.

Cosmo Servidio,
Regional Administrator, Region III.

For the reasons stated in the preamble, EPA amends 40 CFR parts 52 and 81 as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart XX—West Virginia

■ 2. In § 52.2520, amend paragraph (e) by adding in the table an entry for “2010 Sulfur Dioxide Maintenance Plan” at the end of the table to read as follows:

§ 52.2520 Identification of plan.

* * * * *
(e) * * *

Name of non-regulatory SIP revision	Applicable geographic area	State submittal date	EPA approval date	Additional explanation
* * * * *	* * * * *	* * * * *	* * * * *	* * * * *
2010 Sulfur Dioxide Maintenance Plan.	Steubenville Area (Cross Creek Tax District, Brooke County).	08/22/19	7/10/2020, [insert Federal Register citation].	Docket No. 2019–0577.

■ 3. Section 52.2525 is amended by adding paragraph (d) to read as follows:

§ 52.2525 Control strategy: Sulfur dioxide.

(d) EPA approves the maintenance plan for Cross Creek Tax District, Brooke County, West Virginia, submitted by the Department of Environmental Protection on August 22, 2019.

PART 81—DESIGNATION OF AREAS FOR AIR QUALITY PLANNING PURPOSES

■ 4. The authority citation for part 81 continues to read as follows:

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

Subpart C—Section 107 Attainment Status Designations

■ 5. In § 81.349 amend the table “West Virginia—2010 Sulfur Dioxide NAAQS [Primary]” by revising the entry for “Steubenville, OH-WV” to read as follows:

§ 81.349 West Virginia.

* * * * *

WEST VIRGINIA—2010 SULFUR DIOXIDE NAAQS
[Primary]

Designated area ^{1 3}	Designation	
	Date ²	Type
Steubenville, OH-WV	8/12/2020	
Brooke County (part)	8/12/2020	Attainment.
Area bounded by the Cross Creek Tax District	8/12/2020	
* * * * *	* * * * *	* * * * *

¹ Includes any Indian country in each county or area, unless otherwise specified. EPA is not determining the boundaries of any area of Indian country in this table, including any area of Indian country located in the larger designation area. The inclusion of any Indian country in the designation area is not a determination that the state has regulatory authority under the Clean Air Act for such Indian country.

² This date is April 9, 2018, unless otherwise noted.

³ Mineral County will be designated by December 31, 2020.

* * * * *

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 1

[WT Docket No. 20–208; DA 20–685; FRS 16914]

Covered Geographic Licenses

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Wireless Telecommunications Bureau of Federal Communications Commission amends rule section 1.907. The intended effect of the amendment to rule section 1.907 is to conform the rule with the Commission's intentions in recent rulemaking actions.

DATES: Effective July 13, 2020.

ADDRESSES: 445 12th Street SW, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Jessica Quinley, Wireless Telecommunications Bureau, Mobility Division, 202–418–1991 or Jessica.Quinley@fcc.gov.

SUPPLEMENTARY INFORMATION: This is a summary of the *Order* in WT Docket No. 20–208, DA 20–685, released June 30, 2020. The full text of the *Order* is available for public inspection at the following internet address: <https://www.fcc.gov/document/order-amending-commission-rule-section-1907>. Alternative formats are available for people with disabilities (Braille, large print, electronic files, audio format), by sending an email to FCC504@fcc.gov or calling the Consumer and Governmental Affairs Bureau at 202–418–0530 (voice) or 202–418–0432 (TTY).

Synopsis

1. In this Order, the Wireless Telecommunications Bureau (Bureau) makes a ministerial change to Commission rule section 1.907 regarding the Wireless Radio Services to conform the definition of “Covered Geographic Licenses” to the Commission’s intentions in recent rulemaking actions.

2. In the July 2019 *2.5 GHz R&O*, the Commission amended the definition of “Covered Geographic Licenses” in section 1.907 to add “Educational Broadband Service (part 27, subpart M).” The Commission, however, deferred the effective date of the rule changes stemming from the *2.5 GHz R&O* for six months from the date of **Federal Register** publication, and the rules became effective on April 27, 2020. In the February 2020 *3.7 GHz*

R&O, the Commission amended the definition of “Covered Geographic Licenses” in section 1.907 to add “3.7 GHz Service (part 27, subpart O),” but inadvertently omitted “Educational Broadband Service (part 27, subpart M)” from the definition. Although the *3.7 GHz R&O*, as corrected by the Second Erratum, was published in the **Federal Register** on April 23, 2020, before the addition of Educational Broadband Service to section 1.907 became effective on April 27, 2020, the rule amendments stemming from the *3.7 GHz R&O* became effective on June 22, 2020 after that addition, thereby inadvertently deleting it. As a result, “Educational Broadband Service (part 27, subpart M)” is no longer listed in the “Covered Geographic Licenses” definition.

3. The Administrative Procedure Act allows an agency to forgo notice and comment “when the agency for good cause finds . . . that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.” Here, we find good cause on the grounds that the notice and comment procedure is unnecessary. The Commission added the term “Educational Broadband Service (part 27, subpart M)” to the definition of “Covered Geographic Licenses” pursuant to a full notice and comment process. The subsequent omission of that term was inadvertent. The reinsertion of “Educational Broadband Service (part 27, subpart M)” into the definition of “Covered Geographic Licenses” in section 1.907 is therefore a routine correction to address an administrative oversight.

4. Similarly, an agency may make a rule effective immediately upon publication in the **Federal Register**, rather than providing for a 30-day waiting period, if the agency finds “good cause.” In determining whether good cause exists for an amended rule to take effect fewer than 30 days after **Federal Register** publication, an agency must “balance the necessity for immediate implementation against principles of fundamental fairness which require that all affected persons be afforded a reasonable amount of time to prepare for the effective date of its ruling.” The immediate implementation of the amended definition is necessary to avoid needlessly prolonging an obvious inaccuracy in the rule and delaying the return of the rule language to its clearly intended meaning. The immediate effective date also would not impose any burdens on affected persons. No additional time is necessary for affected persons to prepare for the effectiveness of the amended rule

because it merely reinstates a term that had been published in its adopted form by the Commission six months before its effective date (*i.e.*, from October 25, 2019, to April 27, 2020)—providing the public with a significantly longer preparatory period than the typically required minimum of 30 days—and which had been an effective part of the rule for almost two months thereafter, up until about a week ago, when its inadvertent deletion occurred (*i.e.*, from April 27 until June 22). In addition, the amended rule does not require affected parties to take, or refrain from taking, any particular action. Thus, we find good cause to make the amended rule effective upon **Federal Register** publication.

5. Accordingly, is it *ordered* that, pursuant to sections 1, 4(i), 5, 301, 303, and 307 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154(i), 155, 301, 303, 307, this *Order* is adopted.

6. *It is further ordered* that the rule amendment adopted herein *will become effective upon publication* in the **Federal Register**.

7. This action is taken under delegated authority pursuant to sections 0.131 and 0.331 of the Commission’s rules, 47 CFR 0.131, 0.331.

Lists of Subjects in 47 CFR Part 1

Administrative practice and procedure.

Federal Communications Commission.

Amy Brett,

Associate Division Chief, Competition and Infrastructure Policy Division, Wireless Telecommunications Bureau.

Final Rule

For the reasons discussed in the preamble, the Wireless Telecommunications Bureau of the Federal Communications Commission amends 47 CFR part 1 as follows:

PART 1—PRACTICE AND PROCEDURE

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

Authority: 47 U.S.C. chs. 2, 5, 9, 13; 28 U.S.C. 2461, unless otherwise noted.

■ 2. Section 1.907 is amended by revising the definition of “covered geographic licenses” to read as follows:

§ 1.907 Definitions.

* * * * *

Covered geographic licenses. Covered geographic licenses consist of the following services: 1.4 GHz Service (part 27, subpart I, of this chapter); 1.6 GHz Service (part 27, subpart J); 24 GHz Service and Digital Electronic Message

Services (part 101, subpart G, of this chapter); 218–219 MHz Service (part 95, subpart F, of this chapter); 220–222 MHz Service, excluding public safety licenses (part 90, subpart T, of this chapter); 600 MHz Service (part 27, subpart N); 700 MHz Commercial Services (part 27, subpart F and H); 700 MHz Guard Band Service (part 27, subpart G); 800 MHz Specialized Mobile Radio Service (part 90, subpart S); 900 MHz Specialized Mobile Radio Service (part 90, subpart S); 3.7 GHz Service (part 27, subpart O); Advanced Wireless Services (part 27, subparts K and L); Air-Ground Radiotelephone Service (Commercial Aviation) (part 22, subpart G, of this chapter); Broadband Personal Communications Service (part 24, subpart E, of this chapter); Broadband Radio Service (part 27, subpart M); Cellular Radiotelephone Service (part 22, subpart H); Citizens Broadband Radio Service (part 96, subpart C, of this chapter); Dedicated Short Range Communications Service, excluding public safety licenses (part 90, subpart M); Educational Broadband Service (part 27, subpart M); H Block Service (part 27, subpart K); Local Multipoint Distribution Service (part 101, subpart L); Multichannel Video Distribution and Data Service (part 101, subpart P); Multilateration Location and Monitoring Service (part 90, subpart M); Multiple Address Systems (EAs) (part 101, subpart O); Narrowband Personal Communications Service (part 24, subpart D); Paging and Radiotelephone Service (part 22, subpart E; part 90, subpart P); VHF Public Coast Stations, including Automated Maritime Telecommunications Systems (part 80, subpart J, of this chapter); Upper Microwave Flexible Use Service (part 30 of this chapter); and Wireless Communications Service (part 27, subpart D).

* * * * *

[FR Doc. 2020–14885 Filed 7–10–20; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 54

[WC Docket Nos. 17–287, 11–42, 09–197; FCC 19–111; FRS 16877]

Bridging the Digital Divide for Low-Income Consumers, Lifeline and Link Up Reform and Modernization, Telecommunications Carriers Eligible for Universal Service Support

AGENCY: Federal Communications Commission.

ACTION: Final rule; announcement of effective date.

SUMMARY: In this document, the Federal Communications Commission (Commission) announces that the Office of Management and Budget (OMB) has approved, for a period of three years, a revision to an information collection associated with the rules for the Lifeline and Link Up Reform and Modernization contained in the Commission's Order, FCC 19–111. This document is consistent with the Fifth Report and Order, Memorandum Opinion and Order and Order on Reconsideration, and Further Notice of Proposed Rulemaking, which stated that the Commission would publish a document in the **Federal Register** announcing the effective date of the new information collection requirements.

DATES: The amendments to amendatory instructions 6.b. (§ 54.404(b)(12)) and 11 (§ 54.410(f)) published at 84 FR 71308, December 27, 2019, are effective October 13, 2020.

FOR FURTHER INFORMATION CONTACT: Nicholas Page, Telecommunications Access Policy Division, Wireline Competition Bureau, (202) 418–7400 or TTY: (202) 418–0484. For additional information concerning the Paperwork Reduction Act information collection requirements contact Nicole Ongele at (202) 418–2991 or via email: Nicole.Ongele@fcc.gov.

SUPPLEMENTARY INFORMATION: The Commission submitted new information collection requirements for review and approval by OMB, as required by the Paperwork Reduction Act (PRA) of 1995, on April 29, 2020, which were approved by the OMB on June 15, 2020. The information collection requirements are contained in the Commission's Fifth Report and Order, Memorandum Opinion and Order and Order on Reconsideration, and Further Notice of Proposed Rulemaking (*2019 Lifeline Order*), FCC 19–111 published at 84 FR 71308, December 27, 2019. The OMB Control Number is 3060–0819. The Commission publishes this document as an announcement of the effective date of the rules published December 27, 2019 that required PRA approval. If you have any comments on the burden estimates listed herein, or how the Commission can improve the collections and reduce any burdens caused thereby, the Commission will accept your comments via email at PRA@fcc.gov. Please include the OMB Control Number, 3060–0819, in your correspondence. Due to the COVID–19 pandemic, the Commission's headquarters will be closed to the general public and will

only be accepting electronic submissions until further notice.

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

Synopsis

As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), the Commission is notifying the public that it received OMB approval on June 15, 2020, for the information collection requirements contained in 47 CFR 54.404(b)(12) and 47 CFR 54.410(f). Under 5 CFR part 1320, an agency may not conduct or sponsor a collection of information unless it displays a current, valid OMB Control Number.

No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act that does not display a current, valid OMB Control Number. The OMB Control Number is 3060–0819.

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

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

OMB Control Number: 3060–0819.

OMB Approval Date: June 15, 2020.

OMB Expiration Date: June 30, 2023.

Title: Bridging the Digital Divide for Low-Income Consumers, Lifeline and Link Up Reform and Modernization, Telecommunications Carriers Eligible for Universal Service Support.

Form No.: FCC Form 481, 497, 555, 5629, 5630, and 5631.

Type of Review: Revision of a currently approved collection.

Respondents: Individuals or households and business or other for-profit enterprises.

Number of Respondents and Responses: 18,335,775 respondents; 20,102,235 responses.

Estimated Time per Response: 0.0167–125 hours.

Frequency of Response: Annual, biennial, monthly, daily and on occasion reporting requirements, recordkeeping requirement and third-party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority is contained in Sections 1, 4(i), 5, 201, 205, 214, 219, 220, 254, 303(r), and 403 of the Communications Act of 1934, as amended, and section 706 of the Communications Act of 1996,

as amended; 47 U.S.C. 151, 154(i), 155, 201, 205, 214, 219, 220, 254, 303(r), 403, and 1302.

Total Annual Burden: 8,531,854 hours.

Total Annual Cost: \$937,500.

Privacy Impact Assessment: Yes. The Commission completed a Privacy Impact Assessment (PIA) for some of the information collection requirements contained in this collection. The PIA was published in the **Federal Register** at 82 FR 38686 on August 15, 2017. The PIA may be reviewed at: http://www.fcc.gov/omd/privacyact/Privacy_Impact_Assessment.html.

Nature and Extent of Confidentiality: Some of the requirements contained in this information collection affect individuals or households, and thus, there are impacts under the Privacy Act. The FCC's system of records notice (SORN) associated with this collection is FCC/WCB-1, "Lifeline Program."

The Commission will use the information contained in FCC/WCB-1 to cover the personally identifiable information (PII) that is required as part of the Lifeline Program (Lifeline).

As required by the Privacy Act of 1974, as amended, 5 U.S.C. 552a, the Commission published FCC/WCB-1 Lifeline Program in the **Federal Register** on August 15, 2017 (82 FR 38686).

Also, respondents may request materials or information submitted to the Commission or to the Universal Service Administrative Company (USAC or Administrator) be withheld from public inspection under 47 CFR 0.459 of the FCC's rules. We note that USAC must preserve the confidentiality of all data obtained from respondents; must not use the data except for purposes of administering the universal service programs; and must not disclose data in company-specific form unless directed to do so by the Commission.

Needs and Uses: This collection is used to restore the traditional state and federal roles in designating eligible telecommunications carriers (ETC) and eliminate the Lifeline Broadband Provider (LBP) category as a result of the *2019 Lifeline Order*. This revision codifies a requirement that enrollment representatives must register with USAC before interacting with USAC's systems. This revision also implements several process and procedural changes to further bolster program integrity efforts, requiring minor modifications to the previously approved requirements. These changes have a moderate impact

on the overall burden, increasing the burden hours for some requirements and decreasing the burden hours for other requirements.

Federal Communications Commission.

Cecilia Sigmund,

Federal Register Liaison Officer, Office of the Secretary.

[FR Doc. 2020-13611 Filed 7-10-20; 8:45 am]

BILLING CODE 6712-01-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 200227-0066; RTID 0648-XY095]

Fisheries of the Exclusive Economic Zone Off Alaska; Kamchatka Flounder in the Bering Sea and Aleutian Islands Management Area

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting directed fishing for Kamchatka flounder in the Bering Sea and Aleutian Islands management area (BSAI). This action is necessary to prevent exceeding the 2020 Kamchatka flounder initial total allowable catch (ITAC) in the BSAI.

DATES: Effective 1200 hours, Alaska local time (A.l.t.), July 8, 2020, through 2400 hours, A.l.t., December 31, 2020.

FOR FURTHER INFORMATION CONTACT:

Steve Whitney, 907-586-7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the BSAI according to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The 2020 Kamchatka flounder ITAC in the BSAI is 5,780 metric tons (mt) as established by the final 2020 and 2021 harvest specifications for groundfish in the BSAI (85 FR 13553, March 9, 2020).

In accordance with § 679.20(d)(1)(i), the Administrator, Alaska Region, NMFS (Regional Administrator), has determined that the 2020 Kamchatka flounder ITAC in the BSAI will soon be reached. Therefore, the Regional Administrator is establishing a directed fishing allowance of 2,000 mt, and is setting aside the remaining 3,780 mt as incidental catch to support other anticipated groundfish fisheries. In accordance with § 679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance has been reached. Consequently, NMFS is prohibiting directed fishing for Kamchatka flounder in the BSAI.

While this closure is effective the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a trip.

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the closure of Kamchatka flounder to directed fishing in the BSAI. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of July 7, 2020.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by § 679.20 and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: July 8, 2020.

Ngagne Jafnar Gueye,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2020-15073 Filed 7-8-20; 4:15 pm]

BILLING CODE 3510-22-P

Proposed Rules

Federal Register

Vol. 85, No. 134

Monday, July 13, 2020

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2019–0955]

RIN 1625–AA09

Drawbridge Operation Regulation; New River, Fort Lauderdale, FL

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to change the operating schedule that governs the Florida East Coast (FEC) Railroad Bridge across the New River, mile 2.5, at Fort Lauderdale, Florida. This proposed change will allow the drawbridge to operate on a more predictable schedule. This proposed action is expected to better serve the reasonable needs of both vessel and rail traffic.

DATES: Comments and related material must reach the Coast Guard on or before August 12, 2020.

ADDRESSES: You may submit comments identified by docket number USCG–2019–0955 using Federal e-Rulemaking Portal at <https://www.regulations.gov>.

See the “Public Participation and Request for Comments” portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email LT Samuel Rodriguez-Gonzalez, U.S. Coast Guard, Sector Miami Waterways Management Division; telephone 305–535–4307, email Samuel.Rodriguez-Gonzalez@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
 DHS Department of Homeland Security
 FR Federal Register
 OMB Office of Management and Budget
 NPRM Notice of Proposed Rulemaking
 (Advance, Supplemental)

§ Section
 U.S.C. United States Code
 FL Florida
 FECR Florida East Coast Railway
 FEC Florida East Coast
 VTUS–F Virgin Trains USA-Florida, LLC
 MIA SF Marine Industries Association of South Florida

II. Background, Purpose and Legal Basis

Virgin Train USA Florida (VTUS–F), with support from the bridge owner, Florida East Coast Railway (FECR), requested a change to the drawbridge operating schedule due to an increase in rail traffic in recent years. The operating schedule for the bridge set forth in 33 CFR 117.313(c) no longer balances the needs of vessel and rail traffic.

The Florida East Coast (FEC) Railroad Bridge across the New River, mile 2.5, at Fort Lauderdale, Florida is a single-leaf bascule railroad bridge with a four-foot vertical clearance at mean high water in the closed position. Traffic on the waterway includes both commercial and recreational vessels.

On January 23, 2020, the Coast Guard published a Test Deviation entitled Drawbridge Operation Regulation; New River, Fort Lauderdale, FL in the **Federal Register** (85 FR 3852). We received seven comments.

Five comments were against the proposed changes. Two comments stated that sufficient data was not presented to support a six-month test deviation. The Coast Guard published the Test Deviation based on data provided by the maritime community regarding the unpredictability of openings and the failure of the bridge owner to comply with the drawbridge operating regulation. The data, which was reported to Coast Guard Sector Miami and the Seventh District, provided sufficient information to indicate a clear need to publish a Test Deviation to address a need for predictability to facilitate reasonable maritime traffic. Three comments addressed a concern that vessel operators would have to wait up to 50 minutes for the bridge to open and stated there should be equal access to the waterway. This interpretation of the proposed rule does not accurately reflect the regulation or the Coast Guard’s intent. The bridge will remain in the open position and available to mariners when trains are not crossing, except during inspections and minor

repairs that should not interfere with the 10-minute opening or, at certain times, an additional 10-minute opening. The Coast Guard must ensure that the reasonable needs of navigation are met, not necessarily all the needs. The Test Deviation provided a predictable schedule for maritime traffic that ensured the reasonable needs of navigation could be met.

The bridge owner provided comments in support of implementing the test deviation as the permanent operating schedule for the FEC Railroad Bridge. They stated that predictable and sufficient openings, as well as sufficient closures to facilitate rail operations, appeared to be sufficient to satisfy both the marine community and railroads. Additionally, they provided an abbreviated vessel traffic study during the month of March 2020 conducted by an independent company. Data was collected between March 3 and March 18, 2020, via recorded video from the Marine Industries Association of South Florida’s (MIA SF) New River Live Feed camera mounted west of the bridge and directed east toward the bridge. A two-day field survey was conducted to test the validity of the data collected during the video review. The contractor observed 1,786 boats over the entire study period, with an average queue time of 4 minutes. The majority of boaters did not queue due to FEC bridge closure: 73% to 80% of boats crossed through the open bridge immediately upon approach during the Video Review and Field Survey, respectively. For the 20% to 27% of boaters who queued, the average queue time ranged from 10 to 17 minutes. Over the study period, the average queue time for all observed boats ranged from 2 to 5 minutes.

MIA SF provided comments in support of the test deviation; however, they stated that long overdue improvements in infrastructure are needed to overcome the unreasonable obstruction of the waterway and the fundamental conflict that an increase in train operations poses to marine operations. This comment is outside the scope of this NPRM. MIA SF indicated measures instituted by the test deviation have done much to address the intermodal conflicts, but also suggested minor modifications. MIA SF specifically addressed the lowering of the drawbridge after the published schedule when no rail traffic is passing

and an additional requirement to promptly raise the drawbridge once rail traffic has cleared the drawbridge. The proposed rule does allow for the bridge to remain in the closed to navigation position for inspections and minor repairs that do not interfere with the published schedule. Additionally, 33 CFR 117.9—Delaying opening of a draw, does note “Trains are usually controlled by the block method . . . Land and water traffic should pass over or through the draw as soon as possible in order to prevent unnecessary delays in the opening and closure of the draw.” MIA SF also addressed drawbridge maintenance management, general communications and how to ensure the marine community is informed. The proposed rule requires the bridge owner to maintain a website and mobile application that displays required opening times, a 24-hour advance notice of the schedule and to the extent reasonably practicable, at least 60-minutes advance notice of schedule changes or delays. Additionally, the proposed rule requires the bridge owner receive Coast Guard approval prior to engaging in routine maintenance that may affect the operating schedule. Lastly, concerns regarding the bridge owner’s course of action in case of a vessel or facility fire, as well as other emergencies were raised. When an emergency situation is declared, the bridge owner is required to follow 33 CFR 117.31 which addresses drawbridge operations for emergency vehicles and emergency vessels.

FE CR requested a modification to the proposed rule for overnight drawbridge operations. FE CR stated that during overnight hours when vessel traffic is minimal, the 10-minute opening requirement every hour should be removed. This proposed rule removes the 10-minute opening requirement between midnight and 4:59 a.m., however the requirement stating the bridge shall not be closed to navigation for more than 60 consecutive minutes remains at all times.

III. Discussion of Proposed Rule

The proposed rule will allow the drawbridge to operate on a more predictable schedule. Under this proposed regulation, the draw of the FEC Railroad Bridge would provide a pre-determined 10-minute opening between 5:00 a.m. and 11:59 p.m. An additional 10-minute opening would be provided at various times throughout the day. A mobile application and website shall be maintained depicting the operational status of the drawbridge. These proposed changes are necessary to improve the flow of marine traffic on

the New River by providing predictable, pre-determined openings and increased communications through various media sources.

This proposed change would still allow vessels that are capable of transiting under the bridge, without an opening, to do so at any time while taking into account the reasonable needs of other modes of transportation. Vessels in distress and public vessels of the United States must be allowed to pass at any time or as soon as the train has cleared the bridge.

IV. Regulatory Analyses

We developed this proposed rule after considering numerous statutes and Executive Orders related to rulemaking. Below we summarize our analyses based on 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. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This NPRM has not been designated a “significant regulatory action,” under Executive Order 12866. Accordingly, the NPRM has not been reviewed by the Office of Management and Budget (OMB) and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the ability that vessels can continue to transit the bridge at designated times throughout the day and when trains are not crossing or when a vessel is in distress.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980 (RFA), 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 certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the bridge may be small entities, for the reasons stated in section IV.A above this

proposed rule would not have a significant economic impact on any vessel owner or operator.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

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 proposed 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 contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

C. Collection of Information

This proposed rule would call for no 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 proposed 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 proposed rule does not have tribal implications under Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments) because it would 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. If you believe this proposed rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

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 proposed rule will not result in such an expenditure, we do discuss the effects of this proposed rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning Policy COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA)(42 U.S.C. 4321–4370f). The Coast Guard has 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 proposed rule promulgates the operating regulations or procedures for drawbridges. Normally such actions are categorically excluded from further review, under paragraph L49, of Chapter 3, Table 3–1 of the U.S. Coast Guard Environmental Planning Implementation Procedures.

Neither a Record of Environmental Consideration nor a Memorandum for the Record are required for this rule. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact 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.

V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking, and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this

document to which each comment applies, and provide a reason for each suggestion or recommendation.

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

We accept anonymous comments. All comments received will be posted without change to <https://www.regulations.gov> and will include any personal information you have provided. <http://www.regulations.gov/privacynotice>. For more about privacy and submissions in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

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

List of Subjects in 33 CFR Part 117

Bridges.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

■ 1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 33 CFR 1.05–1; Department of Homeland Security Delegation No. 0170.1.

■ 2. Revise § 117.313 paragraph (c) to read as follows:

§ 117.313 New River

* * * * *

(c) The draw Florida East Coast (FEC) Railroad Bridge across the New River, mile 2.5, at Fort Lauderdale shall operate as follows:

(1) The drawbridge shall be maintained in the fully open-to-navigation position for vessels at all times, except during periods when it is closed for the passage of rail traffic, inspections and minor repairs that do not interfere with the pre-determined opening times outlined in this part.

(2) The drawbridge shall not be closed to navigation for more than 60 consecutive minutes.

(3) The drawbridge shall open and remain open to navigation for a fixed 10-minute period each hour from 5 a.m. to 11:59 p.m., except that the drawbridge shall be open at the following times which shall serve as the hourly fixed 10-minute period:

—7:00 a.m. until 7:10 a.m.

—9:00 a.m. until 9:10 a.m.

—4:00 p.m. until 4:10 p.m.

—6:00 p.m. until 6:10 p.m.

—10:00 p.m. until 10:10 p.m.

(i) Additionally, in each hour from 12:00 p.m. to 2:59 p.m., the drawbridge shall open and remain open to navigation for an additional 10-minute period.

(ii) The 10-minute opening periods shall be published on a quarterly basis by the drawbridge owner and reflected on the owner's website and mobile application.

(4) The drawbridge shall have a drawbridge tender onsite at all times who is capable of physically tending and operating the drawbridge by local control, if necessary, or when ordered by the Coast Guard.

(i) The drawbridge tender shall provide estimated times of drawbridge openings and closures, upon request.

(ii) Operational information will be provided 24 hours a day on VHF–FM channels 9 and 16 or by telephone at (305) 889–5572. Signs shall be posted visible to marine traffic and displaying VHF radio contact information, website and application information, and the telephone number for the bridge tender.

(5) In the event of a drawbridge operational failure, or other emergency circumstances impacting normal drawbridge operations, the drawbridge owner shall immediately notify the Coast Guard Captain of the Port Miami and provide an estimated time of repair and return to normal operations.

(6) A drawbridge log shall be maintained including drawbridge opening and closing times. The drawbridge log should include reasons for those drawbridge closings that interfere with scheduled openings in this part. This log shall be provided to the Coast Guard upon request.

(7) A website and mobile application shall be maintained to publish:

(i) Drawbridge opening times required by this subsection;

(ii) Timely updates to schedules;

(iii) At least 24-hour advance notice for each schedule in order to facilitate planning by maritime operators; and

(iv) To the extent reasonably practicable, at least 60-minutes advance notice of schedule changes or delays.

(8) The drawbridge shall display the following lights:

(i) When the drawbridge is in the fully open position, green lights shall be displayed to indicate that vessels may pass.

(ii) When rail traffic approaches the block signal, the lights shall go to flashing red, then the drawbridge lowers and locks, and the lights shall remain flashing red.

(iii) After the rail traffic has cleared the drawbridge, the drawbridge shall open and the lights return to green.

* * * * *

Dated: June 29, 2020

Eric C. Jones,

*Rear Admiral, U.S. Coast Guard, Commander
Seventh Coast Guard District.*

[FR Doc. 2020–14578 Filed 7–10–20; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 162

[Docket Number USCG–2019–0899]

RIN 1625–AC04

Inland Waterways Navigation: St. Marys River, Sault Ste. Marie, Michigan

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard is proposing to exempt vessels under 20 meters (65 feet) in length operating in the St. Marys River along Michigan’s eastern Upper Peninsula from certain speed rules. Exempting such vessels from these rules is necessary because enforcement is impractical and the rules impede the operations of public response vessels. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before August 12, 2020.

ADDRESSES: You may submit comments identified by docket number USCG–2019–0899 using the Federal eRulemaking Portal at <https://www.regulations.gov>. See the “Public Participation and Request for Comments” portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email LTJG Blake Bonifas, Waterways Management, Ninth Coast Guard District, Cleveland, OH, telephone (216) 902–6066, email Blake.E.Bonifas@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, Purpose, and Legal Basis

The inland navigation rules for the St. Marys River along Michigan’s eastern Upper Peninsula are prescribed by 33 CFR 162.117. These rules include speed limits for stretches of the St. Marys River demarcated by lights.

U.S. Coast Guard Vessel Traffic Services (VTS) St. Mary’s River monitors and directs vessel traffic movement within the VTS St. Marys River area through a Vessel Movement Reporting System (VMRS). This VTS area overlaps the length of the St. Marys River governed by the speed rules in § 162.117(g). The VMRS requires users, generally including commercial vessels of 20 meters or more, to report information, including their position, course, and speed. These users report their information through radio communications and Automatic Identification System (AIS). Because VTS St. Marys River tracks speed for VMRS users, it can and does enforce the speed rules in § 162.117(g) on these users.

Many non-VMRS vessels transit the length of the St. Marys River governed by the speed rules in § 162.117(g). These vessels generally include private vessels under 20 meters. As non-VMRS users, these vessels are not required to report their speed to the VTS St. Marys River. Additionally, unlike commercial vessels of 20 meters or more, these vessels are not required to operate with AIS, the prevalent means of reporting location, course, and speed to VTS St. Marys River. Because the VTS St. Marys River cannot track these non-VMRS vessels, it cannot, realistically, enforce the speed rules in § 162.117(g) on these vessels.

The speed rules in § 162.117(g) also impact the operational effectiveness of public response vessels in the St. Marys River. These vessels include small boats, generally under 20 meters, operated by the U.S. Coast Guard and federal, Canadian, state, and local partners. These small boats respond to pollution incidents, marine casualties, and perform search and rescue and law enforcement operations throughout the St. Marys River. These operations require public vessels to deploy and be on-scene rapidly. The speed rules

impede response times and degrade operational effectiveness to the detriment of the boating public and industry.

Because the speed rules in 162.117(g) are not enforceable on non-VMRS users and impact operational effectiveness of public response boats, this rule proposes to exempt vessels under 20 meters (65 feet) from these speed rules.

This proposed exemption is not anticipated to impact the St. Marys River VTS, VMRS, or its users. Additionally, it is not intended to relieve vessels under 20 meters from the responsibility to boat safely and exercise good seamanship. This proposed rule is issued under the authority of 46 U.S.C. 70034.

III. Discussion of Proposed Rule

The Coast Guard is proposing to amend the speed rules in 33 CFR 162.117(g), because, as they are currently written, they are too broad and unnecessarily restrict vessel operations. Specifically, this rule proposes to exempt vessels under 20 meters (65 feet) from the speed rules in 162.117(g). The regulatory text we are proposing appears at the end of this document.

IV. Regulatory Analyses

We developed this proposed 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. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This NPRM has not been designated a “significant regulatory action,” under Executive Order 12866. Accordingly, the NPRM has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the fact that we do not anticipate that it will adversely affect the economy, will not interfere with other agencies, will not adversely alter the budget of any grant of loan recipients, and will not raise any novel legal or policy issues. Rather, permitting vessels under 20 meters to operate free of the speed rules in 33 CFR 162.117(g)

will lessen restrictions on the public and enable public vessels to engage unimpeded in response operations.

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 certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities.

This proposed amendment will lessen navigation restrictions on public entities, a large majority of recreational vessel owners and private businesses who operate small commercial vessels.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

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 proposed 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. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

C. Collection of Information

This proposed rule would 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 proposed 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 proposed rule does not have tribal implications under Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments) because it would 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. If you believe this proposed rule has implications for federalism or Indian tribes, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

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 proposed rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this proposed rule under Department of Homeland Security Directive 023–01 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 made a preliminary determination 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 proposed rule involves an amendment to navigation regulations for speed limits within a waterway. Normally such actions are categorically excluded from further review under paragraph L60(a) in Table 3–1 of U.S. Coast Guard Environmental Planning Implementing Procedures. A preliminary Record of Environmental Consideration supporting this determination is available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

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.

V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking, and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

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

We accept anonymous comments. All comments received will be posted without change to <https://www.regulations.gov> and will include any personal information you have provided. For more about privacy and submissions in response to this document, see DHS’s Correspondence System of Records notice (84 FR 48645, September 26, 2018).

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

List of Subjects in 33 CFR Part 162

Navigation (water), Waterways.

For the reasons discussed in the preamble, the Coast Guard is proposing to amend 33 CFR part 162 as follows:

PART 162—INLAND WATERWAYS NAVIGATION REGULATIONS

■ 1. The authority citation for part 162 is revised to read as follows:

Authority: 46 U.S.C 70034; Department of Homeland Security Delegation No. 0170.1.

■ 2. In § 162.117, revise paragraph (g)(1) to read as follows:

§ 162.117 St. Marys River, Sault Ste. Marie, Michigan.

* * * * *

(g) *Speed Rules.* (1) The following speed limits indicate speed over the ground. Vessels, other than those under 20 meters (65 feet) in length, must adhere to the following speed limits.

* * * * *

Dated: June 9, 2020.

D.L. Cottrell,

Rear Admiral, U.S. Coast Guard, Commander, Ninth Coast Guard District.

[FR Doc. 2020-14100 Filed 7-10-20; 8:45 am]

BILLING CODE 9110-04-P

Notices

Federal Register

Vol. 85, No. 134

Monday, July 13, 2020

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

Forest Service

Idaho Panhandle Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Idaho Panhandle Resource Advisory Committee (RAC) will hold a virtual meeting. The committee is authorized under the Secure Rural Schools and Community Self-Determination Act (the Act) and operates in compliance with the Federal Advisory Committee Act. The purpose of the committee is to improve collaborative relationships and to provide advice and recommendations to the Forest Service concerning projects and funding consistent with Title II of the Act. RAC information and virtual meeting information can be found at the following website: <https://www.fs.usda.gov/main/ipnf/workingtogether/advisorycommittees>.

DATES: The meeting will be held on Thursday, August 6, 2020, at 1:00 p.m. (PDT).

All RAC meetings are subject to cancellation. For status of the meeting prior to attendance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

ADDRESSES: The meeting will be held virtually. For virtual meeting information, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

Written comments may be submitted as described under **SUPPLEMENTARY INFORMATION**. All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at the Idaho Panhandle National Forest's Supervisor's Office. Please call ahead to facilitate that inspection.

FOR FURTHER INFORMATION CONTACT:

Phillip Blundell, RAC Coordinator, by phone at 208-783-2101 or by email at phillip.blundell@usda.gov.

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1-800-877-8339 between 8:00 a.m. and 8:00 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to:

1. Introduce and orient the new RAC members;
2. Discuss the status of 2019 RAC approved projects; and
3. Discuss the solicitation and review of new Title II project proposals.

This meeting is open to the public. The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should request in writing by Thursday, July 23, 2020, to be scheduled on the agenda. Anyone who would like to bring related matters to the attention of the committee may file written statements with the committee staff before or after the meeting. Written comments, requests for time for oral comments or requests for instructions to participate virtually must be sent to Phillip Blundell, RAC Coordinator, Post Office Box 159, Smelterville, Idaho 83868; by email to phillip.blundell@usda.gov or by phone at 208-783-2101.

Meeting Accommodations: If you are a person requiring reasonable accommodation, please make requests in advance for sign language interpreting, assistive listening devices, or other reasonable accommodation. All reasonable accommodation requests are managed on a case-by-case basis.

Dated: July 7, 2020.

Cikena Reid,

USDA Committee Management Officer.

[FR Doc. 2020-14958 Filed 7-10-20; 8:45 am]

BILLING CODE 3411-15-P

DEPARTMENT OF AGRICULTURE

Office of Partnerships and Public Engagement

[FOA No.: OPPE-014 & OPPE-016]

Funding Opportunity Announcement: Outreach and Assistance for Socially Disadvantaged Farmers and Ranchers and Veteran Farmers and Ranchers

Catalog of Federal Domestic Assistance (CFDA) No.: 10.443—Outreach and Assistance for Socially Disadvantaged Farmers and Ranchers and Veteran Farmers and Ranchers.

AGENCY: Office of Partnerships and Public Engagement (OPPE), Agriculture (USDA).

ACTION: Funding Opportunity Announcement (FOA) for Fiscal Years 2020 and FY 2021.

SUMMARY: This notice announces the availability of funds for two fiscal years (FY 2020 and FY2021) and solicits applications from community-based and non-profit organizations, institutions of higher education, and Tribal entities to compete for financial assistance through the Outreach and Assistance for Socially Disadvantaged Farmers and Ranchers and Veteran Farmers and Ranchers Program (hereinafter referred to as the "2501 Program").

DATES: Only one project proposal may be submitted per eligible entity. Proposals must be submitted through <http://www.grants.gov> and received by September 11, 2020, at 11:59 p.m. EST. Proposals submitted after this deadline will *not* be considered for funding.

The OPPE will host at least two (2) teleconferences during the open period of this announcement as provided below. Additional sessions may be necessary to answer questions and clarify requirements. There is no registration required to participate.

- July 14, 2020 at 2:00 p.m. EST, Telephone Number: (877) 692-8955, Passcode: 4438047
- July 28, 2020 at 2:00 p.m. EST, Telephone Number: (877) 692-8955, Passcode: 6433267

ADDRESSES:

Filing a Complaint of Discrimination

To file a program discrimination complaint, you may obtain a complaint form by sending an email to cr-info@ascr.usda.gov. You or your authorized

representative must sign the complaint form. You are not required to use the complaint form. You may write a letter instead. If you write a letter, it must contain all the information requested in the form and be signed by you or your authorized representative. Incomplete information will delay the processing of your complaint. Employment civil rights complaints will not be accepted through this email address.

Send your completed complaint form or letter to USDA by mail, fax, or email:

Mail: U.S. Department of Agriculture, Director, Office of Adjudication, 1400 Independence Avenue SW, Washington, DC 20250-9410.

Fax: (202) 690-7442.

Email: program.intake@usda.gov.

For Further Information, or for Programmatic Complaints, Please Contact: U.S. Department of Agriculture, Office of Partnerships and Public Engagement, Attn: 2501 Program Director, Jamie L. Whitten Building, Room 520-A, 1400 Independence Avenue SW, Washington, DC 20250; Phone: (202) 720-6350; Fax: (202) 720-7704; Email: 2501grants@usda.gov.

Persons with Disabilities: Persons who require alternative means for communication (braille large print, audiotape, etc.), should contact USDA's TARGET Center at (202) 720-2600 (voice and TDD). Additionally, alternative means for submissions due to disability status will be approved on a case-by-case basis.

SUPPLEMENTARY INFORMATION: The overall goal of the 2501 Program is to encourage and assist socially disadvantaged farmers and ranchers, veteran farmers and ranchers, and beginning farmers and ranchers with owning and operating farms and ranches and in participating equitably in the full range of agricultural, forestry, and related programs offered by USDA. In partnership with the OPPE, eligible entities may compete for funding on projects that provide education and training in agriculture, agribusiness, forestry, agriculturally related services, and USDA programs and to conduct outreach initiatives designed to accomplish those goals. This partnership includes working closely with USDA Liaisons to coordinate outreach and training initiatives, attend OPPE-led events in your proposed service territory, and collaborate with your State Food and Agriculture Council (Farm Service Agency, Natural Resource Conservation Service, and Rural Development).

Funding/Awards: The total funding provided in the 2018 Farm Bill for this competitive program is approximately

\$15 million. The OPPE will award grants from this announcement, subject to availability of funds and the quality of applications received. All applicants will compete based on their organization's entity type (e.g., nonprofit organization or higher education institution), as described below. The maximum project period is three (3) years. The maximum amount of requested federal funding for projects shall not exceed \$450,000 over the 3-year period. Additionally, the maximum award per year is \$150,000. Projects that are part of multi-year initiatives will be funded in accordance with the approved statement of work and the OPPE Guidelines. Additionally, USDA has the discretion to fund multi-year projects to maximize outreach, education and technical assistance ensuring geographical distribution of funds as required in section 7 U.S.C. 2279(c)(4)(G).

Funds will be awarded to eligible entities that have documented knowledge of and experience with USDA programs and experience in providing agricultural education or other agriculturally related services to socially disadvantaged farmers and ranchers or veteran farmers and ranchers during the 3-year period preceding the submission of an application. The Secretary shall give priority to nongovernmental and community-based organizations (see Section V. Application Review Information).

An applicant MUST be an entity or organization. "Individuals" do not meet the eligibility criteria.

Funds under this program may not be used for the planning, repair, rehabilitation, acquisition, or construction of a building or facility. Program funds may not be used for start-up or financing costs for businesses or for an organization's capacity building. Program funds may also not be used as small agricultural loans for individual farmers or used to incentivize individuals to attend an event.

Eligible entities may receive subsequent years funding provided that:

- (a) Activities and associated costs do not overlap with projects awarded in previous years; and
- (b) Recipients are current and compliant with existing financial and progress reporting. The progress of existing projects, along with the percentage of funds used to date, may impact funding decisions.

The OPPE reserves the right to approve one-year no cost extensions (no additional funds) for one-year projects.

Funding will be awarded based on peer competition within the three

categories described below along with the amount of anticipated funding for each category. The OPPE reserves the right to allocate funding between the three categories based upon the number and quality of applications received. There is no commitment by the OPPE to fund any particular application or to select a specific number of recipients within each category.

Category #1: Eligible entities described in Sections III.A.2, III.A.3, and III.A.4 (1890 Land Grant colleges and universities, 1994 Tribal Land-Grant, Alaska Native and American Indian Tribal colleges and universities, and Hispanic-Serving Institutions of higher education).

Category #2: Eligible entities described in Sections III.A.1 and III.A.6 (i.e., nonprofit organizations, community-based organizations, including a network or a coalition of community-based organizations, Indian Tribes (as defined in 25 U.S.C. 450b), and National Tribal organizations).

Category #3: Eligible entities described in Sections III.A.5 and III.A.7 (i.e., all other institutions of higher education including 1862 colleges, nonprofit organizations without a 501(c)(3) status certification from the IRS, and other organizations or institutions, including those that received funding under this program before January 1, 1996).

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I. Funding Opportunity Description

A. Background

The OPPE is committed to ensuring that socially disadvantaged and veteran farmers and ranchers are able to equitably participate in USDA programs. Differences in demographics, culture, economics, and other factors preclude a single approach to identifying solutions that can benefit our underserved farmers and ranchers. Community-based and non-profit organizations, higher education institutions, and eligible Tribal entities with an expertise in working with socially disadvantaged farmers and ranchers or veteran farmers and ranchers can play a critical role in addressing the unique difficulties they face and can help improve their ability to start and maintain successful agricultural businesses. With 2501

Program funding, organizations can provide agricultural education and training and extend our outreach efforts to connect with and assist local socially disadvantaged and veteran farmers and ranchers to provide them with information on available USDA resources.

1. The 2501 Program was authorized by the Food, Agriculture, Conservation, and Trade Act of 1990. The Food, Conservation, and Energy Act of 2008 expanded the authority of the Secretary of Agriculture (the Secretary) to provide awards under the program and transferred the administrative authority to the OPPE. The Agricultural Act of 2014 further expanded the program to include outreach and assistance to veterans. The 2501 Program extends USDA's capacity to work with members of farming and ranching communities by funding projects that enhance the equitable participation of socially disadvantaged and veteran farmers and ranchers in USDA programs. It is the OPPE's intention to build lasting relationships between USDA, recipient organizations, and socially disadvantaged and veteran farmers and ranchers.

2. Only one proposal will be accepted from each organization. This does not apply to applicants in the State of Massachusetts. The State fiscal transfer agent may submit multiple proposals ensuring that only one proposal is submitted on behalf of each of its individual fiscally sponsored organizations.

B. Scope of Work

The 2501 Program provides funding to eligible organizations with at least 3 years of documented history working with socially disadvantaged farmers or ranchers or veteran farmers or ranchers for projects designed to provide education and training in agriculture and to assist socially disadvantaged or veteran farmers and ranchers in owning and operating viable agricultural enterprises. This is a non-construction grant. Proposals must be consistent with requirements stated in 7 U.S.C. 2279(c)(3). Under this statute, the education, training and outreach program funds shall be used exclusively:

1. To enhance coordination of the outreach, education, and training efforts authorized under agriculture programs;

2. To assist the Secretary of Agriculture in:

a. Reaching current and prospective socially disadvantaged farmers or ranchers or veteran farmers or ranchers in a linguistically appropriate manner; and

b. improving the participation of those farmers and ranchers in USDA programs.

There are five priority areas that support the goals of the 2501 Program. Proposals from eligible entities must address at least two of the five following priority areas:

1. Assist socially disadvantaged or veteran farmers and ranchers in owning and operating successful farms and ranches;

2. Improve participation among socially disadvantaged or veteran farmers and ranchers in USDA programs;

3. Build relationships between current and prospective farmers and ranchers who are socially disadvantaged or veterans and USDA's local, state, regional, and National offices;

4. Introduce agriculture-related information to socially disadvantaged or veteran farmers and ranchers through innovative training and technical assistance techniques; and

5. Introduce agricultural education targeting youth and beginning socially disadvantaged and veteran farmers and ranchers in rural and persistent poverty communities.

The OPPE is required to seek input from stakeholders providing education and training under this grant program at least annually. This is to ensure that the program is responsive to the concerns of entities providing assistance (7 U.S.C. 2279(c)(4)(J)). To fulfill this obligation, the OPPE may require Project Directors to attend an Annual Partnership Symposium that can be expensed with awarded grant funds not to exceed \$1,000 per award year. The symposium will allow participants, USDA officials, and other agriculture-related industry participants to network, encourage partnerships, share best practices, discuss programmatic requirements, share information on new and enhanced USDA programs and services, and obtain programmatic stakeholder feedback. Stakeholder input will also be accepted by those unable to attend the annual symposium in person by September 30th of each fiscal year at: 2501grants@usda.gov.

C. Anticipated Outputs (Activities), Outcomes (Results), and Performance Measures

1. Outputs (Activities). The term "output" means an outreach, educational component, or assistance activity, task, or associated work product related to improving the ability of socially disadvantaged or veteran farmers and ranchers to own and operate farms and ranches, assistance with agriculture related activities, or

guidance for participation in USDA programs. Outputs may be quantitative or qualitative but must be measurable during the period of performance.

Examples of outputs from the projects to be funded under this announcement may describe an organization's activities and their participants such as: Number of workshops or meetings held and number of participants attending (including a list of participants with contact information); frequency of services or training delivered and to whom; development of products, curriculum, or resources provided. Other examples include but are not limited to the following:

a. Number of socially disadvantaged and/or veteran farmers or ranchers served;

b. number of conferences or training sessions held and number of socially disadvantaged and/or veteran farmers and ranchers that attended;

c. type and topic of educational materials distributed at outreach events;

d. creation of a program to enhance the operational viability of socially disadvantaged and/or veteran farmers and ranchers;

e. number of applications completed by socially disadvantaged and/or veteran farmers or ranchers submitted for consideration for USDA programs; or

f. activity that supports increased participation of socially disadvantaged farmers and/or ranchers and/or veteran farmers and ranchers in USDA programs.

Progress and Financial Reports will be required, as specified in Section VI, Subsection C, "Reporting Requirement."

2. Outcomes (Results). The term "outcome" means the difference or effect that has occurred as a result from carrying out an activity, workshop, meeting, or from delivery of services related to a programmatic goal or objective. Outcomes refer to the final impact, change, or result that occurs as a direct result of the activities performed in accomplishing the objectives and goals of your project. Outcomes may refer to results that are agricultural, behavioral, social, or economic in nature. Outcomes may reflect an increase in knowledge or skills, a greater awareness of available resources or programs, or actions taken by stakeholders as a result of learning. Specifically, outcomes must be quantitative as it relates to the project goals and objectives.

Project Directors will be required to document anticipated outcomes that are funded under this announcement including, but not limited to the following:

a. Documenting the number of new farmers and/or ranchers your organization assisted as a result of your project and the type of assistance;

b. Documenting race, sex, national origin, disability and number of socially disadvantaged and/or veteran farmers or ranchers *applying* for USDA programs and services by program area;

c. Documenting race, sex, national origin, disability and number of USDA program applications *approved* for funding, by program area, for socially disadvantaged or veteran farmers or ranchers as a result of your activities;

d. Documenting the number of socially disadvantaged or veteran farmers and/or ranchers that have better access to USDA Programs as a result of your outreach and/or training efforts;

e. Documenting the enhanced sustainability and retention of farming operations among socially disadvantaged or veteran farmers or ranchers;

f. Documenting higher profitability and economic stability among socially disadvantaged or veteran farmers or ranchers resulting from increased access to marketing and enhanced sales opportunities for their products; and

g. Documenting an increase in the number and types of USDA programs and services utilized as a result of your project.

3. Performance Measures.

Performance measures are tied to the goals or objectives of each activity and ultimately the overall purpose of the project. They provide insight into the effectiveness of proposed activities by indicating areas where a project may need adjustments. Applicants must develop performance measure expectations which will occur as a result of their proposed activities. These expectations will be used as a mechanism to track the progress and success of a project. Project performance measures should include statements such as: Whether workshops or technical assistance will meet the needs of farmers or ranchers in the service area and why; how much time will be spent in group training or individual hands-on training of farmers and ranchers; or whether activities will meet the demands of stakeholders. Project performance measures must include the assumptions used to make those estimates.

Consider the following questions when developing performance measurement statements:

- What is the measurable short-term and long-term impact our project will have on serving the needs of our stakeholders?

- How will my organization measure the effectiveness and efficiency of our proposed activities to meet the overall goals and objectives for this project?

II. Award Information

A. Statutory Authority

The statutory authority for this action is 7 U.S.C. 2279(c), which authorizes award funding for projects designed to provide outreach and assistance to socially disadvantaged or veteran farmers or ranchers.

B. Expected Amount of Funding

The total estimated funding expected to be available for awards in fiscal years 2020 and 2021 under this competitive opportunity is approximately \$15 million.

C. Project Period

The performance period for projects selected from this solicitation will not begin prior to the effective award date listed in the grant agreement. The maximum project period is three (3) years.

D. Award Type

Funding for selected projects will be in the form of a grant agreement which must be fully executed no later than September 30 annually. The anticipated Federal involvement will be limited to the following activities:

1. Approval of recipients' final budget and Project Narrative or statement of work accompanying the grant agreement;

2. Monitoring of recipients' performance through quarterly, annual (for multi-year projects) and final financial and performance reports; and

3. Evaluation of recipients' use of federal funds through desk audits and on-site visits.

III. Eligibility Information

A. Eligible Entities

1. Any non-profit, community-based organizations, networks, or a coalition of community-based organizations with at least 3 years of documented expertise in working with socially disadvantaged farmers or ranchers or veteran farmers or ranchers that:

- Demonstrates experience in providing agricultural education or other agriculturally related services on USDA programs and services to socially disadvantaged or veteran farmers or ranchers;

- provides documentary evidence of work with, and on behalf of, socially disadvantaged or veteran farmers or ranchers during the 3-year period preceding the submission of a proposal for assistance under this program; and

- does not or has not engaged in activities prohibited under Section 501(c)(3) of the Internal Revenue Code of 1986.

2. An 1890 or 1994 institution of higher education (as defined in 7 U.S.C. 7601).

3. An American Indian Tribal community college or an Alaska Native cooperative college.

4. A Hispanic-Serving Institution of higher education (as defined in 7 U.S.C. 3103).

5. Any other institution of higher education (as defined in 20 U.S.C. 1001) that has demonstrated experience in providing agricultural education or other agricultural-related services to socially disadvantaged or veteran farmers or ranchers.

6. An Indian Tribe (as defined in 25 U.S.C. 5304) or a national tribal organization that has demonstrated experience in providing agricultural education or other agriculturally related services to socially disadvantaged or veteran farmers or ranchers.

7. All other organizations or institutions that received funding under this program before January 1, 1996, but only with respect to projects that the Secretary considers similar to projects previously carried out by the entity under this program.

B. Cost-Sharing or Matching

There are no cost-sharing nor matching requirements associated with this program. Applicants may charge their negotiated indirect cost rate or 10 percent, whichever is lower. Indirect cost rates exceeding 10 percent will not be permitted.

C. Threshold Eligibility Criteria

Applications from eligible entities that meet all criteria will be evaluated as follows:

1. Proposals must comply with the submission instructions and requirements set forth in Section IV of this announcement. Pages in excess of the page limitation will not be considered.

2. Proposals must be received through *Grants.gov* as specified in Section IV of this announcement on or before the proposal submission deadline. Applicants will receive an electronic confirmation receipt of their proposal from *Grants.gov*.

3. Proposals received after the submission deadline will not be considered. *Please note that in order to submit proposals, organizations must create accounts in Grants.gov and in the System for Awards Management (www.SAM.gov); both of which could take several weeks.* Therefore, it is

strongly suggested that organizations begin this process immediately. Registering early could prevent unforeseen delays in submitting your proposal.

4. Proposals must address a minimum of two priority areas to provide outreach and assistance to socially disadvantaged or veteran farmers or ranchers as stated in Section I, Part B, Scope of Work.

5. Recipients of a 2501 Grant with a Period of Performance that extends beyond 90 days of the current fiscal year are not eligible to apply. For example, current 2501 Grant recipients must complete their projects by December 31, 2020, to be eligible to apply. Organizations that were awarded a 2501 Grant in FY2019 whose Period of Performance extends beyond this date are ineligible.

6. Incomplete or partial applications will not be eligible for consideration.

IV. Proposal and Submission Information

A. Data Universal Numbering System

In accordance with the Federal Funding Accountability and Transparency Act (FFATA) and the USDA implementation, all applicants must obtain and provide an identifying number from Dun and Bradstreet's (D&B) Data Universal Numbering System (DUNS). Applicants can receive a DUNS number, at no cost, by calling the toll-free DUNS number request line at (866) 705-5711 or visiting the D&B website at www.dnb.com.

B. System for Award Management (SAM)

It is a requirement to register for SAM (<http://www.sam.gov>). There is NO fee to register for this site. *This registration must be maintained and updated annually.* Applicants can register or update their profile, at no cost, by visiting the SAM website at www.sam.gov. This is a requirement to registering for *Grants.gov* where all organizations must submit their application.

Per 2 CFR part 200, applicants are required to: (1) Be registered in SAM prior to submitting an application; (2) provide a valid unique entity identifier in the application; and (3) continue to maintain an active SAM registration with current information at all times during which the organization has an active Federal award or an application or plan under consideration by a Federal awarding agency. The OPPE may not make a Federal award to an applicant until the applicant has complied with all applicable unique entity identifier and SAM requirements.

If an applicant has not fully complied with the requirements by the time the OPPE is ready to make a Federal award, the OPPE may determine that the applicant is not qualified to receive a Federal award and use that determination as a basis for making a Federal award to another applicant.

SAM contains the publicly available data for all active exclusion records entered by the Federal Government identifying those parties excluded from receiving Federal contracts, certain subcontracts, and certain types of Federal financial and non-financial assistance and benefits. All applicant organizations and their key personnel will be vetted through SAM to ensure they are in compliance with this requirement and not on the Excluded Parties List. Organizations identified as having delinquent Federal debt may contact the Treasury Offset Program at (800) 304-3107 for instructions on resolution but will not be awarded a 2501 Program grant prior to resolution.

Should an applicant be awarded a grant, ezFedGrants (USDA's financial grants management system) is linked with SAM to ensure funding payments are directed properly as entities must enter their banking information through SAM; as a result, Federal agencies cannot award funding to any organization not properly/fully registered in SAM.

C. Obtain Proposal Package From Grants.gov (www.grants.gov)

All applicants must register for an account on *Grants.gov* to submit their application. There is no cost for registration. All applications must be submitted through *Grants.gov*. This website is managed by the Department of Health and Human Services, not the OPPE. Many Federal agencies use this website to post Funding Opportunity Announcements (FOA). Please click on the "Support" tab to contact their customer support personnel if you need help with submitting your application.

Applicants may download individual grant proposal forms from *Grants.gov*. For assistance with *Grants.gov*, please consult the Applicant User Guide at <http://grants.gov/assets/ApplicantUserGuide.pdf>.

Applicants are required to submit proposals through *Grants.gov*. Applicants will be required to register with *Grants.gov* to begin the proposal submission process. We strongly suggest you initiate this process immediately to avoid processing delays due to registration requirements.

Federal agencies post funding opportunities on *Grants.gov*. The OPPE is not responsible for submission issues

associated with *Grants.gov*. If you experience submission issues, please contact *Grants.gov* support staff for assistance.

Proposals must be submitted by September 11, 2020, via *Grants.gov* at 11:59 p.m. EST. Proposals submitted after this deadline *will not* be considered.

D. Content of Proposal Package Submission

All submissions must contain completed and electronically signed original application forms, as well as a Project Narrative and a Budget Narrative as described below:

1. Forms, documents, and attachments. The forms listed below can be found in the proposal package at *Grants.gov* and must be submitted with all applications. Required forms are provided in the package as fillable forms. Applicants must download and complete these forms and submit them in the application submission portal at *Grants.gov*. PDF documents listed below are documents the applicant must create and submit in PDF format. Please use the checklist of documents below to submit your application through *Grants.gov*:

- Standard Form (SF) 424, Application for Federal Assistance
- Project/Performance Site Location(s)
- Project Abstract Summary
- Project Narrative File (this is where you will attach your Project Narrative in PDF format)
- Standard Form (SF) 424A, Budget Information—Non-Construction Programs
- Budget Narrative File (this is where you will attach your Budget Narrative in PDF format)
- Standard Form (SF) 424B, Assurances—Non-Construction Programs
- Key Contacts Form (please provide first, middle, and last names)
- Form AD-1047 Certification Regarding Debarment, Suspension, and Other Responsibility Matters (Primary Covered Transactions)
- Form AD-1048 Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion (lower Tier Covered Transactions)
- Form AD-1049 Certification Regarding Drug-Free Workplace Requirements (Grants)
- Form AD-3030 Representations Regarding Felony Conviction and Tax Delinquent Status for Corporate Applicants
- Form AD-3031, Assurance Regarding Felony Conviction or Tax Delinquent Status for Corporate Applicants

- Attachments Form (where you may place all your appendices)

Please note, additional required forms from organizations being awarded 2501 Grant funds will be provided for execution upon grant approval.

2. Below is further guidance, where needed, for completing the forms, documents, and attachment forms listed above.

SF-424, Application for Federal Assistance

Complete all highlighted areas on this form. Please pay particular attention to block 18a of the SF-424. This is the amount of Federal funding you are requesting under the 2501 Program. This form is the official requesting document and the amount that will be considered if you should have any discrepancies between this form and your Budget Information Form, SF-424A. Ensure this form is completed with accuracy; particularly email addresses and phone numbers. The OPPE may not be able to reach you if your information is incorrect.

Project/Performance Site Location(s)

Complete all highlighted areas on this form. Add additional locations if your project will be carried out at additional sites.

Project Abstract Summary

A Project Abstract Summary is a concise summary about your project. No points will be given or subtracted for the Project Summary Page as it will be used only for informational purposes. It may be used in its entirety or in part for media purposes to include press releases, informational emails to potential stakeholders or partners, to provide upper echelons of government with a snapshot of an organization, and for demographic purposes. Please do not restate the objectives of the 2501 Program (*i.e.* “to provide outreach and assistance for socially disadvantaged farmers and ranchers and veterans farmers and ranchers”); the Project Abstract Summary should reflect the goal of your specific project. Please limit your Project Abstract Summary to 250 words and include the following:

- Your organization’s name;
- Name of your project;
- Three or four sentences describing your project;
- The primary populations/communities you serve;
- The project’s geographic service area (counties, state(s), etc.); and
- Project Director’s name, email address, and telephone number.

Project Narrative (Not To Exceed 30 Double-Spaced Pages)

The Project Narrative is a document that you create. It must *include a timeline of proposed activities*. *Formatting requirements for Project Narratives are 1-inch margins and 12-point font*, Number each page of the Project Narrative to indicate the total number of pages (*i.e.*, 1 of 30, 2 of 30, etc.). *To ensure fairness and uniformity for all applicants, Project Narratives not conforming to this stipulation may not be considered.*

- Project proposals should include a well-conceived strategy for addressing the priority areas stated in Section I, Part B, Scope of Work. Organizations should state which priority areas will be addressed. Additionally, proposals must: (1) Define and establish the existence of the needs of socially disadvantaged farmers or ranchers or veteran farmers or ranchers, or both; (2) identify the geographic area of service; and (3) discuss the potential impact of the project; and (4) clearly document how you plan to fulfill the requirement to coordinate efforts with the USDA Liaisons and SFAC in your service territory.

- Programmatic Capability: Project proposals must: (1) identify the experience of the organization(s) taking part in the project (past successes); (2) identify the names of organizations that will be your partners in the project if any; (3) identify the qualifications, relevant experience, education, and publications of each Project Director or collaborator; (4) specifically address the work to be completed by key personnel and their roles and responsibilities within the scope of the proposed project. This includes partnering scenarios whereas each partners’ roles and responsibilities must be defined.

- Financial Management Experience: Document a demonstrated ability to successfully manage and complete your project by including details of past successfully completed projects and financial management experiences.

- Tracking and Measuring: Clearly document a detailed plan for tracking and measuring the progress and results of the project in terms of achieving expected project outputs and outcomes as stated in Section I, Part C, Performance Measures.

- In an organized format, create a timeline for each task to be accomplished during the period of performance timeframe. Relate each task to one of the five priority areas in Section I, Part B. The timeline is part of the 20-page limit but can be as simple

as a one-page description of tasks. The timeline may be in a table format.

Please attach your Project Narrative in PDF format to the Mandatory Project Narrative form in your *Grants.gov* package.

SF-424A, Budget Information—Non-Construction Programs

Please provide as much information as possible on the SF-424A; particularly for multi-year projects. For example, on page 1 of SF-424A, line 1 across may indicate year one of your project, line 2 across may indicate year two of your project, and line 3 across may indicate year three of your project. On page 1A of SF-424A, columns 1 through 3 may represent each year of your project. All cost categories on page 1A of this form are considered direct costs. Please remember that your indirect cost rate *may not exceed the 10 percent statutory limitation* on indirect costs found in 7 U.S.C. 2279(l)(7).

Budget Narrative (Not To Exceed 5 Pages)

The Budget Narrative is a document that you create. It must be no more than five pages. It does NOT have to be double spaced. You may use tables. The Budget Narrative should identify and describe the costs associated with the proposed project, including sub-awards or contracts and indirect costs. These costs should be very detailed and descriptive as to their purpose. Please review 2 CFR part 200, subpart E, to ensure your project is not planned with unallowable costs. Applicants may charge their negotiated indirect cost rate or 10 percent, whichever is lower.

Indirect cost rates exceeding 10 percent will not be permitted. Other funding sources may also be identified in the Budget Narrative. Each cost indicated must be reasonable, allocable, necessary, and allowable under Federal Cost Principles (2 CFR part 200, subpart E—Cost Principles) in order to be funded.

Special notes when creating your budget:

1. 2501 Program funds may not be used for the planning, repair, rehabilitation, acquisition, or construction of a building or facility. Program funds may not be used for start-up or financing costs for businesses or for capacity building. Program funds may also not be used as small agricultural loans for individual farmers or used to incentivize individuals to attend an event.

2. Costs must be deemed reasonable. This includes salaries for key personnel which may not exceed the prevailing wage rates established by the

Department of Labor by occupation and geographical area (see 2 CFR 200.404 and appendix II(D)).

3. Food for conferences may not exceed \$10 per person. Additionally, cattle for demonstration projects only, may not exceed \$4000, which includes any transportation costs, feed/feeding lot, etc.). Grant funds may NOT be used to pay attendees as an incentive for participation in conferences nor be advertised as such. For a list of unallowable costs, please see 2 CFR part 200, subpart E.

Please attach your Budget Narrative in PDF format to the Mandatory Budget Narrative form in your *Grants.gov* package.

SF 424B, Assurances—Non-Construction Programs

Please review, complete, and submit this form as required.

Key Contacts Form

Provide first, middle, and last names of all key personnel that will be working on the proposed project. All organizations should submit at least a Project Director or Manager and a Financial Representative. Additional Key Contacts Forms may be used as necessary. *Please ensure this form is completed with accuracy. Individuals not listed on an applicants' Key Contacts Form will not receive information about or access to data that concerns the applicant organization.*

Form AD-1047 Certification Regarding Debarment, Suspension, and Other Responsibility Matters (Primary Covered Transactions)

Please review, complete, and submit this form as required.

Form AD-1048 Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion (Lower Tier Covered Transactions)

Please review, complete, and submit this form as required.

Form AD-1049 Certification Regarding Drug-Free Workplace Requirements (Grants)

Please review, complete, and submit this form as required.

Form AD-3030 Representations Regarding Felony Conviction and Tax Delinquent Status for Corporate Applicants

Please review, complete, and submit this form as required.

Form AD-3031, Assurance Regarding Felony Conviction or Tax Delinquent Status for Corporate Applicants

Please review, complete, and submit this form as required.

Attachments Form for Appendices

Organizations may submit abbreviated Articles of Incorporation for recently established organizations (must have been established at least 3 years prior to this application); résumés for key personnel; Letters of Commitment; Letters of Intent, Partnership Agreements, or Memoranda of Understanding with partner organizations; Letters of Support; 501(c)(3) certification from the IRS (if applicable), or other supporting documentation which is encouraged but not required. Using this form in your *Grants.gov* application package, applicants can consolidate all supplemental materials into one attachment or attach appendices documents individually. Do *not* include documents from other sections as an Appendix.

DO NOT PASSWORD PROTECT ANY OF YOUR SUBMITTED DOCUMENTS OR FORMS. Password protected documents cannot be viewed by the OPPE or the Peer Review Panel.

E. Sub-Awards and Partnerships

Funding may be used to provide sub-awards, which includes using sub-awards to fund partnerships; however, the recipient must utilize at least 50 percent of the total funds awarded, and no more than three sub-awards will be permitted. All sub-awardees must comply with applicable requirements for sub-awards. Applicants must provide documentation of a competitive bidding process for services, contracts, and products, including consultants and contractors, and conduct cost and price analyses to the extent required by applicable procurement regulations.

The OPPE awards funds to *one eligible applicant* as the lead award recipient. Please indicate a lead applicant as the responsible party if other organizations are named as partners or co-applicants or members of a coalition or consortium. The lead award recipient will be held accountable to the OPPE for the proper administrative requirements and expenditure of all funds.

F. Submission Dates and Times

The closing date and time for receipt of proposal submissions is September 11, 2020, at 11:59 p.m., EST, via *Grants.gov*. Proposals received after the submission deadline will be considered late without further consideration.

Proposals must be submitted through *Grants.gov* without exception. Additionally, organizations must also be registered in the System of Awards Management (SAM) at *www.sam.gov*.

Creating an account for both websites can take several weeks to receive account verification and/or PIN numbers. Please allow sufficient time to complete access requirements for these websites. *Grants.gov* supports many Federal granting agencies and their applicants. Delaying the submission of your application until the last day could be result in your application not being received on time due to issues pertaining to a high volume of users, system maintenance, issues with registration, having a pending registration because of a backlogged system, and expired *SAM.gov* registrations. The proposal submission deadline is firm.

G. Confidential Information

In accordance with 2 CFR part 200, the names of entities submitting proposals, as well as proposal contents and evaluations, will be kept confidential to the extent permissible by law. Any information that the applicant wishes to have considered as confidential, privileged, or proprietary should be clearly marked as such in the proposal. If an applicant chooses to include confidential or proprietary information in the proposal, it will be kept confidential to the extent permitted by law.

H. Pre-Submission Proposal Assistance

1. The OPPE may not assist individual applicants by reviewing draft proposals or providing advice on how to respond to evaluation criteria. However, the OPPE will respond to questions from individual applicants regarding eligibility criteria, administrative issues related to the submission of the proposal, and requests for clarification regarding the announcement. Any questions should be submitted to *2501grants@usda.gov*. Additionally, the OPPE will host public teleconferences to address questions and clarify requirements during the open period of this solicitation. Dates, time, and phone numbers are provided on Page 1 of this announcement.

2. The OPPE will post questions and answers relating to this funding opportunity during its open period on the Frequently Asked Questions (FAQs) section of our website: <http://www.outreach.usda.gov/grants/>. Reviewing this section of our website will likely save you valuable time. The OPPE will update the FAQs on a weekly

basis and conduct teleconferences on an as-needed basis.

3. Please visit our website: <https://www.outreach.usda.gov/grants/index.htm> to review the most recent Terms and Conditions for administering our grants. This version is subject to change upon new program requirements.

4. Applicants selected for funding must inform their participants that USDA, or any of its third-party representatives, may contact them for quality assurance.

V. Application Review Information

A. Evaluation Criteria

Only eligible entities whose proposals meet the threshold criteria in Section III of this announcement will be reviewed according to the evaluation criteria set

forth below. Applicants should explicitly and fully address these criteria as part of their proposal package. Each proposal will be evaluated under the regulations established under 2 CFR part 200.

An External Peer Review Panel (Panel) will use a point system to rate each proposal, awarding a maximum of 105 points for nonprofit and community-based organizations (75 points, plus an additional 30 discretionary points for secretarial priorities) and 100 points for all other applicants (70 points, plus an additional 30 discretionary points for secretarial priorities). Each proposal will be reviewed by at least two members of the Peer Review Panel. Panel members will review, and score all submitted applications. The Panel will numerically score and rank each

application and funding will be awarded within the three funding categories. Funding decisions will be based on the Panel's recommendations. Final funding decisions will be made by the designated approving official and are *not appealable*.

Please be patient as processing all submitted applications, vetting key personnel, proposal reviews, approval process, and agreement creation is a lengthy process that takes approximately two to three months. All applicants will be notified electronically of their application status when final selections have been made and will be provided an opportunity for application feedback as provided within the correspondence.

B. Evaluation Criteria for New Grants Proposals

Criteria	Maximum points
1. <i>Project Narrative</i> : Under this criterion, your proposal must address <i>at least two</i> of the five priority areas identified in Section I, Part B, Scope of Work and will be evaluated to the extent to which the narrative includes a well-conceived strategy for addressing those requirements and objectives (see Section IV, Part D.2. Project Narrative, for additional information). Please note that applicants may assist <i>either</i> socially disadvantaged farmers and ranchers, or veteran farmers and ranchers, or both groups in the proposal. There are no additional points for addressing both of these groups. Conversely, there are <i>no points deducted</i> if your proposal addresses only one of these groups.	30
In addition, the OPPE may award up to 30 discretionary points (six (5) points for each bullet shown below) for the following (see Section I, Part B, Scope of Work):	30
<ul style="list-style-type: none"> • Nongovernmental and community-based organizations with a documented history working with socially disadvantaged and/or veteran farmers or ranchers (2018 Farm Bill provision). • Projects that are carried out in states or communities identified as Opportunity Zones (https://www.cdfifund.gov/Pages/Opportunity-Zones.aspx) • Projects located in rural (https://eligibility.sc.egov.usda.gov/eligibility/welcomeAction.do) or persistent poverty communities (https://www.ers.usda.gov/data-products/county-typology-codes.aspx) that address the following five (5) priorities: e-Connectivity, Economic Development, Innovation and Technology, Workforce Development, and Quality of Life (such as reducing recidivism, access to mental health programs, etc.). See the USDA Rural Task Force Report (https://www.usda.gov/sites/default/files/documents/rural-prosperity-report.pdf); • Projects designed to assist socially disadvantaged beginning and/or youth farmers and/or ranchers (as defined in 7 U.S.C. 2279); • Projects with an emphasis on partnering and leveraging funding with other organizations, entities or programs to maximize areas of coverage in conducting training and outreach services (i.e., nonprofits, for profits, Federal, state, tribal and local entities, higher education institutions, etc.). Partners' roles and responsibilities must be defined to determine the involvement and efforts to increase training and outreach to socially disadvantaged farmers and ranchers to qualify for these points. • Projects with a focus on socially disadvantaged and veteran heirs' property issues/resolution; financial literacy; and increased profitability of agricultural operations of socially disadvantaged and veteran farmers and ranchers through effective and proven marketing opportunities to increase access to capital and markets. 	
2. <i>Programmatic Capability</i> : Under this criterion, applicants will be evaluated based on their ability to successfully complete and manage the proposed project considering the applicant's: Organizational experience, staff expertise and qualifications, and the organization's resources (see Section IV, Part D, 2. Programmatic Capability). The organization must also clearly document its historical successes and future plans to continue assisting socially disadvantaged and veteran farmers and ranchers.	10
3. <i>Financial Management Experience</i> : Under this criterion, applicants will be evaluated based on their demonstrated ability to successfully complete and manage the proposed project considering the applicants' past performance in successfully completing and managing prior funding agreements (see Section IV, Part D, 2. Financial Management Experience). Past performance documentation on successfully completed projects may be at the Federal, state, or local community level. Per 2 CFR 200.205, if an applicant is a prior recipient of Federal awards, their record in managing that award will be reviewed, including timeliness of compliance with applicable reporting requirements and conformance to the terms and conditions of previous Federal awards.	5

Criteria	Maximum points
<p>4. <i>Tracking and Measuring:</i> Under this criterion, the applicant's proposal will be evaluated based upon clearly documenting a detailed plan for tracking and measuring their progress toward achieving the expected project outputs (see Section I, Part C, 1. Outputs Activities). Applicants should indicate how they intend to clearly document the effectiveness of their project in achieving proposed thresholds or benchmarks in relation to stated goals and objectives (see Section I, Part C, 2 Outcomes Results). For example, state how your organization plans to connect socially disadvantaged or veteran farmers or ranchers with USDA agricultural programs. Specifically, how many new or existing farmers and ranchers were assisted in <i>applying</i> for USDA's programs and services, versus the number of farmers and ranchers <i>approved</i>. Applicants must clearly demonstrate how they will ensure timely and successful completion of the project with a reasonable time schedule for execution of the tasks associated with the project. This criterion should clearly address how you will quantify the tracking of your progress and measuring the success of your planned project (see Section I, Part C, 3. Performance Measures).</p>	15
<p>5. <i>Budget:</i> Under this criterion, your proposed project budget will be evaluated to determine whether costs are reasonable, allowable, allocable, and necessary to accomplish the proposed goals and objectives (see 2 CFR 200.404 and appendix II–D). The proposed budget must provide a detailed breakdown of the approximate funding used for each major activity (see Section IV, Part D.2. Budget Narrative). Additionally, indirect costs (10 percent maximum) must be appropriately applied. For a list of unallowable costs, please see 2 CFR part 200, subpart E.</p>	10

C. Selection of Reviewers

All applications will be reviewed by the Panel. Panel members are selected based upon training and experience in assisting socially disadvantaged and veteran farmers and ranchers. This assistance includes, but is not limited to, bringing increased awareness of USDA's programs and services in underserved communities, outreach, technical assistance, cooperative extension services, civil rights, education, statistical and ethnographic data collection and analysis, and agricultural programs, and are drawn from a diverse group of experts, including applicant peers, to create a balanced panel.

VI. Award Administration Information

A. Award Notices

Proposal Notifications and Feedback

1. Successful applicants will be notified by the OPPE via telephone, email, and/or postal mail that its proposed project has been recommended for award. The notification will be sent to the *Project Manager* listed on the SF-424, Application for Federal Assistance. Project Managers should be the Authorized Organizational Representative (AOR) and authorized to sign on behalf of the organization. It is imperative that this individual is responsive to notifications by the OPPE. If the individual is no longer in the position, please notify the OPPE immediately to submit the new contact for the application by updating your organization's Key Contacts form and forwarding a résumé of the new key personnel. The grant agreement will be forwarded to the recipient for execution and must be returned to the OPPE Director, who is the authorizing official. Once grant documents are executed by all parties, authorization to begin work

will be given. At a minimum, this process can take up to 30 days from the date of notification.

2. Within 10 days of award status notification, unsuccessful applicants may request feedback on their application. Feedback will be provided as expeditiously as possible. Feedback sessions will be scheduled contingent upon the number of requests and in accordance with 7 CFR 2500.026.

B. Administrative and National Policy Requirements

All awards resulting from this solicitation will be administered in accordance with the Office of Management and Budget (OMB) Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards codified at 2 CFR part 200, as supplemented by USDA implementing regulations at 2 CFR parts 400 and 415, and the OPPE Federal Financial Assistance Programs—General Award Administrative Procedures, 7 CFR part 2500. In compliance with its obligations under Title VI of the Civil Rights Act of 1964 and Executive Order 13166, it is the policy of the OPPE to provide timely and meaningful access for persons with Limited English Proficiency (LEP) to projects, programs, and activities administered by Federal grant recipients. Recipient organizations must comply with these obligations upon acceptance of grant agreements as written in the OPPE's Terms and Conditions. Following these guidelines is essential to the success of our mission to improve access to USDA programs for socially disadvantaged and veteran farmers and ranchers.

C. Reporting Requirement

Your approved statement of work, timeline, and budget are your guiding documents in carrying out the activities of your project and for your reporting

requirements. Please familiarize yourself with USDA's grants management system called ezFedGrants: <https://www.nfc.usda.gov/FSS/ClientServices/ezFedGrants/>. In accordance with 2 CFR part 200, the following reporting requirements will apply to awards provided under this FOA. The OPPE reserves the right to revise the schedule and format of reporting requirements as necessary in the award agreement.

1. Quarterly Progress Reports and Financial Reports will be required as follows:

- *Quarterly Progress Reports.* The recipient is required to provide a detailed narrative of project performance and activities as described in the award agreement. Quarterly progress reports must be submitted to the designated OPPE official via ezFedGrants within 30 days after the end of each calendar quarter. This includes, but is not limited to, activities completed, events held, and the release of sign-in sheets with participants' contact information.

- *Quarterly Financial Reports.* The recipient must submit SF 425, Federal Financial Report to the designated OPPE official via ezFedGrants within 30 days after the end of each calendar quarter.

2. Annual reports may be required for multi-year projects.

3. Final Progress and Financial Reports will be required upon project completion. The Final Progress Report must include a summary of the project or activity throughout the funding period, achievements of the project or activity, and a discussion of overall successes and issues experienced in conducting the project or project activities. It should convey the impact your project had on the communities you served and discuss the project's accomplishments in achieving expected outcomes. This requirement includes, but is not limited to, the number of new

USDA applicants as a result of your award, the number of approved applicants for USDA programs and services, increased awareness of USDA programs and services, etc.

4. The final Financial Report should consist of a complete SF-425 indicating the total costs of the project. Final Progress and Financial Reports must be submitted to the designated OPPE

official via ezFedGrants within 90 days after the completion of the award period as follows:

Report	Performance period	Due date	Grace period
Form SF-425, Federal Financial Report and Progress Report (<i>Due Quarterly</i>).	1 October thru 31 December	12/31/2020	1/30/2021
	1 January thru 31 March	3/31/2021	4/30/2021
	1 April thru 30 June	6/30/2021	7/30/2021
	1 July thru 30 September	9/30/2021	10/30/2021
Annual (for multi-year project) and Final Progress and Financial Reports	Earlier of December 30, 2021, or 90 days after project completion.		

* Dates subject to change at the discretion of the OPPE.

Signed this 23 day of June 2020.
Jacqueline Davis-Slay,
Deputy Director, Office of Partnerships and Public Engagement.
 [FR Doc. 2020-14321 Filed 7-10-20; 8:45 am]
BILLING CODE 3412-89-P

DEPARTMENT OF COMMERCE

U.S. Census Bureau

Notice of Correction; 2020 Census Post-Enumeration Survey Initial and Final Housing Unit Follow-Up

AGENCY: U.S. Census Bureau, Commerce.

ACTION: Notice; correction; Notice of changes to the 2020 Census Post-Enumeration Survey (PES) Initial Housing Follow-Up (IHUFU) field operation.

SUMMARY: This document constitutes a notice of intent to provide a 30-day comment period on schedule changes, procedures for collecting information changes and estimate of hour of burden changes to the approved information collection for the 2020 Census Post-Enumeration Survey (PES) Initial Housing Follow-Up (IHUFU) field operation. The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other federal agencies to take this opportunity to comment on proposed and/or continuing information

collections, as required by the Paperwork Reduction Act of 1995. **SUPPLEMENTARY INFORMATION:** The U.S. Census Bureau is issuing this notice to inform the public of changes in schedule, procedures for collecting information, and estimate of hour of burden, associated with the notice for public comment, titled “2020 Census Post-Enumeration Survey Initial and Final Housing Unit Follow-Up,” published in the **Federal Register** on April 17, 2019 (Vol. 84, No. 74, pp. 16000-16002).

The following highlights the proposed revisions and the reasons:

1. The PES IHUFU and IHUFU Quality Control operations will occur July 23, 2020, through September 21, 2020, instead of May 6, 2020, through June 19, 2020, because of COVID-19 restrictions.
2. Procedure changes for collecting information for the PES IHUFU field operation are proposed to minimize personal contact because of COVID-19. Originally, listers were instructed to contact a household member (or a proxy or by observation as a last resort) to complete IHUFU form (D-1303) at each housing unit (HU) selected for follow-up. Now listers are allowed to complete the form by observation first before attempting to interview by telephone or by a personal visit. For addresses that cannot be confirmed by observation, a letter will be sent to the addresses, along with the confidentiality notice, inviting respondents to call the lister to set up a telephone interview. If after five days

the IHUFU case cannot be completed by observation or the respondent has not followed up based on the letter, then a personal visit is required. If the respondent or the lister does not feel comfortable conducting the interview in person at the door, then the lister may ask for the phone number and conduct a telephone interview.

3. The estimated workload is now approximately 253,800 (172,000 original estimate) HUs for PES IHUFU in selected basic collection units (BCUs) in the 50 states and the District of Columbia, and 31,400 (8,000 original estimate) HUs for IHUFU in Puerto Rico. The Census Bureau originally underestimated the workload for 2020 Puerto Rico IHUFU, but the revised numbers reported in this document reflect the correct estimated workload.

From the IHUFU workload, we will select a 15 percent sample of approximately 38,070 (25,800 original estimate) HUs from all BCUs in the 50 states and District of Columbia, and 4,710 (1,200 original estimate) HUs from all BCUs in Puerto Rico for the IHUFU QC operation. To calculate the estimated burden hours, we assumed a theoretical 100 percent response rate and a completion time of five minutes per case. The total estimated respondent burden for the IHUFU operation is approximately 27,333 (17,250) hours. However, since the Collection of Information has changed to primarily observation, the actual total respondent burden is expected to be less.

Operation	Estimated number of respondents	Estimated time per response (in minutes)	Total burden hours
2020 Census Post-Enumeration Survey—Original Estimate			
Initial Housing Unit Follow-Up (stateside)	172,000	5	14,333
Initial Housing Unit Follow-Up (PR)	8,000	5	667
Initial Housing Unit Follow-Up Quality Control (stateside)	25,800	5	2,150
Initial Housing Unit Follow-Up Quality Control (PR)	1,200	5	100

Operation	Estimated number of respondents	Estimated time per response (in minutes)	Total burden hours
Total	207,000 respondents	5	17,250 hours
2020 Census Post-Enumeration Survey—Revised Estimate			
Initial Housing Unit Follow-Up (stateside)	253,800	5	21,150
Initial Housing Unit Follow-Up (PR)	31,400	5	2,617
Initial Housing Unit Follow-up Quality Control (stateside)	38,070	5	3,173
Initial Housing Unit Follow-Up Quality Control (PR)	4,710	5	393
Total	327,980	5	27,333

There are no other proposed changes to the 2020 Census PES IHUFU field operation.

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 0607–1010.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2020–14977 Filed 7–10–20; 8:45 am]

BILLING CODE 3510-07-P

DEPARTMENT OF COMMERCE

Bureau of Economic Analysis

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Expenditures Incurred by Recipients of Biomedical Research and Development Awards From the National Institutes of Health (NIH)

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 April 20, 2020 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: Bureau of Economic Analysis (BEA), Commerce.

Title: Expenditures Incurred by Recipients of Biomedical Research and Development Awards from the National Institutes of Health (NIH).

OMB Control Number: 0608–0069.

Form Number(s): None.

Type of Request: Regular submission, extension of a current information collection.

Number of Respondents: 150.

Average Hours per Response: 16 hours is the average but may vary among respondents because of differences in institution structure, size, and complexity.

Burden Hours: 2,400 hours.

Needs and Uses: The survey obtains the distribution of expenditures incurred by recipients of biomedical research awards from the National Institutes of Health (NIH) and will provide information on how the NIH award amounts are expended across several major categories. This information, along with wage and price data from other published sources, will be used to generate the Biomedical Research and Development Price Index (BRDPI). The Bureau of Economic Analysis (BEA) of the Department of Commerce develops this index for NIH under a reimbursable contract. The BRDPI is an index of prices paid for the labor, supplies, equipment, and other inputs required to perform the biomedical research the NIH supports in its intramural laboratories and through its awards to extramural organizations. The BRDPI is a vital tool for planning the NIH research budget and analyzing future NIH programs. A survey of award

recipients is currently the only means for updating the expenditure category weights that are used to prepare the BRDPI.

A survey questionnaire with a cover letter that includes a brief description of, and rationale for, the survey will be sent to potential respondents by August 2020, 2021, and 2022. A report of the respondent’s expenditures of the NIH award amounts following the proposed format for expenditure categories attached to the survey’s cover letter, will be requested to be returned no later than December 8, which in most years will be approximately 120 days after mailing. Survey respondents will be selected based on award levels, which determine the weight of the respondent in the biomedical research and development price index. BEA proposes to survey 150 organizations that receive NIH biomedical research awards. This will include the top 100 organizations in total awards received; 40 additional organizations that are not primarily in the “Research and Development (R&D) contracts” category; and 10 additional organizations that are primarily in the “R&D contracts” category. Based on awards data for FY 2019 by type of organization, the top 100 organizations received \$20.8 billion in awards (approximately 77 percent of total awards); the remaining awards-receiving organizations received \$6.1 billion.

Affected Public: Universities or other organizations that are NIH award recipients.

Frequency: Annual.

Respondent’s Obligation: Voluntary.

Legal Authority: 45 CFR 75.302, 75.308, 75.361, and 75.364.

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 0608–0069.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2020–13522 Filed 7–10–20; 8:45 am]

BILLING CODE 3510–06–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–870]

Certain Oil Country Tubular Goods From the Republic of Korea: Final Results of Antidumping Duty Administrative Review; 2017–2018

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) determines that SeAH Steel Corporation (SeAH), producer/exporter of certain oil country tubular goods (OCTG) from the Republic of Korea (Korea), sold subject merchandise in the United States at prices below normal value (NV) during the period of review (POR) September 1, 2017 through August 31, 2018, but producer/exporter Hyundai Steel Company (Hyundai Steel) did not sell subject merchandise in the United States below NV during the POR.

DATES: Applicable July 13, 2020.

FOR FURTHER INFORMATION CONTACT: Davina Friedmann, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0698.

SUPPLEMENTARY INFORMATION:

Background

On November 18, 2019, Commerce published the *Preliminary Results* of this administrative review.¹ We invited interested parties to comment on the *Preliminary Results*. Between January 2 and 14, 2020, Commerce received

¹ See *Certain Oil Country Tubular Goods from the Republic of Korea: Preliminary Results of Antidumping Duty Administrative Review; 2017–2018*, 84 FR 63615 (November 18, 2019) (*Preliminary Results*), and accompanying Decision Memorandum.

timely filed case and rebuttal briefs from various interested parties.² On February 7, 2020, we held a public hearing concerning the issues raised in the case and rebuttal briefs.³

On March 12, 2020, we extended the deadline for the final results.⁴ On April 24, 2020, Commerce tolled all deadlines in administrative reviews by 50 days, thereby extending the deadline for these results until July 6, 2020.⁵

These final results cover 32 companies.⁶ Based on an analysis of the comments received, we have made changes to the weighted-average dumping margins determined for the respondents. The weighted-average dumping margins are listed in the

² See Letter from AJU Besteel Co., Ltd. (AJU Besteel), “Certain Oil Country Tubular Goods from the Republic of Korea—Letter in Support of Case Briefs,” dated January 3, 2020; Letter from the following Domestic Interested Parties (DIPs): Maverick Tube Corporation (Maverick), Tenaris Bay City, Inc. (Tenaris), United States Steel Corporation (U.S. Steel), TMK IPSCO, Vallourec Star, L.P., and Welded Tube USA, “Oil Country Tubular Goods from the Republic of Korea: Case Brief of Maverick Tube Corporation and Tenaris Bay City, Inc.,” dated January 3, 2020; Letter from ILJIN Steel Corporation (ILJIN), “Oil Country Tubular Goods from the Republic of Korea: Case Brief,” dated January 3, 2020; Letter from SeAH, “Administrative Review of the Antidumping Order on Oil Country Tubular Goods from Korea: Case Brief of SeAH Steel Corporation,” dated January 3, 2020; Letter from Husteel Co., Ltd. (Husteel), “Oil Country Tubular Goods from the Republic of Korea, 9/1/2017–8/31/2018 Administrative Review, Case No. A–580–870: Case Brief,” dated January 3, 2020; Letter from NEXTEEL Co., Ltd. (NEXTEEL), “Oil Country Tubular Goods from the Republic of Korea: NEXTEEL’s Letter in Support of Respondents’ Case Briefs,” dated January 3, 2020; Letter from United States Steel Corporation (U.S. Steel), “Oil Country Tubular Goods from the Republic of Korea: Case Brief of United States Steel Corporation,” dated January 3, 2020; Letter from Hyundai Steel, “Certain Oil Country Tubular Goods from the Republic of Korea—Case Brief,” dated January 3, 2020; see also Letter from SeAH, “Administrative Review of the Antidumping Order on Oil Country Tubular Goods from Korea—Rebuttal Brief of SeAH Steel Corporation,” dated January 10, 2020; Letter from DIPs, “Oil Country Tubular Goods from the Republic of Korea: Rebuttal Brief of Maverick Tube Corporation and Tenaris Bay City, Inc.,” dated January 10, 2020; Letter from U.S. Steel, “Oil Country Tubular Goods from the Republic of Korea: Rebuttal Brief of United States Steel Corporation,” dated January 10, 2020; and Letter from Hyundai Steel, “Certain Oil Country Tubular Goods from the Republic of Korea—Rebuttal Brief,” dated January 10, 2020.

³ See Hearing Transcript from Neal R. Gross and Co., Inc., filed on ACCESS on February 14, 2020.

⁴ See Memorandum, “Certain Oil Country Tubular Goods from the Republic of Korea: Extension of Time Limit for Final Results of Antidumping Duty Administrative Review,” dated March 12, 2020.

⁵ See Memorandum, “Tolling of Deadlines for Antidumping and Countervailing Duty Administrative Reviews in Response to Operational Adjustments Due to COVID–19,” dated April 24, 2020.

⁶ The 32 companies consist of two mandatory respondents and 30 companies not individually examined.

“Final Results of Review” section, below. Commerce conducted this review in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act).

Scope of the Order⁷

The merchandise covered by the *Order* is certain OCTG, which are hollow steel products of circular cross-section, including oil well casing and tubing, of iron (other than cast iron) or steel (both carbon and alloy), whether seamless or welded, regardless of end finish (e.g., whether or not plain end, threaded, or threaded and coupled) whether or not conforming to American Petroleum Institute (API) or non-API specifications, whether finished (including limited service OCTG products) or unfinished (including green tubes and limited service OCTG products), whether or not thread protectors are attached. The scope of the *Order* also covers OCTG coupling stock. For a complete description of the scope of the *Order*, see the Issues and Decision Memorandum.⁸

Analysis of Comments Received

All issues raised in the case and rebuttal briefs filed by parties in this review are addressed in the Issues and Decision Memorandum. The issues are identified in Appendix I 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 <https://access.trade.gov>. In addition, a complete version of the Issues and Decision Memorandum can be accessed at <http://enforcement.trade.gov/frn/index.html>. The signed and electronic versions of the Issues and Decision Memorandum are identical in content.

Changes Since the Preliminary Results

Based on our analysis of the comments received, we made certain changes to the margin calculations for SeAH and Hyundai Steel. For a discussion of these changes, see the

⁷ See *Certain Oil Country Tubular Goods from India, the Republic of Korea, Taiwan, the Republic of Turkey, and the Socialist Republic of Vietnam: Antidumping Duty Orders; and Certain Oil Country Tubular Goods from the Socialist Republic of Vietnam: Amended Final Determination of Sales at Less Than Fair Value*, 79 FR 53691 (September 10, 2014) (*Order*).

⁸ See Memorandum, “Issues and Decision Memorandum for the Final Results of the 2017–2018 Administrative Review of the Antidumping Duty Order on Certain Oil Country Tubular Goods from the Republic of Korea,” dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

“Margin Calculations” section of the Issues and Decision Memorandum.

Rate for Non-Examined Companies

The statute and Commerce’s regulations do not address the establishment of a rate to be applied to companies not selected for 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 review 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}.”

For these final results, we calculated a weighted-average dumping margin for SeAH that is not zero, *de minimis*, or determined entirely on the basis of facts available. Accordingly, Commerce has assigned to the companies not individually examined (*see* Appendix II for a full list of these companies) a margin of 3.96 percent, which is the weighted-average dumping margin calculated for SeAH for these final results.

Final Results of Review

Commerce determines that the following weighted-average dumping margins exist for the period September 1, 2017 through August 31, 2018:

Exporter or producer	Weighted-average dumping margin (percent)
Hyundai Steel Company	0.00
SeAH Steel Corporation	3.96
All Others ⁹	3.96

Disclosure

Commerce intends to disclose the calculations performed for these final results of review within five days of the date of publication of this notice in the **Federal Register**, in accordance with 19 CFR 351.224(b).

Assessment

Pursuant to section 751(a)(2)(C) of the Act and 19 CFR 351.212(b), Commerce

⁹ See Appendix II for a full list of these companies.

shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review. Commerce intends to issue assessment instructions to CBP 15 days after the date of publication of the final results of this administrative review in the **Federal Register**.

Where the respondent reported reliable entered values, we calculated importer- (or customer-) specific *ad valorem* rates by aggregating the dumping margins calculated for all U.S. sales to each importer (or customer) and dividing this amount by the total entered value of the sales to each importer (or customer).¹⁰ Where Commerce calculated a weighted-average dumping margin by dividing the total amount of dumping for reviewed sales to that party by the total sales quantity associated with those transactions, Commerce will direct CBP to assess importer- (or customer-) specific assessment rates based on the resulting per-unit rates.¹¹ Where an importer- (or customer-) specific *ad valorem* or per-unit rate is greater than *de minimis* (*i.e.*, 0.50 percent), Commerce will instruct CBP to collect the appropriate duties at the time of liquidation.¹² Where an importer- (or customer-) specific *ad valorem* or per-unit rate is zero or *de minimis*, Commerce will instruct CBP to liquidate appropriate entries without regard to antidumping duties.¹³

For the companies which were not selected for individual review, we will assign an assessment rate based on the methodology described in the “Rates for Non-Examined Companies” section, above.

Consistent with Commerce’s assessment practice, for entries of subject merchandise during the POR produced by SeAH, Hyundai Steel, or the non-examined companies for which the producer did not know that its merchandise was destined for the United States, we 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.¹⁴

Cash Deposit Requirements

The following cash deposit requirements will be effective for all

¹⁰ See 19 CFR 351.212(b)(1).

¹¹ *Id.*

¹² *Id.*

¹³ See 19 CFR 351.106(c)(2).

¹⁴ For a full discussion of this practice, *see Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties*, 68 FR 23954 (May 6, 2003).

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 for by section 751(a)(2)(C) of the Act: (1) The cash deposit rates for the companies listed in these final results will be equal to the weighted-average dumping margins established in the final results of this review; (2) for merchandise exported by producers or exporters not covered in this review but covered in a prior segment of this proceeding, the cash deposit rate will continue to be the company-specific rate published for the most recently completed segment in which the company was reviewed; (3) if the exporter is not a firm covered in this review or the original less-than-fair-value (LTFV) investigation, but the producer is, 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 5.24 percent,¹⁵ the all-others rate established in the LTFV investigation. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in Commerce’s presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification Regarding Administrative Protective Order

This notice also serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the

¹⁵ See *Certain Oil Country Tubular Goods from the Republic of Korea: Notice of Court Decision Not in Harmony with Final Determination*, 81 FR 59603 (August 30, 2016).

regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

We are issuing and publishing this notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.213(h).

Dated: July 6, 2020.

Jeffrey I. Kessler

Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Issues and Decision Memorandum

- I. Summary
- II. Background
- III. Scope of the Order
- IV. Changes Since the Preliminary Results
- V. Rate for Non-Examined Companies
- VI. Duty Absorption
- VII. Discussion of the Issues
 - 1–A. Lawfulness of Commerce’s Interpretation of the Particular Market Situation (PMS) Provision
 - 1–B. Evidence of a PMS
 - 1–C. Quantification of PMS Adjustment
 2. Application of Constructed Value (CV) Profit and Selling Expense Ratios to PMS-Adjusted Costs
 3. Calculation of CV Profit and Selling Expenses
 4. Differential Pricing
 5. Hyundai Steel’s Cost Reconciliation
 6. Minor Inputs Obtained from Affiliated Parties
 7. Expenses Related to Raw Material Purchases
 8. Byproducts Reintroduced into Production
 9. Scrap Offsets
 10. U.S. Warehousing Expenses
 11. Warranty Expenses
 12. Packing Expenses for Hyundai Steel’s Prime Sales
 13. Constructed Export Price (CEP) Profit Calculation
 14. Cost of Prime Products Sold in the United States
 15. Freight Revenue Cap
 16. Calculation of General and Administrative (G&A) Expenses Incurred by SeAH’s U.S. Affiliate
- VIII. Recommendation

Appendix II

List of Companies Not Individually Examined

1. AJU Besteel Co., Ltd.
2. BDP International
3. Daewoo America
4. Daewoo International Corporation
5. Dong Yang Steel Pipe
6. Dong-A Steel Co. Ltd.
7. Dongbu Incheon Steel
8. DSEC
9. Emdtbruecker Eisenwerk and Company
10. Hansol Metal
11. Husteel Co., Ltd.
12. Hyundai RB
13. ILJIN Steel Corporation
14. Jim And Freight Co., Ltd.

15. Kia Steel Co. Ltd.
16. KSP Steel Company
17. Kukje Steel
18. Kumkang Kind Co., Ltd.
19. Kurvers
20. NEXTEEL Co., Ltd.
21. POSCO Daewoo America
22. POSCO Daewoo Corporation
23. Steel Canada
24. Samsung
25. Samsung C and T Corporation
26. SeAH Besteel Corporation
27. Sumitomo Corporation
28. TGS Pipe
29. Yonghyun Base Materials
30. ZEECO Asia

[FR Doc. 2020–15052 Filed 7–10–20; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–026, C–570–027]

Certain Corrosion-Resistant Steel Products From the People’s Republic of China: Affirmative Final Determination of Circumvention Involving Costa Rica

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) determines that imports of certain corrosion-resistant steel products (CORE), completed in Costa Rica using carbon hot-rolled steel (HRS) and/or cold-rolled steel (CRS) flat products manufactured in the People’s Republic of China (China), are circumventing the antidumping duty (AD) and countervailing duty (CVD) orders on CORE from China.

DATES: Applicable July 13, 2020.

FOR FURTHER INFORMATION CONTACT: Ariela Garvett, 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) 482–3609.

SUPPLEMENTARY INFORMATION:

Background

On February 18, 2020, Commerce published the *Preliminary Determination*¹ of circumvention of the *China CORE Orders*.² A summary of

¹ See *Certain Corrosion-Resistant Steel Products from the People’s Republic of China: Affirmative Preliminary Determination of Circumvention Involving Costa Rica*, 85 FR 8830 (February 18, 2020) (*Preliminary Determination*) and accompanying Preliminary Decision Memorandum.

² See *Certain Corrosion-Resistant Steel Products from India, Italy, the People’s Republic of China, the Republic of Korea and Taiwan: Amended Final Affirmative Antidumping Determination for India and Taiwan, and Antidumping Duty Orders*, 81 FR

events that occurred since Commerce published the *Preliminary Determination*, as well as a full discussion of the issues raised by parties for this final determination, may be found in the Issues and Decision Memorandum.³ 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 <https://access.trade.gov>. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at <http://enforcement.trade.gov/frn/>. The signed and the electronic versions of the Issues and Decision Memorandum are identical in content.

Scope of the Orders

The products covered by these orders are certain flat-rolled steel products, either clad, plated, or coated with corrosion-resistant metals such as zinc, aluminum, or zinc-, aluminum-, nickel- or iron-based alloys, whether or not corrugated or painted, varnished, laminated, or coated with plastics or other non-metallic substances in addition to the metallic coating. For a complete description of the scope of the orders, see the Issues and Decision Memorandum.

Scope of the Anti-Circumvention Inquiries

These anti-circumvention inquiries cover CORE completed in Costa Rica from HRS and/or CRS substrate input manufactured in China and subsequently exported to the United States (merchandise subject to these inquiries). This final ruling applies to all shipments of merchandise subject to these inquiries entered on or after the date of the initiation of these inquiries.⁴

48390 (July 25, 2016); see also *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) (collectively, *China CORE Orders*).

³ See Memorandum, “Issues and Decision Memorandum for the Anti-Circumvention Inquiries Involving Costa Rica of the Antidumping and Countervailing Duty Orders on Certain Corrosion-Resistant Steel Products from the People’s Republic of China,” dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

⁴ See *Corrosion-Resistant Steel Products from the People’s Republic of China: Initiation of Anti-Circumvention Inquiries on the Antidumping Duty and Countervailing Duty Orders*, 84 FR 43585 (August 21, 2019) (*Initiation Notice*) and accompanying Memorandum, “Certain Corrosion-Resistant Steel Products from the People’s Republic of China: Initiation of Anti-Circumvention Inquiries on the Antidumping Duty and Countervailing Duty Orders,” dated August 12, 2019 (Initiation Decision Memorandum).

Importers and exporters of CORE produced in Costa Rica using: (1) HRS manufactured in Costa Rica or other third countries, (2) CRS manufactured in Costa Rica using HRS produced in Costa Rica or other third countries, or (3) CRS manufactured in other third countries, must certify that the HRS and/or CRS processed into CORE in Costa Rica did not originate in China, as provided for in the certifications attached to this **Federal Register** notice. Otherwise, their merchandise will be subject to AD and CVD requirements.

Methodology

Commerce is conducting these anti-circumvention inquiries in accordance with section 781(b) of the Tariff Act of 1930, as amended (the Act). Because China is a non-market economy, within the meaning of section 771(18) of the Act,⁵ Commerce calculated the value of Chinese-origin input costs using prices of factors of production and market economy values, as discussed in section 773(c) of the Act. Additionally, because an interested party (*i.e.*, Metas A.) did not cooperate to the best of its ability in responding to Commerce's requests for information, we have based parts of our determination on the facts available, with adverse inferences, pursuant to sections 776(a) and (b) of the Act. See Preliminary Decision Memorandum for a full description of the methodology. We have continued to apply this methodology for our final determination.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs by parties in these inquiries are addressed in the Issues and Decision Memorandum. A list of the issues raised is attached to this notice as Appendix I.

Based on our analysis of the comments received from interested parties and our findings at verification, we made no revisions to the *Preliminary Determination* with regard to our analysis under the anti-circumvention factors of section 781(b) of the Act.⁶

⁵ See *Antidumping Duty Investigation of Certain Aluminum Foil from the People's Republic of China: Affirmative Preliminary Determination of Sales at Less-Than-Fair Value and Postponement of Final Determination*, 82 FR 50858, 50861 (November 2, 2017), and accompanying Preliminary Decision Memorandum at "China's Status as a Non-Market Economy," unchanged in *Certain Aluminum Foil from the People's Republic of China: Final Determination of Sales at Less Than Fair Value*, 83 FR 9282 (March 5, 2018).

⁶ We have made certain changes to the language in the certifications to provide guidance on who should complete the exporter certification, and to improve the identification of parties involved in the sale.

Final Affirmative Determination of Circumvention

We determine that exports to the United States of CORE completed in Costa Rica from HRS and/or CRS substrate manufactured in China are circumventing the *China CORE Orders*. We therefore find it appropriate to determine that merchandise subject to these inquiries should be considered to be within the scope of the *China CORE Orders*, and to instruct U.S. Customs and Border Protection (CBP) to continue to suspend liquidation of any entries of CORE completed in Costa Rica using HRS and/or CRS substrate manufactured in China.

Continuation of Suspension of Liquidation

As stated above, Commerce has made an affirmative determination of circumvention of the *China CORE Orders* by exports to the United States of CORE completed in Costa Rica using Chinese-origin HRS and/or CRS substrate. In accordance with 19 CFR 351.225(1)(3), Commerce will direct CBP to continue to suspend liquidation and to require a cash deposit of estimated duties on unliquidated entries of CORE completed in Costa Rica using Chinese-origin HRS and/or CRS substrate that were entered, or withdrawn from warehouse, for consumption on or after August 12, 2019, the date of initiation of these anti-circumvention inquiries. The suspension of liquidation and cash deposit instructions will remain in effect until further notice.

CORE produced in Costa Rica from HRS or CRS substrate that is not of Chinese-origin is not subject to these inquiries. However, imports of such merchandise are subject to certification requirements, and cash deposits may be required if the certification requirements are not satisfied. Accordingly, if an importer imports CORE produced in Costa Rica and claims that the CORE was produced from non-Chinese HRS or CRS substrate, in order not to be subject to AD and/or CVD requirements, the importer and exporter are required to meet the certification and documentation requirements described in Appendices II, III, and IV. The party that made the sale to the United States should fill out the exporter certification.

In order to prevent evasion, Commerce will instruct CBP that in the situation where parties have not maintained the requisite certification regarding the origin of the substrate for an entry, CBP should suspend the entry and collect cash deposits at the AD rate

established for the China-wide entity (199.43 percent) and the CVD rate established for all other Chinese producers and/or exporters (39.05 percent) pursuant to the *China CORE Orders*.⁷

Further, for this final determination, we continue to determine that the following company is not eligible for the certification process: Metas A.⁸ Accordingly, importers of CORE from Costa Rica produced and/or exported by this ineligible company are similarly ineligible for the certification process with regard to imports of CORE produced by or sourced from this company. Additionally, exporters are not eligible to certify shipments of merchandise produced by the above-listed company. Accordingly, CBP shall suspend the entry and collect cash deposits for entries of merchandise produced and/or exported by Metas A. at the AD rate established for the China-wide entity (199.43 percent) and the CVD rate established for all other Chinese producers and/or exporters (39.05 percent) pursuant to the *China CORE Orders*.

Notification Regarding Administrative Protective Order

This notice will serve as the only reminder to all parties subject to administrative protective order (APO) of their responsibility concerning the destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

This determination is issued and published in accordance with section 781(b) of the Act and 19 CFR 351.225(f).

Dated: July 6, 2020.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Issues and Decision Memorandum

- I. Summary
- II. Background
- III. Scope of the Orders
- IV. Scope of the Anti-Circumvention Inquiries
- V. Changes Since the Preliminary

⁷ See *China CORE Orders*, 81 FR at 48389 and 48393.

⁸ See *Preliminary Determination*, 85 FR at 8831, and accompanying Preliminary Decision Memorandum at 10, 25–26.

- Determination
- VI. Statutory Framework
- VII. Statutory Analysis
- VIII. Discussion of the Issues
 - Comment 1: Whether Metalco Should Be Eligible for Certification
- IX. Recommendation

Appendix II

Certification Requirements

If an importer imports certain corrosion-resistant steel products (CORE) from Costa Rica and claims that the CORE was not produced from hot-rolled steel and/or cold-rolled steel substrate (substrate) manufactured in the People's Republic of China (China), the importer is required to complete and maintain the importer certification attached hereto as Appendix III and all supporting documentation. Where the importer uses a broker to facilitate the entry process, it should obtain the entry summary number from the broker. Agents of the importer, such as brokers, however, are not permitted to make this certification on behalf of the importer.

The exporter of such merchandise is required to complete and maintain the exporter certification, attached as Appendix IV, and is further required to provide the importer a copy of that certification and all supporting documentation. The party that made the sale to the United States should fill out the exporter certification.

For any such certifications completed on the date of publication of this final determination through 20 days after the date of publication, exporters and importers should use the certifications attached to the *Preliminary Determination*. For any such certifications completed on or after 21 days after the date of publication of this final determination, exporters and importers should use the certifications contained below that have changed from the certifications issued with the *Preliminary Determination*.

For entries on or after the date of publication of this notice in the **Federal Register**, for which certifications are required, importers should complete the required certification at or prior to the date of entry summary, and exporters should complete the required certification and provide it to the importer at or prior to the date of shipment. For all such entries made within the first 20 days after publication of this notice, exporters and importers should use the certifications attached to the *Preliminary Determination*. For all entries made on or after 21 days after publication of this notice, exporters and importers should use the certifications contained below that have changed from the certifications issued with the *Preliminary Determination*.

The importer and exporter are also required to maintain sufficient documentation supporting their certifications. The importer will not be required to submit the certifications or supporting documentation to U.S. Customs and Border Protection (CBP) as part of the entry process at this time. However, the importer and the exporter will be required to present the certifications and supporting documentation to Commerce and/or CBP, as applicable, upon request by the respective

agency. Additionally, the claims made in the certifications and any supporting documentation are subject to verification by Commerce and/or CBP. The importer and exporter are required to maintain the certifications and supporting documentation for the later of: (1) A period of five years from the date of entry or (2) a period of three years after the conclusion of any litigation in United States courts regarding such entries.

In the situation where no certification is maintained for an entry, and AD/CVD orders from China potentially apply to that entry, Commerce intends to instruct CBP to suspend the entry and collect cash deposits at the applicable rates from the *China CORE Orders* (i.e., the AD rate established for the China-wide entity (199.43 percent) and the CVD rate established for all other Chinese producers and/or exporters (39.05 percent)).⁹

Appendix III

Importer Certification

I hereby certify that:

(A) My name is {IMPORTING COMPANY OFFICIAL'S NAME} and I am an official of {NAME OF IMPORTING COMPANY}, located at {ADDRESS OF IMPORTING COMPANY}.

(B) I have direct personal knowledge of the facts regarding the importation into the Customs territory of the United States of the corrosion resistant steel products produced in Costa Rica that entered under entry number(s), identified below, and which are covered by this certification. "Direct personal knowledge" refers to facts the certifying party is expected to have in its own records. For example, the importer should have direct personal knowledge of the importation of the product (e.g., the name of the exporter) in its records.

(C) If the importer is acting on behalf of the first U.S. customer, complete this paragraph, if not put "NA" at the end of this paragraph:

The corrosion resistant steel products covered by this certification were imported by {NAME OF IMPORTING COMPANY} on behalf of {NAME OF U.S. CUSTOMER}, located at {ADDRESS OF U.S. CUSTOMER}.

(D) The corrosion resistant steel products covered by this certification were shipped to {NAME OF PARTY TO WHOM MERCHANDISE WAS FIRST SHIPPED IN THE UNITED STATES}, located at {ADDRESS OF SHIPMENT}.

(E) I have personal knowledge of the facts regarding the production of the corrosion resistant steel products identified below. "Personal knowledge" includes facts obtained from another party (e.g., correspondence received by the importer (or exporter) from the producer regarding the country of manufacture of the imported products).

(F) The corrosion resistant steel products covered by this certification were not manufactured using hot-rolled steel and/or cold-rolled steel substrate produced in China.

(G) This certification applies to the following entries (repeat this block as many times as necessary):

Entry Summary #:

Entry Summary Line Item #:

Foreign Seller:

Foreign Seller's address:

Foreign Seller's Invoice #:

Foreign Seller's Invoice Line Item #:

Producer:

Producer's Address:

(H) I understand that {NAME OF IMPORTING COMPANY} is required to maintain a copy of this certification and sufficient documentation supporting this certification (i.e., documents maintained in the normal course of business, or documents obtained by the certifying party, for example, mill certificates, production records, invoices, etc.) for the later of: (1) A period of five years from the date of entry or (2) a period of three years after the conclusion of any litigation in the United States courts regarding such entries.

(I) I understand that {NAME OF IMPORTING COMPANY} is required to provide this certification and supporting records, upon request, to U.S. Customs and Border Protection (CBP) and/or the Department of Commerce (Commerce).

(J) I understand that {NAME OF IMPORTING COMPANY} is required to maintain a copy of the exporter's certification (attesting to the production and/or export of the imported merchandise identified above), and any supporting records provided by the exporter to the importer, for the later of: (1) a period of five years from the date of entry or (2) a period of three years after the conclusion of any litigation in United States courts regarding such entries.

(K) I understand that {NAME OF IMPORTING COMPANY} is required, upon request, to provide a copy of the exporter's certification and any supporting records provided by the exporter to the importer, to CBP and/or Commerce.

(L) I understand that the claims made herein, and the substantiating documentation, are subject to verification by CBP and/or Commerce.

(M) I understand that failure to maintain the required certifications, and/or failure to substantiate the claims made herein, and/or failure to allow CBP and/or Commerce to verify the claims made herein, may result in a de facto determination that all entries to which this certification applies are within the scope of the antidumping/countervailing duty order on corrosion resistant steel products from China. I understand that such finding will result in:

(i) Suspension of liquidation of all unliquidated entries (and entries for which liquidation has not become final) for which these requirements were not met;

(ii) the requirement that the importer post applicable antidumping duty and/or countervailing duty cash deposits (as appropriate) equal to the rates determined by Commerce; and

(iii) the revocation of {NAME OF IMPORTING COMPANY}'s privilege to certify future imports of corrosion resistant steel products from Costa Rica as not manufactured using hot-rolled steel and/or cold-rolled steel substrate from China.

(N) I understand that agents of the importer, such as brokers, are not permitted to make this certification.

⁹ See *China CORE Orders*, 81 FR at 48389 and 48393.

(O) This certification was completed at or prior to the date of entry summary.

(P) I am aware that U.S. law (including, but not limited to, 18 U.S.C. 1001) imposes criminal sanctions on individuals who knowingly and willfully make material false statements to the U.S. government.

Signature _____

NAME OF COMPANY OFFICIAL _____

TITLE _____

DATE _____

Appendix IV

Exporter Certification

Special Instructions: The party that made the sale to the United States should fill out the exporter certification.

I hereby certify that:

(A) My name is {COMPANY OFFICIAL'S NAME} and I am an official of {NAME OF COMPANY}, located at {ADDRESS};

(B) I have direct personal knowledge of the facts regarding the production and exportation of the corrosion resistant steel products identified below. "Direct personal knowledge" refers to facts the certifying party is expected to have in its own books and records. For example, an exporter should have direct personal knowledge of the producer's identity and location.

(C) The corrosion resistant steel products produced in Costa Rica and covered by this certification were not manufactured using hot-rolled steel and/or cold-rolled steel substrate produced in China.

(D) This certification applies to the following sales to {NAME OF U.S. CUSTOMER}, located at {ADDRESS OF U.S. CUSTOMER}. (repeat this block as many times as necessary):

Foreign Seller's Invoice # to U.S. Customer:
Foreign Seller's Invoice to U.S. Customer
Line item #:

Producer Name:

Producer's Address:

Producer's Invoice # to Foreign Seller: (If the foreign seller and the producer are the same party, put NA here.)

(E) The corrosion resistant steel products covered by this certification were shipped to {NAME OF U.S. PARTY TO WHOM MERCHANDISE WAS SHIPPED}, located at {U.S. ADDRESS TO WHICH MERCHANDISE WAS SHIPPED}.

(F) I understand that {NAME OF EXPORTING COMPANY} is required to maintain a copy of this certification and sufficient documentation supporting this certification (*i.e.*, documents maintained in the normal course of business, or documents obtained by the certifying party, for example, mill certificates, production records, invoices, etc.) for the later of: (1) A period of five years from the date of entry or (2) a period of three years after the conclusion of any litigation in the United States courts regarding such entries.

(G) I understand that {NAME OF EXPORTING COMPANY} must provide a copy of this Exporter Certification to the U.S. importer by the date of shipment;

(H) I understand that {NAME OF EXPORTING COMPANY} is required to provide a copy of this certification and supporting records, upon request, to U.S. Customs and Border Protection (CBP) and/or the Department of Commerce (Commerce).

(I) I understand that the claims made herein, and the substantiating documentation, are subject to verification by CBP and/or Commerce.

(J) I understand that failure to maintain the required certification, and/or failure to substantiate the claims made herein, and/or failure to allow CBP and/or Commerce to verify the claims made herein, may result in a de facto determination that all sales to which this certification applies are within the scope of the antidumping/countervailing duty order on corrosion resistant steel products from China. I understand that such finding will result in:

(i) Suspension of all unliquidated entries (and entries for which liquidation has not become final) for which these requirements were not met; and

(ii) The requirement that the importer post applicable antidumping duty and/or countervailing duty cash deposits (as appropriate) equal to the rates as determined by Commerce; and

(iii) the revocation of {NAME OF EXPORTING COMPANY}'s privilege to certify future exports of corrosion resistant steel products from Costa Rica as not manufactured using hot-rolled steel and/or cold-rolled steel substrate from China.

(K) This certification was completed at or prior to the date of shipment.

(L) I am aware that U.S. law (including, but not limited to, 18 U.S.C. 1001) imposes criminal sanctions on individuals who knowingly and willfully make material false statements to the U.S. government.

Signature _____

NAME OF COMPANY OFFICIAL _____

TITLE _____

DATE _____

[FR Doc. 2020-15074 Filed 7-10-20; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-570-026, C-570-027]

Certain Corrosion-Resistant Steel Products From the People's Republic of China: Negative Final Determination of Circumvention Involving Guatemala

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) determines that imports of certain corrosion-resistant steel products (CORE), completed in Guatemala using carbon hot-rolled steel (HRS) and/or cold-rolled steel (CRS) flat products manufactured in the People's

Republic of China (China), are not circumventing the antidumping duty (AD) and countervailing duty (CVD) orders on CORE from China at this time.

DATES: Applicable July 13, 2020.

FOR FURTHER INFORMATION CONTACT:

Drew Jackson, 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) 482-4406.

SUPPLEMENTARY INFORMATION:

Background

On February 18, 2020, Commerce published in the **Federal Register** its preliminary determination¹ that imports of CORE completed in Guatemala are not circumventing the *China CORE Orders* at this time.² A summary of events that occurred since Commerce published the *Preliminary Determination*, as well as a full discussion of the issues raised by parties for this final determination, may be found in the Issues and Decision Memorandum.³ 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 <https://access.trade.gov>. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at <http://enforcement.trade.gov/frn/>. The signed and the electronic versions of the Issues and Decision Memorandum are identical in content.

Scope of the Orders

The products covered by these orders are certain flat-rolled steel products, either clad, plated, or coated with corrosion-resistant metals such as zinc, aluminum, or zinc-, aluminum-, nickel-

¹ See *Certain Corrosion-Resistant Steel Products from the People's Republic of China: Negative Preliminary Determination of Circumvention Involving Guatemala*, 85 FR 8840 (February 18, 2020) (*Preliminary Determination*) and accompanying Preliminary Decision Memorandum.

² See *Certain Corrosion-Resistant Steel Products from India, Italy, the People's Republic of China, the Republic of Korea and Taiwan: Amended Final Affirmative Antidumping Determination for India and Taiwan, and Antidumping Duty Orders*, 81 FR 48390 (July 25, 2016); see also *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) (collectively, *China CORE Orders*).

³ See Memorandum, "Issues and Decision Memorandum for the Anti-Circumvention Inquiries Involving Guatemala of the Antidumping and Countervailing Duty Orders on Certain Corrosion-Resistant Steel Products from the People's Republic of China," dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

or iron-based alloys, whether or not corrugated or painted, varnished, laminated, or coated with plastics or other non-metallic substances in addition to the metallic coating. For a complete description of the scope of the orders, see the Issues and Decision Memorandum.

Scope of the Anti-Circumvention Inquiries

These anti-circumvention inquiries cover CORE completed in Guatemala from HRS and/or CRS substrate input manufactured in China and subsequently exported to the United States (merchandise subject to these inquiries).

Analysis of Comments Received

All issues raised in the case and rebuttal briefs by parties in these inquiries are addressed in the Issues and Decision Memorandum. A list of the issues raised is attached to this notice at the Appendix.

Based on our analysis of the comments received from interested parties and our findings at verification, we made no revisions to the *Preliminary Determination*.

Final Negative Determination of Circumvention

We determine that exports to the United States of CORE completed in Guatemala from HRS and/or CRS substrate manufactured in China are not circumventing the *China CORE Orders* at this time.

Notification Regarding Administrative Protective Order

This notice will serve as the only reminder to all parties subject to administrative protective order (APO) of their responsibility concerning the destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

This determination is issued and published in accordance with section 781(b) of the Tariff Act of 1930 (amended) and 19 CFR 351.225(f).

Dated: July 6, 2020.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix—List of Topics Discussed in the Issues and Decision Memorandum

- I. Summary
- II. Background
- III. Scope of the Orders
- IV. Scope of the Anti-Circumvention Inquiries
- V. Changes Since the Preliminary Determination
- VI. Statutory Framework
- VII. Statutory Analysis
- VIII. Discussion of the Issues
 - Comment 1: Whether Ternium Guatemala Consumed Chinese-Origin Steel During the POI
 - Comment 2: Whether to Implement a Certification Regime
- IX. Recommendation

[FR Doc. 2020–15040 Filed 7–10–20; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–881]

Certain Cold Rolled Steel Flat Products From the Republic of Korea: Final Results of Antidumping Duty Administrative Review; 2017–2018

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) determines that Hyundai Steel Company (Hyundai) and POSCO/POSCO Daewoo Co., Ltd. (POSCO/PDW), producers/exporters of certain cold rolled steel flat products (cold-rolled steel) from the Republic of Korea (Korea), did not sell subject merchandise in the United States at prices below normal value during the period of review (POR) September 1, 2017 through August 31, 2018.

DATES: Applicable July 13, 2020.

FOR FURTHER INFORMATION CONTACT: Michael J. Heaney or Marc Castillo, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4475 or (202) 482–0519, respectively.

SUPPLEMENTARY INFORMATION:

Background

On November 18, 2019, Commerce published the *Preliminary Results* of

this administrative review.¹ For a history of events that occurred since the *Preliminary Results*, see the Issues and Decision Memorandum.² We invited interested parties to comment on the *Preliminary Results*. Between January 3, 2020 and January 13, 2020, Commerce received timely filed case briefs and rebuttal briefs from various interested parties.

On March 12, 2020, we extended the deadline for the final results.³ On April 24, 2020, Commerce tolled all deadlines in administrative reviews by 50 days, thereby extending these final results until July 6, 2020.⁴

Commerce conducted this review in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act).

Scope of the Order

The product covered by the *Order*⁵ is cold-rolled steel the Republic of Korea. For a complete description of the scope of the *Order*, see the Issues and Decision Memorandum.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs filed by parties in this review are addressed in the Issues and Decision Memorandum, which is hereby adopted with this notice. The issues are identified in the 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 <https://access.trade.gov>. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly on the internet at <http://>

¹ See *Certain Cold Rolled Steel Flat Products from the Republic of Korea: Preliminary Results of Antidumping Duty Administrative Review; 2017–2018*, 84 FR 63607 (November 18, 2019) (*Preliminary Results*) and accompanying Preliminary Decision Memorandum (PDM).

² See Memorandum, “Issues and Decision Memorandum for the Final Results of the 2017–2018 Administrative Review of the Antidumping Duty Order on Certain Cold-Rolled Steel Flat Products from the Republic of Korea,” dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

³ See Memorandum, “Certain Cold-Rolled Steel Flat Products from the Republic of Korea: Extension of Deadline for Final Results of Antidumping Duty Administrative Review,” dated March 12, 2020.

⁴ See Memorandum, “Tolling of Deadlines for Antidumping and Countervailing Duty Administrative Reviews in Response to Operational Adjustments Due to COVID–19,” dated April 24, 2020.

⁵ See *Certain Cold Rolled Steel Flat Products from Brazil, India, the Republic of Korea, and the United Kingdom: Amended Final Affirmative Antidumping Determinations for Brazil and the United Kingdom and Antidumping Duty Orders*, 81 FR 64432 (September 20, 2016) (*Order*).

enforcement.trade.gov/frn/index.html. The signed Issues and Decision Memorandum and the electronic version are identical in content.

Changes Since the Preliminary Results

Based on our analysis of the comments received, we made certain changes to the margin calculations for POSCO/PDW and Hyundai Steel. For a discussion of these changes, see the Issues and Decision Memorandum.

Rates for Non-Examined Companies

The Act 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}.”

For these final results, we have calculated 0.00 percent weighted-average dumping margins for both Hyundai and POSCO/PDW, and we have not calculated any margins which are not zero, *de minimis*, or determined entirely on the basis of facts available. Accordingly, we have assigned to the companies not individually examined (*i.e.*, Dongbu Steel Co., Ltd. and Dongbu Steel Incheon Steel Co., Ltd.) a margin of 0.00 percent, which is the average of the margins calculated for POSCO/PDW and Hyundai.

Results of Review

Commerce determines that the following weighted-average dumping margins exist for the period September 1, 2017 through August 31, 2018:

Producer/Exporter	Weighted-average dumping margin (percent)
Hyundai Steel Company	0.00
POSCO/POSCO Daewoo Co., Ltd	0.00
Non-Examined Companies	0.00

Disclosure

Commerce intends to disclose the calculations performed for these final results of review within five days of the date of publication of this notice in the **Federal Register**, in accordance with 19 CFR 351.224(b).

Assessment

Pursuant to section 751(a)(2)(C) of the Act and 19 CFR 351.212(b), Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review. Commerce intends to issue assessment instructions to CBP 15 days after the date of publication of the final results of this administrative review in the **Federal Register**.

Where a respondent reported reliable entered values of their U.S. sales, we calculated importer- (or customer-) specific *ad valorem* assessment rates by aggregating the dumping margins calculated for all U.S. sales to each importer (or customer) and dividing this amount by the total entered value of the sales to each importer (or customer).⁶ Where Commerce calculated a weighted-average dumping margin by dividing the total amount of dumping for reviewed sales to that party by the total sales quantity associated with those transactions, Commerce intends to direct CBP to assess importer- (or customer-) specific assessment rates based on the resulting per-unit rates.⁷ Where an importer- (or customer-) specific *ad valorem* or per-unit rate is greater than *de minimis* (*i.e.*, 0.50 percent), Commerce intends to instruct CBP to collect the appropriate duties at the time of liquidation.⁸ Where an importer- (or customer-) specific *ad valorem* or per-unit rate is zero or *de minimis*, Commerce intends to instruct CBP to liquidate appropriate entries without regard to antidumping duties.⁹

For the companies which were not selected for individual review, we intend to assign an assessment rate based on the methodology described in the “Rates for Non-Examined Companies” section, above.

Consistent with Commerce’s assessment practice, for entries of subject merchandise during the POR produced by POSCO/PDW, Hyundai Steel, or the non-examined companies for which the producer did not know that its merchandise was destined for the United States, we intend to instruct

⁶ See 19 CFR 351.212(b)(1).
⁷ *Id.*
⁸ *Id.*
⁹ See 19 CFR 351.106(c)(2).

CBP to liquidate unreviewed entries at the all-others rate, if there is no rate for any intermediate company(ies) involved in the transaction.¹⁰

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the notice of final results of this administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication, as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for Hyundai, POSCO/PDW, and other companies listed in the final results of review will be equal to the weighted-average dumping margin established in the final results of this administrative review; (2) for merchandise exported by producers or exporters not covered in this 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 in which they were reviewed; (3) if the exporter is not a firm covered in this 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 merchandise; (4) the cash deposit rate for all other producers or exporters will continue to be 20.33 percent,¹¹ the all-others rate established in the less-than-fair-value investigation. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in Commerce’s presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification Regarding Administrative Protective Order

This notice also serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the

¹⁰ For a full discussion of this practice, see *Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties*, 68 FR 23954 (May 6, 2003).
¹¹ See *Order*.

disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

We are issuing and publishing this notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: July 6, 2020.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

- I. Summary
- II. Background
- III. Scope of the Order
- IV. Changes Since the Preliminary Results
- V. Rate for Non-Examined Companies
- VI. Discussion of the Issues
 1. Existence of a Particular Market Situation
 2. Quantification of Particular Market Situation Adjustment
 3. Applicability of Particular Market Situation Adjustment to Self-Produced Inputs
 4. POSCO/PDW CEP Offset
 5. Hyundai Manufacturer Codes
- VII. Recommendation

[FR Doc. 2020-15051 Filed 7-10-20; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-570-026, C-570-027]

Certain Corrosion-Resistant Steel Products From the People's Republic of China: Affirmative Final Determination of Circumvention Involving the United Arab Emirates

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) determines that imports of certain corrosion-resistant steel products (CORE), completed in the United Arab Emirates (UAE) using carbon hot-rolled steel (HRS) and/or cold-rolled steel (CRS) flat products manufactured in the People's Republic of China (China), are circumventing the antidumping duty (AD) and

countervailing duty (CVD) orders on CORE from China.

DATES: Applicable July 13, 2020.

FOR FURTHER INFORMATION CONTACT: Eva Kim or Jeff Pedersen, 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) 482-8283 and (202) 482-2769, respectively.

SUPPLEMENTARY INFORMATION:

Background

On February 18, 2020, Commerce published the *Preliminary Determination*¹ of circumvention of the *China CORE Orders*.² A summary of events that occurred since Commerce published the *Preliminary Determination*, as well as a full discussion of the issues raised by parties for this final determination, may be found in the Issues and Decision Memorandum.³ 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 <https://access.trade.gov>. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at <http://enforcement.trade.gov/frn/>. The signed and the electronic versions of the Issues and Decision Memorandum are identical in content.

Scope of the Orders

The products covered by these orders are certain flat-rolled steel products, either clad, plated, or coated with corrosion-resistant metals such as zinc, aluminum, or zinc-, aluminum-, nickel- or iron-based alloys, whether or not

¹ See *Certain Corrosion-Resistant Steel Products from the People's Republic of China: Affirmative Preliminary Determination of Circumvention Involving the United Arab Emirates*, 85 FR 8841 (February 18, 2020) (*Preliminary Determination*) and accompanying Preliminary Decision Memorandum.

² See *Certain Corrosion-Resistant Steel Products from India, Italy, the People's Republic of China, the Republic of Korea and Taiwan: Amended Final Affirmative Antidumping Determination for India and Taiwan, and Antidumping Duty Orders*, 81 FR 48390 (July 25, 2016); see also *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) (collectively, *China CORE Orders*).

³ See Memorandum, "Issues and Decision Memorandum for the Anti-Circumvention Inquiries Involving the United Arab Emirates of the Antidumping and Countervailing Duty Orders on Certain Corrosion-Resistant Steel Products from the People's Republic of China," dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

corrugated or painted, varnished, laminated, or coated with plastics or other non-metallic substances in addition to the metallic coating. For a complete description of the scope of the orders, see the Issues and Decision Memorandum.

Scope of the Anti-Circumvention Inquiries

These anti-circumvention inquiries cover CORE completed in the UAE from HRS and/or CRS substrate input manufactured in China and subsequently exported to the United States (merchandise subject to these inquiries). This final ruling applies to all shipments of merchandise subject to these inquiries entered on or after the date of the initiation of these inquiries.⁴ Importers and exporters of CORE produced in the UAE using: (1) HRS manufactured in the UAE or other third countries, (2) CRS manufactured in the UAE using HRS produced in the UAE or other third countries, or (3) CRS manufactured in other third countries, must certify that the HRS and/or CRS processed into CORE in the UAE did not originate in China, as provided for in the certifications attached to this **Federal Register** notice. Otherwise, their merchandise will be subject to AD and CVD requirements.

Methodology

Commerce is conducting these anti-circumvention inquiries in accordance with section 781(b) of the Tariff Act of 1930, as amended (the Act). Because China is a non-market economy, within the meaning of section 771(18) of the Act,⁵ Commerce calculated the value of Chinese-origin input costs using prices of factors of production and market economy values, as discussed in section 773(c) of the Act. Additionally, because an interested party (*i.e.*, Asian Ispat FZ LLC.) did not cooperate to the best of its ability in responding to Commerce's

⁴ See *Corrosion-Resistant Steel Products from the People's Republic of China: Initiation of Anti-Circumvention Inquiries on the Antidumping Duty and Countervailing Duty Orders*, 84 FR 43585 (August 21, 2019) (*Initiation Notice*) and accompanying Memorandum, "Certain Corrosion-Resistant Steel Products from the People's Republic of China: Initiation of Anti-Circumvention Inquiries on the Antidumping Duty and Countervailing Duty Orders," dated August 12, 2019 (Initiation Decision Memorandum).

⁵ See *Antidumping Duty Investigation of Certain Aluminum Foil from the People's Republic of China: Affirmative Preliminary Determination of Sales at Less-Than-Fair Value and Postponement of Final Determination*, 82 FR 50858, 50861 (November 2, 2017), and accompanying Preliminary Decision Memorandum at "China's Status as a Non-Market Economy," unchanged in *Certain Aluminum Foil from the People's Republic of China: Final Determination of Sales at Less Than Fair Value*, 83 FR 9282 (March 5, 2018).

requests for information, we have based parts of our determination on the facts available, with adverse inferences, pursuant to sections 776(a) and (b) of the Act. See Preliminary Decision Memorandum for a full description of the methodology. We have continued to apply this methodology for our final determination.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs by parties in these inquiries are addressed in the Issues and Decision Memorandum. A list of the issues raised is attached to this notice as Appendix I.

Based on our analysis of the comments received from interested parties and our findings at verification, we made no revisions to the *Preliminary Determination* with regard to our analysis under the anti-circumvention factors of section 781(b) of the Act. Additionally, based on our analysis of the comments received from interested parties, we have made certain changes to the language in the certifications to provide guidance on who should complete the exporter certification, and to improve the identification of parties involved in the sale.⁶

Final Affirmative Determination of Circumvention

We determine that exports to the United States of CORE completed in the UAE from HRS and/or CRS substrate manufactured in China are circumventing the *China CORE Orders*. We therefore find it appropriate to determine that merchandise subject to these inquiries should be considered to be within the scope of the *China CORE Orders*, and to instruct U.S. Customs and Border Protection (CBP) to continue to suspend liquidation of any entries of CORE completed in the UAE using HRS and/or CRS substrate manufactured in China.

Continuation of Suspension of Liquidation

As stated above, Commerce has made an affirmative determination of circumvention of the *China CORE Orders* by exports to the United States of CORE completed in the UAE using Chinese-origin HRS and/or CRS substrate. In accordance with 19 CFR 351.225(1)(3), Commerce will direct CBP to continue to suspend liquidation and to require a cash deposit of estimated duties on unliquidated entries of CORE completed in the UAE using Chinese-origin HRS and/or CRS

substrate that were entered, or withdrawn from warehouse, for consumption on or after August 12, 2019, the date of initiation of these anti-circumvention inquiries.

The suspension of liquidation and cash deposit instructions will remain in effect until further notice.

CORE produced in the UAE from HRS or CRS substrate that is not of Chinese-origin is not subject to these inquiries. However, imports of such merchandise are subject to certification requirements, and cash deposits may be required if the certification requirements are not satisfied. Accordingly, if an importer imports CORE produced in the UAE and claims that the CORE was produced from non-Chinese HRS or CRS substrate, in order not to be subject to AD and/or CVD requirements, the importer and exporter are required to meet the certification and documentation requirements described in Appendices II, III, and IV. The party that made the sale to the United States should fill out the exporter certification.

In order to prevent evasion, Commerce will instruct CBP that in the situation where parties have not maintained the requisite certification regarding the origin of the substrate for an entry, CBP should suspend the entry and collect cash deposits at the AD rate established for the China-wide entity (199.43 percent) and the CVD rate established for all other Chinese producers and/or exporters (39.05 percent) pursuant to the *China CORE Orders*.⁷

Further, for this final determination, we continue to determine that the following company is not eligible for the certification process: Asian Ispat FZ LLC. ⁸ Accordingly, importers of CORE from the UAE produced and/or exported by this ineligible company are similarly ineligible for the certification process with regard to imports of CORE produced by or sourced from this company. Additionally, exporters are not eligible to certify shipments of merchandise produced by the above-listed company. Accordingly, CBP shall suspend the entry and collect cash deposits for entries of merchandise produced and/or exported by Asian Ispat FZ LLC at the AD rate established for the China-wide entity (199.43 percent) and the CVD rate established for all other Chinese producers and/or exporters (39.05 percent) pursuant to the *China CORE Orders*.

⁷ See *China CORE Orders*, 81 FR at 48389 and 48393.

⁸ See *Preliminary Determination*, 85 FR at 8842, and accompanying Preliminary Decision Memorandum at 28.

Notification Regarding Administrative Protective Order

This notice will serve as the only reminder to all parties subject to administrative protective order (APO) of their responsibility concerning the destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

This determination is issued and published in accordance with section 781(b) of the Act and 19 CFR 351.225(f).

Dated: July 6, 2020.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Issues and Decision Memorandum

- I. Summary
- II. Background
- III. Scope of the Orders
- IV. Scope of the Anti-Circumvention Inquiries
- V. Statutory Framework
- VI. Statutory Analysis
- VII. Discussion of the Issues
 - Comment 1: Whether the Order on Chinese CORE Has Been Circumvented
 - Comment 2: Application of NME Methodology
 - Comment 3: HTS Classification of Cold-Rolled Steel
 - Comment 4: Whether UIS Should Be Subject to the Certification Process
 - Comment 5: Whether the Certifications Should Be Modified to Include Dufenco's Situation
 - Comment 6: Clarification of Response Reported in Verification Report
- VIII. Recommendation

Appendix II

Certification Requirements

If an importer imports certain corrosion-resistant steel products (CORE) from the United Arab Emirates and claims that the CORE was not produced from hot-rolled steel and/or cold-rolled steel substrate (substrate) manufactured in the People's Republic of China (China), the importer is required to complete and maintain the importer certification attached hereto as Appendix III and all supporting documentation. Where the importer uses a broker to facilitate the entry process, it should obtain the entry summary number from the broker. Agents of the importer, such as brokers, however, are not permitted to make this certification on behalf of the importer.

The exporter of such merchandise is required to complete and maintain the exporter certification, attached as Appendix

⁶ See Comment 5 of the Issues and Decision Memorandum.

IV, and is further required to provide the importer a copy of that certification and all supporting documentation. The party that made the sale to the United States should fill out the exporter certification.

For any such certifications completed on the date of publication of this final determination through 20 days after the date of publication, exporters and importers should use the certifications attached to the *Preliminary Determination*. For any such certifications completed on or after 21 days after the date of publication of this final determination, exporters and importers should use the certifications contained below that have changed from the certifications issued with the *Preliminary Determination*.

For entries on or after the date of publication of this notice in the **Federal Register**, for which certifications are required, importers should complete the required certification at or prior to the date of entry summary, and exporters should complete the required certification and provide it to the importer at or prior to the date of shipment. For all such entries made within the first 20 days after publication of this notice, exporters and importers should use the certifications attached to the *Preliminary Determination*. For all entries made on or after 21 days after publication of this notice, exporters and importers should use the certifications contained below that have changed from the certifications issued with the *Preliminary Determination*.

The importer and exporter are also required to maintain sufficient documentation supporting their certifications. The importer will not be required to submit the certifications or supporting documentation to U.S. Customs and Border Protection (CBP) as part of the entry process at this time. However, the importer and the exporter will be required to present the certifications and supporting documentation to Commerce and/or CBP, as applicable, upon request by the respective agency. Additionally, the claims made in the certifications and any supporting documentation are subject to verification by Commerce and/or CBP. The importer and exporter are required to maintain the certifications and supporting documentation for the later of: (1) A period of five years from the date of entry or (2) a period of three years after the conclusion of any litigation in United States courts regarding such entries.

In the situation where no certification is maintained for an entry, and AD/CVD orders from China potentially apply to that entry, Commerce intends to instruct CBP to suspend the entry and collect cash deposits at the applicable rates from the *China CORE Orders* (i.e., the AD rate established for the China-wide entity (199.43 percent) and the CVD rate established for all other Chinese producers and/or exporters (39.05 percent)).⁹

Appendix III

Importer Certification

I hereby certify that:

(A) My name is {IMPORTING COMPANY OFFICIAL'S NAME} and I am an official of

{NAME OF IMPORTING COMPANY}, located at {ADDRESS OF IMPORTING COMPANY}.

(B) I have direct personal knowledge of the facts regarding the importation into the Customs territory of the United States of the corrosion resistant steel products produced in the United Arab Emirates that entered under entry number(s), identified below, and which are covered by this certification. "Direct personal knowledge" refers to facts the certifying party is expected to have in its own records. For example, the importer should have direct personal knowledge of the importation of the product (e.g., the name of the exporter) in its records.

(C) If the importer is acting on behalf of the first U.S. customer, complete this paragraph, if not put "NA" at the end of this paragraph: The corrosion resistant steel products covered by this certification were imported by {NAME OF IMPORTING COMPANY} on behalf of {NAME OF U.S. CUSTOMER}, located at {ADDRESS OF U.S. CUSTOMER}.

(D) The corrosion resistant steel products covered by this certification were shipped to {NAME OF PARTY TO WHOM MERCHANDISE WAS FIRST SHIPPED IN THE UNITED STATES}, located at {ADDRESS OF SHIPMENT}.

(E) I have personal knowledge of the facts regarding the production of the corrosion resistant steel products identified below. "Personal knowledge" includes facts obtained from another party (e.g., correspondence received by the importer (or exporter) from the producer regarding the country of manufacture of the imported products).

(F) The corrosion resistant steel products covered by this certification were not manufactured using hot-rolled steel and/or cold-rolled steel substrate produced in China.

(G) This certification applies to the following entries (repeat this block as many times as necessary):

Entry Summary #:
Entry Summary Line Item #:
Foreign Seller:
Foreign Seller's address:
Foreign Seller's Invoice #:
Foreign Seller's Invoice Line Item #:
Producer:
Producer's Address:

(H) I understand that {NAME OF IMPORTING COMPANY} is required to maintain a copy of this certification and sufficient documentation supporting this certification (i.e., documents maintained in the normal course of business, or documents obtained by the certifying party, for example, mill certificates, production records, invoices, etc.) for the later of: (1) A period of five years from the date of entry or (2) a period of three years after the conclusion of any litigation in the United States courts regarding such entries.

(I) I understand that {NAME OF IMPORTING COMPANY} is required to provide this certification and supporting records, upon request, to U.S. Customs and Border Protection (CBP) and/or the Department of Commerce (Commerce).

(J) I understand that {NAME OF IMPORTING COMPANY} is required to maintain a copy of the exporter's certification

(attesting to the production and/or export of the imported merchandise identified above), and any supporting records provided by the exporter to the importer, for the later of: (1) A period of five years from the date of entry or (2) a period of three years after the conclusion of any litigation in United States courts regarding such entries.

(K) I understand that {NAME OF IMPORTING COMPANY} is required, upon request, to provide a copy of the exporter's certification and any supporting records provided by the exporter to the importer, to CBP and/or Commerce.

(L) I understand that the claims made herein, and the substantiating documentation, are subject to verification by CBP and/or Commerce.

(M) I understand that failure to maintain the required certifications, and/or failure to substantiate the claims made herein, and/or failure to allow CBP and/or Commerce to verify the claims made herein, may result in a de facto determination that all entries to which this certification applies are within the scope of the antidumping/countervailing duty order on corrosion resistant steel products from China. I understand that such finding will result in:

(i) Suspension of liquidation of all unliquidated entries (and entries for which liquidation has not become final) for which these requirements were not met;

(ii) the requirement that the importer post applicable antidumping duty and/or countervailing duty cash deposits (as appropriate) equal to the rates determined by Commerce; and

(iii) the revocation of {NAME OF IMPORTING COMPANY}'s privilege to certify future imports of corrosion resistant steel products from the United Arab Emirates as not manufactured using hot-rolled steel and/or cold-rolled steel substrate from China.

(N) I understand that agents of the importer, such as brokers, are not permitted to make this certification.

(O) This certification was completed at or prior to the date of entry summary.

(P) I am aware that U.S. law (including, but not limited to, 18 U.S.C. 1001) imposes criminal sanctions on individuals who knowingly and willfully make material false statements to the U.S. government.

Signature _____

NAME OF COMPANY OFFICIAL

TITLE

DATE

Appendix IV

Exporter Certification

Special Instructions: The party that made the sale to the United States should fill out the exporter certification.

I hereby certify that:

(A) My name is {COMPANY OFFICIAL'S NAME} and I am an official of {NAME OF COMPANY}, located at {ADDRESS};

(B) I have direct personal knowledge of the facts regarding the production and exportation of the corrosion resistant steel products identified below. "Direct personal

⁹ See *China CORE Orders*, 81 FR at 48389 and 48393.

knowledge” refers to facts the certifying party is expected to have in its own books and records. For example, an exporter should have direct personal knowledge of the producer’s identity and location.

(C) The corrosion resistant steel products produced in the United Arab Emirates and covered by this certification were not manufactured using hot-rolled steel and/or cold-rolled steel substrate produced in China.

(D) This certification applies to the following sales to {NAME OF U.S. CUSTOMER}, located at {ADDRESS OF U.S. CUSTOMER}. (repeat this block as many times as necessary):

Foreign Seller’s Invoice # to U.S. Customer:
Foreign Seller’s Invoice to U.S. Customer

Line item #:

Producer Name:

Producer’s Address:

Producer’s Invoice # to Foreign Seller: (If the foreign seller and the producer are the same party, put NA here.)

(E) The corrosion resistant steel products covered by this certification were shipped to {NAME OF U.S. PARTY TO WHOM MERCHANDISE WAS SHIPPED}, located at {U.S. ADDRESS TO WHICH MERCHANDISE WAS SHIPPED}.

(F) I understand that {NAME OF EXPORTING COMPANY} is required to maintain a copy of this certification and sufficient documentation supporting this certification (*i.e.*, documents maintained in the normal course of business, or documents obtained by the certifying party, for example, mill certificates, production records, invoices, etc.) for the later of: (1) A period of five years from the date of entry or (2) a period of three years after the conclusion of any litigation in the United States courts regarding such entries.

(G) I understand that {NAME OF EXPORTING COMPANY} must provide a copy of this Exporter Certification to the U.S. importer by the date of shipment;

(H) I understand that {NAME OF EXPORTING COMPANY} is required to provide a copy of this certification and supporting records, upon request, to U.S. Customs and Border Protection (CBP) and/or the Department of Commerce (Commerce).

(I) I understand that the claims made herein, and the substantiating documentation, are subject to verification by CBP and/or Commerce.

(J) I understand that failure to maintain the required certification, and/or failure to substantiate the claims made herein, and/or failure to allow CBP and/or Commerce to verify the claims made herein, may result in a de facto determination that all sales to which this certification applies are within the scope of the antidumping/countervailing duty order on corrosion resistant steel products from China. I understand that such finding will result in:

(i) suspension of all unliquidated entries (and entries for which liquidation has not become final) for which these requirements were not met; and

(ii) the requirement that the importer post applicable antidumping duty and/or countervailing duty cash deposits (as appropriate) equal to the rates as determined by Commerce; and

(iii) the revocation of {NAME OF EXPORTING COMPANY}’s privilege to certify future exports of corrosion resistant steel products from the United Arab Emirates as not manufactured using hot-rolled steel and/or cold-rolled steel substrate from China.

(K) This certification was completed at or prior to the date of shipment.

(L) I am aware that U.S. law (including, but not limited to, 18 U.S.C. 1001) imposes criminal sanctions on individuals who knowingly and willfully make material false statements to the U.S. government.

Signature _____

NAME OF COMPANY OFFICIAL

TITLE

DATE

[FR Doc. 2020–15078 Filed 7–10–20; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–123]

Certain Corrosion Inhibitors from the People’s Republic of China: Preliminary Affirmative Countervailing Duty Determination, and Alignment of Final Determination With Final Antidumping Duty Determination

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that countervailable subsidies are being provided to producers and exporters of certain corrosion inhibitors from the People’s Republic of China (China). The period of investigation (POI) is January 1, 2019 through December 31, 2019. Interested parties are invited to comment on this preliminary determination

DATES: Applicable July 13, 2020.

FOR FURTHER INFORMATION CONTACT: Theodore Pearson or Nicholas Czajkowski, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2631 or (202) 482–1395, respectively.

SUPPLEMENTARY INFORMATION:

Background

This preliminary determination is made in accordance with section 703(b) of the Trade Act of 1930, as amended (the Act). Commerce published the notice of initiation of this investigation on March 3, 2020.¹ On April 1, 2020,

¹ See *Certain Corrosion Inhibitors from the People’s Republic of China: Initiation of*

Commerce postponed the preliminary determination of this investigation, and the revised deadline is now July 6, 2020.²

For a complete description of the events that followed the initiation of this investigation, *see* the Preliminary Decision Memorandum.³ A list of topics discussed in the Preliminary Decision Memorandum is included as Appendix II to this notice. The Preliminary 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>. The signed and electronic versions of the Preliminary Decision Memorandum are identical in content.

Scope of the Investigation

The products covered by this investigation are certain corrosion inhibitors from China. For a complete description of the scope of this investigation, *see* Appendix I.

Scope Comments

In accordance with the preamble to Commerce’s regulations,⁴ the *Initiation Notice* set aside a period of time for parties to raise issues regarding product coverage (*i.e.*, scope).⁵ No parties provided comment on the scope of the investigation.

Methodology

Commerce is conducting this investigation in accordance with section 701 of the Act. For each of the subsidy programs found countervailable, Commerce preliminarily determines that there is a subsidy, *i.e.*, a financial contribution by an “authority” that gives rise to a benefit to the recipient, and that the subsidy is specific.⁶

Commerce notes that, in making these findings, it relied, in part, on facts available and, because it finds that one

Countervailing Duty Investigation, 85 FR 12502 (March 3, 2020) (*Initiation Notice*).

² See *Certain Corrosion Inhibitors from the People’s Republic of China: Postponement of Preliminary Determination in the Countervailing Duty Investigation*, 85 FR 19455 (April 7, 2020).

³ See Memorandum, “Decision Memorandum for the Preliminary Determination of the Countervailing Duty Investigation of Corrosion Inhibitors from the People’s Republic of China,” dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

⁴ See *Antidumping Duties; Countervailing Duties, Final Rule*, 62 FR 27296, 27323 (May 19, 1997).

⁵ See *Initiation Notice*.

⁶ See sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

or more respondents did not act to the best of their ability to respond to Commerce's requests for information, it drew an adverse inference where appropriate in selecting from among the facts otherwise available.⁷ For further information, see "Use of Facts Otherwise Available and Adverse Inferences" in the Preliminary Decision Memorandum.

Alignment

As noted in the Preliminary Decision Memorandum, in accordance with section 705(a)(1) of the Act and 19 CFR 351.210(b)(4), Commerce is aligning the final CVD determination in this investigation with the final determination in the companion antidumping duty (AD) investigation of certain corrosion inhibitors from China based on a request made by Wincom Incorporated (the petitioner).⁸ Consequently, the final CVD determination will be issued on the same date as the final AD determination, which is currently scheduled to be issued no later than November 26, 2020, unless postponed.

All-Others Rate

Sections 703(d) and 705(c)(5)(A) of the Act provide that, in the preliminary determination, Commerce shall determine an estimated all-others rate for companies not individually examined. The rate shall be an amount equal to the weighted average of the estimated subsidy rates established for those companies individually examined, excluding any rates that are zero, *de minimis*, or rates based entirely under section 776 of the Act.

In this investigation, as discussed in the Preliminary Decision Memorandum, Commerce calculated individual estimated countervailable subsidy rates for Jiangyin Delian Chemical Co., Ltd. (Delian) and Nantong Botao Chemical Co., Ltd. (Botao) that were not zero, *de minimis*, or based entirely under section 776 of the Act. Therefore, Commerce calculated an all-others rate using a simple average of the individual estimated subsidy rates calculated for Botao and Delian using each company's values for the merchandise under consideration because publicly ranged sales data was unavailable.⁹

⁷ See sections 776(a) and (b) of the Act.

⁸ See Petitioner's Letter, "Certain Corrosion Inhibitors from the People's Republic of China: Petitioner's Request to Align Countervailing Duty Investigation Final Determination with Antidumping Duty Investigation Final Determination," dated June 3, 2020.

⁹ With two respondents under examination, Commerce normally calculates (A) a weighted-average of the estimated subsidy rates calculated for the examined respondents; (B) a simple average of

Preliminary Determination

Commerce preliminarily determines that the following estimated countervailable subsidy rates exist:

Company	Subsidy rate (percent)
Jiangyin Delian Chemical Co., Ltd	92.23
Nantong Botao Chemical Co., Ltd	54.37
CAC Shanghai Chemical Co., Ltd.,	237.19
Jiangyin Gold Fuda Chemical Co., Ltd	237.19
Xinji Xi Chen Re Neng Co., Ltd	237.19
All Others	73.30

Suspension of Liquidation

In accordance with section 703(d)(1)(B) and (d)(2) of the Act, Commerce will direct U.S. Customs and Border Protection (CBP) to suspend liquidation of entries of subject merchandise as described in the scope of the investigation section entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**. Further, pursuant to 19 CFR 351.205(d), Commerce will instruct CBP to require a cash deposit equal to the rates indicated above.

Disclosure

Commerce intends to disclose its calculations and analysis performed to interested parties in this preliminary determination within five days of its public announcement, or if there is no public announcement, within five days of the date of this notice in accordance with 19 CFR 351.224(b).

Verification

As provided in section 782(i)(1) of the Act, Commerce intends to verify the information relied upon in making its final determination.

Public Comment

Case briefs or other written comments may be submitted to the Assistant

the estimated subsidy rates calculated for the examined respondents; and (C) a weighted-average of the estimated subsidy rates calculated for the examined respondents using each company's publicly-ranged U.S. sale quantities for the merchandise under consideration. Commerce then compares (B) and (C) to (A) and selects the rate closest to (A) as the most appropriate rate for all other producers and exporters. See, e.g., *Ball Bearings and Parts Thereof from France, Germany, Italy, Japan, and the United Kingdom: Final Results of Antidumping Duty Administrative Reviews, Final Results of Changed-Circumstances Review, and Revocation of an Order in Part*, 75 FR 53661, 53663 (September 1, 2010). As complete publicly ranged sales data are not available, Commerce based the all-others rate on a simple average of the mandatory respondents' subsidy rates.

Secretary for Enforcement and Compliance no later than seven days after the date on which the last verification report is issued in this investigation. Rebuttal briefs, limited to issues raised in case briefs, may be submitted no later than seven days after the deadline date for case briefs.¹⁰ 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.

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 the U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, 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.

Parties are reminded that briefs and hearing requests are to be filed electronically using ACCESS and that electronically filed documents must be received successfully in their entirety by 5 p.m. Eastern Time on the due date. Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information, until July 17, 2020, unless extended.¹¹

International Trade Commission Notification

In accordance with section 703(f) of the Act, Commerce will notify the International Trade Commission (ITC) of its determination. If the final determination is affirmative, the ITC will determine before the later of 120 days after the date of this preliminary determination or 45 days after the final determination.

¹⁰ See 19 CFR 351.309; see also 19 CFR 351.303 (for general filing requirements); and Temporary Rule Modifying AD/CVD Service Requirements Due to COVID-19; Extension of Effective Period, 85 FR 29615 (May 18, 2020) (*Temporary Rule*).

¹¹ See *Temporary Rule*.

Notification to Interested Parties

This determination is issued and published pursuant to sections 703(f) and 777(i) of the Act and 19 CFR 351.205(c).

Dated: July 6, 2020.

Jeffrey I. Kessler

Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The merchandise covered by this investigation is tolyltriazole and benzotriazole. This includes tolyltriazole and benzotriazole of all grades and forms, including their sodium salt forms. Tolyltriazole is technically known as Tolyltriazole IUPAC 4,5 methyl benzotriazole. It can also be identified as 4,5 methyl benzotriazole, tolyltriazole, TTA, and TTZ.

Benzotriazole is technically known as IUPAC 1,2,3-Benzotriazole. It can also be identified as 1,2,3-Benzotriazole, 1,2-Aminozophenylene, 1H-Benzotriazole, and BTA.

All forms of tolyltriazole and benzotriazole, including but not limited to flakes, granules, pellets, prills, needles, powder, or liquids, are included within the scope of this investigation.

The scope includes tolyltriazole/sodium tolyltriazole and benzotriazole/sodium benzotriazole that are combined or mixed with other products. For such combined products, only the tolyltriazole/sodium tolyltriazole and benzotriazole/sodium benzotriazole component is covered by the scope of this investigation. Tolyltriazole and sodium tolyltriazole that have been combined with other products is included within the scope, regardless of whether the combining occurs in third countries.

Tolyltriazole, sodium tolyltriazole, benzotriazole and sodium benzotriazole that is otherwise subject to this investigation is not excluded when commingled with tolyltriazole, sodium tolyltriazole, benzotriazole, or sodium benzotriazole from sources not subject to this investigation. Only the subject merchandise component of such commingled products is covered by the scope of this investigation.

A combination or mixture is excluded from this investigation if the total tolyltriazole or benzotriazole component of the combination or mixture (regardless of the source or sources) comprises less than 5 percent of the combination or mixture, on a dry weight basis.

Notwithstanding the foregoing language, a tolyltriazole or benzotriazole combination or mixture that is transformed through a chemical reaction into another product, such that, for example, the tolyltriazole or benzotriazole can no longer be separated from the other products through a distillation or other process is excluded from this investigation.

Tolyltriazole has the Chemical Abstracts Service (CAS) registry number 299385-43-1. Tolyltriazole is classified under Harmonized

Tariff Schedule of the United States (HTSUS) subheading 2933.99.8220.

Sodium Tolyltriazole has the CAS registry number 64665-57-2 and is classified under HTSUS subheading 2933.99.8290.

Benzotriazole has the CAS registry number 95-14-7 and is classified under HTSUS subheading 2933.99.8210.

Sodium Benzotriazole has the CAS registry number 15217-42-2. Sodium Benzotriazole is classified under HTSUS subheading 2933.99.8290.

Although the HTSUS subheadings and CAS registry numbers are provided for convenience and customs purposes, the written description of the scope of this investigation is dispositive.

Appendix II

List of Topics Discussed in the Preliminary Decision Memorandum

- I. Summary
- II. Background
- III. Scope Comments
- IV. Scope of the Investigation
- V. Subsidies Valuation
- VI. New Subsidy Allegations
- VII. Use of Facts Otherwise Available and Adverse Inferences
- VIII. Benchmarks
- IX. Analysis of Programs
- X. Calculation of All-Others Rate
- XI. ITC Notification
- XII. Disclosure and Public Comments
- XIII. Verification
- XIV. Recommendation

[FR Doc. 2020-15053 Filed 7-10-20; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-201-847]

Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes From Mexico: Final Results of Antidumping Duty Administrative Review and Final Determination of No Shipments; 2017-2018

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) finds that the producers/exporters subject to this administrative review made sales of subject merchandise at less than normal value during the period of review (POR), September 1, 2017 through August 31, 2018.

DATES: Applicable July 13, 2020.

FOR FURTHER INFORMATION CONTACT: David Crespo or Jacob Garten, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone:

(202) 482-3693 or (202) 482-3342, respectively.

SUPPLEMENTARY INFORMATION:

Background

This review covers 11 producers/exporters of the subject merchandise. Commerce selected two companies, Maquilacero S.A. de C.V. (Maquilacero) and Productos Laminados de Monterrey S.A. de C.V. (Prolamsa) (collectively, the respondents), for individual examination. The producers/exporters not selected for individual examination are listed in the "Final Results of the Review" section of this notice.

On November 18, 2019, Commerce published the *Preliminary Results*.¹ We invited interested parties to comment on the *Preliminary Results*.² On December 18, 2019, Independence Tube Corporation and Southland Tube, Incorporated, both Nucor companies (collectively, domestic parties), and Maquilacero filed case briefs³. On December 23, 2019, the domestic parties, Prolamsa, and Maquilacero all filed rebuttal briefs.⁴ For a description of the events that occurred since the preliminary results, see the Issues and Decision Memorandum.⁵ On February 11, 2020, we postponed the final results by 59 days after the publication of the Preliminary Results, until May 15, 2020.⁶ On April 24, 2020, Commerce tolled all deadlines in administrative

¹ See *Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes from Mexico: Preliminary Results of Antidumping Duty Administrative Review and Preliminary Determination of No Shipments; 2017-2018*, 84 FR 63610 (November 18, 2019) (*Preliminary Results*).

² *Id.*

³ See Domestic Parties' Case Brief, "Heavy-Walled Rectangular Welded Carbon Steel Pipes and Tubes from Mexico: Case Brief and Request to Participate in Hearing if Held," dated December 18, 2019; and Maquilacero's Case Brief, "Heavy Walled Rectangular Welded Carbon Steel Pipes from Mexico: Case Brief of Maquilacero S.A. de C.V.," dated December 18, 2019.

⁴ See Domestic Parties' Rebuttal Brief, "Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes from Mexico: Rebuttal Brief," dated December 23, 2019; Maquilacero's Rebuttal Brief, "Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes from Mexico: Rebuttal Brief," dated December 23, 2020; and Prolamsa's Rebuttal Brief, "Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes from Mexico: Rebuttal Brief and Request to Participate in Hearing, if Held," dated December 23, 2019.

⁵ See Memorandum, "Issues and Decision Memorandum for the Antidumping Duty Administrative Review: Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes from Mexico; 2017-2018," dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

⁶ See Memorandum, "Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes from Mexico: Extension of Deadline for Final Results of Antidumping Duty Administrative Review," dated February 11, 2020.

reviews by 50 days, thereby extending the deadline for these final results until July 6, 2020.⁷

Commerce conducted this administrative review in accordance with section 751 of the Tariff Act of 1930, as amended (the Act).

cope of the Order

The merchandise subject to the order is certain heavy walled rectangular welded steel pipes and tubes of rectangular (including square) cross section, having a nominal wall thickness of not less than 4 mm. The merchandise includes, but is not limited to, the American Society for Testing and Materials (ASTM) A-500, grade B specifications, or comparable domestic or foreign specifications. Included products are those in which: (1) Iron predominates, by weight, over each of the other contained elements; (2) the carbon content is 2 percent or less, by weight; and (3) none of the elements below exceeds the quantity, by weight, respectively indicated:

- 2.50 percent of manganese, or
- 3.30 percent of silicon, or
- 1.50 percent of copper, or
- 1.50 percent of aluminum, or
- 1.25 percent of chromium, or
- 0.30 percent of cobalt, or
- 0.40 percent of lead, or
- 2.0 percent of nickel, or
- 0.30 percent of tungsten, or
- 0.80 percent of molybdenum, or
- 0.10 percent of niobium (also called columbium), or
- 0.30 percent of vanadium, or
- 0.30 percent of zirconium.

The product is currently classified under following Harmonized Tariff Schedule of the United States (HTSUS) item numbers 7306.61.1000. Subject merchandise may also be classified under 7306.61.3000. Although the HTSUS numbers and ASTM specification are provided for convenience and for customs purposes, the written product description remains dispositive. For a full description of the scope, see the Issues and Decision Memorandum.⁸

Analysis of Comments Received

All issues raised in the case and rebuttal briefs are listed in the appendix to this notice and addressed in the Issues and Decision Memorandum. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and

⁷ See Memorandum, “Tolling of Deadlines for Antidumping and Countervailing Duty Administrative Reviews in Response to Operational Adjustments Due to COVID-19,” dated April 24, 2020.

⁸ See Issues and Decision Memorandum.

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 <http://enforcement.trade.gov/frn/index.html>. The signed and electronic versions of the Issues and Decision Memorandum are identical in content.

Determination of No Shipments

As noted in the *Preliminary Results*, we received no shipment claims from two companies involved in this administrative review, Ternium México, S.A. de C.V. (Ternium) and Tuberia Nacional S.A. de C.V. (TUNA). In the *Preliminary Results*, we preliminarily determined that Ternium and TUNA had no reviewable transactions during the POR. We received no comments from interested parties with respect to these claims. Therefore, because the record indicates that these companies did not export subject merchandise to the United States during the POR, we continue to find that Ternium and TUNA had no reviewable transactions during the POR.

Changes Since the Preliminary Results

Based on a review of the record and comments received from interested parties regarding our *Preliminary Results*, we made certain changes to the preliminary weighted-average dumping margins for Maquilacero and Prolamsa, and those companies not selected for individual review.⁹

Final Results of the Review

We are assigning the following weighted-average dumping margins to the firms listed below for the period September 1, 2017 through August 31, 2018:

Producers/exporters	Weighted-average dumping margin (percent)
Maquilacero S.A. de C.V.	4.89
Productos Laminados de Monterrey S.A. de C.V.	7.47
Arco Metal S.A. de C.V.*	6.64
Forza Steel S.A. de C.V.*	6.64
Industrias Monterrey, S.A. de C.V.*	6.64
Perfiles y Herrajes LM S.A. de C.V.*	6.64
PYTCO S.A. de C.V.*	6.64
Regiomontana de Perfiles y Tubos S.A. de C.V.*	6.64
Ternium S.A. de C.V.**

⁹ See Issues and Decision Memorandum.

Producers/exporters	Weighted-average dumping margin (percent)
Tuberia Nacional S.A. de C.V.**
Tuberias Procarsa S.A. de C.V.* ¹⁰	6.64

* Review-Specific Average Rate¹¹
 ** No shipments or sales subject to this review.

We intend to disclose the calculations performed for these final results to parties in this proceeding within five days of the date of publication of this notice, in accordance with 19 CFR 351.224(b).

Assessment Rates

Pursuant to section 751(a)(2)(C) of the Act, and 19 CFR 351.212(b)(1), Commerce has determined, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review.

Where the respondent did not report entered value or reported amounts based on average data, we calculated the entered value in order to calculate the assessment rate. Where either the respondent’s weighted-average dumping margin is zero or *de minimis* within the meaning of 19 CFR 351.106(c)(1), or an importer-specific rate is zero or *de minimis*, we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties. We further will instruct CBP to take into account the “provisional measures deposit cap,” in accordance with 19 CFR 351.212(d). The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by the final results of this review.¹²

Commerce’s “reseller policy” will apply to entries of subject merchandise during the POR produced by companies included in these final results of review for which the reviewed companies did not know that the merchandise they sold to the intermediary (*e.g.*, a reseller, trading company, or exporter) was destined for the United States. In such instances, we will instruct CBP to liquidate unreviewed entries at the all-others rate if there is no rate for the

¹⁰ We incorrectly listed this company as Tuberia Procarsa S.A. de C.V. in the *Preliminary Results*. We have corrected the name for these final results.

¹¹ This rate is based on the rates for the respondents that were selected for individual review, excluding rates that are zero, *de minimis*, or based entirely on facts available. See section 735(c)(5)(A) of the Act.

¹² See section 751(a)(2)(C) of the Act.

intermediate company(ies) involved in the transaction.

For the companies which were not selected for individual review, we will assign an assessment rate based on the average of the cash deposit rates calculated for Maquilacero and Prolamsa.¹³ The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by the final results of this review and for future deposits of estimated duties, where applicable.¹⁴

We intend to issue liquidation instructions to CBP 41 days after publication of the final results of this review.

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of the 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 each specific company listed above will be equal to the weighted-average dumping margin that is established in the final results of this review, except if the rate is less than 0.50 percent and, therefore, *de minimis* within the meaning of 19 CFR 351.106(c)(1), in which case the cash deposit rate will be zero; (2) for previously investigated companies not participating in this review, the cash deposit 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, or the original less-than-fair-value (LTFV) investigation, but the producer is, then the cash deposit rate will be the cash deposit rate established for the most recently completed segment for the producer of the subject merchandise; and (4) the cash deposit rate for all other producers or exporters will continue to be 3.24 percent, the all-others rate established in the LTFV investigation.¹⁵ These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a final reminder to importers of their responsibility

¹³ This rate was calculated as discussed in footnote 10, above.

¹⁴ See section 751(a)(2)(C) of the Act.

¹⁵ See *Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes from the Republic of Korea, Mexico, and the Republic of Turkey: Antidumping Duty Orders*, 81 FR 62865, 62866 (September 13, 2016).

under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Administrative Protective Order

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

We are issuing and publishing this notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(5).

Dated: July 6, 2020.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix—List of Topics Discussed in the Issues and Decision Memorandum

- I. Summary
- II. Background
- III. Margin Calculations
- IV. Discussion of Issues
 - Issues Related to Maquilacero*
 - Comment 1: Ministerial Errors
 - Comment 2: Cost Calculation Methodology
 - Comment 3: Section 232 Duties
 - Comment 4: Affiliated Reseller Purchases
 - Comment 5: Non-Prime Merchandise
 - Comment 6: Scrap Offset
 - Issues Related to Prolamsa*
 - Comment 7: Home Market Level of Trade (LOT) and Constructed Export Price (CEP) Offset
 - Comment 8: Non-Prime Merchandise
 - Comment 9: Overrun Sales
- V. Recommendation

[FR Doc. 2020–15054 Filed 7–10–20; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XA280]

New England Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public hearings.

SUMMARY: The New England Fishery Management Council's is convening several Public Hearings of Draft Amendment 23 to Northeast Multispecies Fishery Management Plan via webinar to consider actions affecting New England fisheries in the exclusive economic zone (EEZ).

Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: These webinars will be held on Wednesday, July 29, 2020; Thursday, July 30, 2020; Tuesday, August 4, 2020; Thursday, August 6, 2020.

ADDRESSES: The meetings will be held via webinar.

All meeting participants and interested parties can register below for each webinar individually.

1. Wednesday, July 29, 2020, from 4–6 p.m. This webinar will be specific to CT and Mid-Atlantic Region, RI and CT/ Mid-Atlantic (NY/NJ/DE/MD/VA/NC)
<https://attendee.gotowebinar.com/register/4552271017165912332>.

Call in information: +1 (562) 247–8422; Access Code: 632–535–527.

2. Thursday, July 30, 2020 from 4–6 p.m.

<https://attendee.gotowebinar.com/register/3530306844985146892>.

Call in information: +1 (415) 930–5321; Access Code: 230–075–756.

3. Tuesday, August 4, 2020 from 4–6 p.m.

<https://attendee.gotowebinar.com/register/1484010152577816332>.

Call in information: +1 (415) 930–5321; Access Code: 587–188–268.

4. Thursday, August 6, 2020 from 4–6 p.m. The Council encourages this webinar be reserved for those without other options to participate. No registration is needed.

<https://global.gotomeeting.com/join/697496061>.

Call in information: +1 (408) 650–3123; Access Code: 697–496–061.

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director,

New England Fishery Management Council; telephone: (978) 465-0492.

SUPPLEMENTARY INFORMATION: *Public comments:* Public comment deadline is August 30, 2020. Mail to Thomas A. Nies, Executive Director, New England Fishery Management Council, 50 Water Street, Mill #2, Newburyport, MA 01950. Mark the outside of the envelope "DEIS for Amendment 23 to the Northeast Multispecies FMP". Comments may also be sent via fax to (978) 465-3116 or submitted via email to comments@nefmc.org with "DEIS for Amendment 23 to the Northeast Multispecies FMP" in the subject line.

Agenda

Council staff will brief the public on Draft Amendment 23 before receiving comments on the amendment. The hearing will begin promptly at the time indicated above. If all attendees who wish to do so have provided their comments prior to the end time indicated, the hearing may conclude early. To the extent possible, the Council may extend hearings beyond the end time indicated above to accommodate all attendees who wish to speak. Scheduling of hearings is ongoing due to the COVID-19 pandemic. If additional hearings are scheduled they will be announced in a separate notice.

Although non-emergency issues not contained on the agenda may come before this Council for discussion, those issues may not be the subject of formal action during these meetings. Council action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency. The public also should be aware that the meeting will be recorded. Consistent with 16 U.S.C. 1852, a copy of the recording is available upon request.

Special Accommodations

These meetings physically accessible to people with disabilities. Requests for sign

language interpretation or other auxiliary aids should be directed to Thomas A. Nies, Executive Director, at (978) 465-0492, at least 5 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: July 7, 2020.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2020-14956 Filed 7-10-20; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648-XA277]

Caribbean Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of a public meeting.

SUMMARY: The Caribbean Fishery Management Council's (Council) Scientific and Statistical Committee (SSC) will hold a two-day public virtual meeting to address the items contained in the tentative agenda included in the **SUPPLEMENTARY INFORMATION.**

DATES: The public virtual meeting will be held on July 27, 2020, from 10 a.m. to 5 p.m., and July 28, 2020, from 10 a.m. to 5 p.m. All meetings will be at Eastern Standard Time.

ADDRESSES: You may join the SSC public virtual meeting (via GoToMeeting) from a computer, tablet or smartphone by entering the following address: <https://www.gotomeet.me/GracielaGarciaMoliner/ssc-virtual-meeting-july-27-28-2020>. You can also dial in using your phone. United States: +1 (224) 501-3412, Access Code: 366-636-421. Join from a video-conferencing room or system. Dial in or type: 67.217.95.2 or inroomlink.goto.com. Meeting ID: 366 636 421. Or dial directly: 366636421@67.217.95.2 or 67.217.95.2##366636421. If you are new to GoToMeeting you can get the app now and be ready when the meeting starts: <https://global.gotomeeting.com/install/366636421>.

In case there are problems with GoToMeeting, and we cannot reconnect via GoToMeeting, the meeting will continue via Google Meet. Join with Google Meet: <https://meet.google.com/iyv-weuo-jth>.

FOR FURTHER INFORMATION CONTACT: Dr. Graciela García-Moliner, Caribbean Fishery Management Council, 270 Muñoz Rivera Avenue, Suite 401, San Juan, Puerto Rico 00918-1903, telephone: (787) 403-8337.

SUPPLEMENTARY INFORMATION: The following items included in the tentative agenda will be discussed:

July 27, 2020, 10 a.m.–10:45 a.m.

—Call to Order
—Adoption of Agenda
—Overview SSC Ecosystem Conceptual Model and Sub-Models

July 27, 2020, 10:45 a.m.–12 p.m.

—Finish the Competing Use of Resources Sub-Model

July 27, 2020, 12 p.m.–1:15 p.m.

—Lunch Break

July 27, 2020, 1:15 p.m.–3 p.m.

—Review all Sub-Models

July 27, 2020, 3 p.m.–3:15 p.m.

—Break

July 27, 2020, 3:15 p.m.–5 p.m.

—What is Missing?
—How to Address Gaps

July 28, 2020, 10 a.m.–12 p.m.

—Finalize Sub-Models
—Review Intra-connections

July 28, 2020, 12 p.m.–1 p.m.

—Lunch Break

July 28, 2020, 1 p.m.–5 p.m.

—Finalize Sub-Models
—Review Interconnections
—Overview Interconnections
—Other Business
—Adjourn

The order of business may be adjusted as necessary to accommodate the completion of agenda items. The meeting will begin on July 27, 2020, at 10 a.m. EST, and will end on July 28, 2020, at 5 p.m. EST. Other than the start time, interested parties should be aware that discussions may start earlier or later than indicated, at the discretion of the Chair. In addition, the meeting may be completed prior to the date established in this notice.

Special Accommodations

Simultaneous interpretation will be provided. Se proveerá interpretación en español. Para interpretación en español puede marcar el siguiente número para entrar en la reunión: US/Canada: llame al +1-888-947-3988, cuando el sistema conteste, entrar el número 1*999996#.

For English interpretation please dial to enter the meeting: US/Canada: call +1-888-947-3988, when the system answers, please enter the number 2*999996#.

For any additional information on this public virtual meeting, please contact Dr. Graciela García-Moliner, Caribbean Fishery Management Council, 270 Muñoz Rivera Avenue, Suite 401, San Juan, Puerto Rico, 00918-1903, telephone: (787) 403-8337.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: July 7, 2020.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2020-14957 Filed 7-10-20; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648-XA279]

Mid-Atlantic Fishery Management Council (MAFMC); Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; public meeting.

SUMMARY: The Mid-Atlantic Fishery Management Council's (Council) Summer Flounder, Scup, and Black Sea Bass Advisory Panel will hold a public webinar meeting, jointly with the Atlantic States Marine Fisheries Commission's Summer Flounder, Scup, and Black Sea Bass Advisory Panel.

DATES: The meeting will be held on Wednesday, July 29, 2020, from 5:30 p.m. until 7:30 p.m.

ADDRESSES: The meeting will be held via webinar, which can be accessed at: <http://mafmc.adobeconnect.com/fsb-ap-jul-2020/>. Meeting audio can also be accessed via telephone by dialing 1-800-832-0736 and entering room number 4472108.

Council address: Mid-Atlantic Fishery Management Council, 800 N State Street, Suite 201, Dover, DE 19901; telephone: (302) 674-2331; www.mafmc.org.

FOR FURTHER INFORMATION CONTACT: Christopher M. Moore, Ph.D., Executive Director, Mid-Atlantic Fishery Management Council, telephone: (302) 526-5255.

SUPPLEMENTARY INFORMATION: The Mid-Atlantic Fishery Management Council's Summer Flounder, Scup, and Black Sea Bass Advisory Panel will meet via webinar jointly with the Atlantic States Marine Fisheries Commission's Summer Flounder, Scup, and Black Sea Bass Advisory Panel. The objectives of this meeting are: (1) Review and comment on the recommendations of the Scientific and Statistical Committee and Monitoring Committee for 2021 specifications for all three species, (2) provide recommendations to the Council and Commission on the February 2021 recreational black sea

bass fishery, and (3) provide recommendations to the Council and Commission on draft alternatives for the Summer Flounder, Scup, and Black Sea Bass Commercial/Recreational Allocation Amendment. Meeting materials will be posted to the Council's website prior to the meeting.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aid should be directed to M. Jan Saunders, (302) 526-5251, at least 5 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: July 7, 2020.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2020-14955 Filed 7-10-20; 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; Conflict of Interest Disclosure for Non-Federal Government Individuals Who Are Candidates To Conduct Peer Reviews Required by the OMB Peer Review Bulletin

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 April 30, 2020, (85 FR 23950) 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: Conflict of Interest Disclosure for Non-Federal Government Individuals Who Are Candidates To Conduct Peer Reviews Required by the OMB Peer Review Bulletin.

OMB Control Number: 0648-0567.

Form Number(s): None.

Type of Request: Regular submission (extension of a current information collection).

Number of Respondents: 321.

Average Hours per Response: 30 minutes for each Conflict of Interest Disclosure form.

Total Annual Burden Hours: 161.

Needs and Uses: This request is for extension of a currently approved collection.

The Office of Management and Budget (OMB) issued government-wide guidance to enhance the practice of peer review of government science documents. OMB's Final Information Quality Bulletin for Peer Review ("Peer Review Bulletin" or PRB) (available at https://obamawhitehouse.archives.gov/omb/memoranda_fy2005_m05-03/) establishes minimum peer review standards for influential scientific information that Federal agencies intend to disseminate.

The Peer Review Bulletin also directs Federal agencies to adopt or adapt the National Academy of Sciences (NAS) policy for evaluating conflicts of interest when selecting peer reviewers who are not Federal government employees (federal employees are subject to Federal ethics requirements). For peer review purposes, the term "conflicts of interest" means any financial or other interest which conflicts with the service of the individual because it could: (1) Significantly impair the individual's objectivity; or (2) create an unfair competitive advantage for any person or organization. NOAA has adapted the NAS policy and developed two confidential conflict disclosure forms which the agency will use to examine prospective reviewers' potential financial conflicts and other interests that could impair objectivity or create an unfair advantage. One form is for peer reviewers of studies related to government regulation and the other form is for all other influential scientific information subject to the Peer Review Bulletin. In addition, the latter form has been adapted by NOAA's Office of Oceanic and Atmospheric Research for potential reviewers of scientific laboratories.

The forms include questions about employment as well as investment and property interests and research funding. Both forms also require the submission of curriculum vitae. NOAA is seeking to collect this information from potential peer reviewers who are not government employees when conducting a peer review pursuant to the PRB. The information collected in the conflict of interest disclosure is essential to

NOAA's compliance with the OMB PRB, and helps to ensure that government studies are reviewed by independent, impartial peer reviewers.

Affected Public: Individuals or households.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

Legal Authority:

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 0648–0567.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2020–15038 Filed 7–10–20; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2020–OS–0066]

Proposed Collection; Comment Request

AGENCY: Federal Voting Assistance Program, Defense Department (DoD).

ACTION: Information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995*, the Federal Voting Assistance Program announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by September 11, 2020.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Mail: DoD cannot receive written comments at this time due to the COVID–19 pandemic. Comments should be sent electronically to the docket listed above.

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

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please contact the Office of Information Management, DoD, at whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil, ATTN Ms. Angela James, or call 571–372–7574.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and Omb Number: Election Administration and Voting Survey (EAVS) Section B Data Standard (ESB Data Standard); OMB Control Number 0704–FVAP.

Needs and Uses: The President of the United States designated the Secretary of Defense to administer the Uniformed and Overseas Citizens Absentee Voting Act (UOCAVA) As Modified by the Military and Overseas Voting Empowerment Act, 52 United States Code (U.S.C.) 20301. UOCAVA is the principal enabling statute that grants authority for the Department of Defense (DoD) to facilitate absentee voting amongst members of the Uniformed Services and Merchant Marine, their eligible family members, and all citizens residing outside the United States who are absent from the United States. The 1988 Executive Order (E.O.) 12642 names the Secretary of Defense as the "Presidential designee" for administering UOCAVA. In the Department of Defense Instruction (DoDI) 1000.04, Federal Voting Assistance Program (FVAP), the Secretary of Defense delegated UOCAVA-related responsibilities first to the Under Secretary of Defense for

Personnel and Readiness (USD[P&R]), and then, in turn, to the FVAP Director. The DoDI 1000.04 also updates the policy and responsibilities for FVAP under E.O. 12642.

The Military and Overseas Voter Empowerment (MOVE) Act of 2009 enacted key reforms to the absentee voting process for military and overseas voters. These reforms include the transmission of balloting materials no later than 45 days prior to each federal election. Additionally, each state must offer military and overseas voters an opportunity to receive balloting materials electronically. Sections 52 U.S.C. 20301 (b [6,11]) and 20308 (b [1]) require FVAP to provide a report to the President and the Congress on program effectiveness and conduct a statistical analysis on UOCAVA voter participation. These sections also state that FVAP shall work with the United States Election Assistance Commission (EAC) and the chief State election official of each State to develop standards for States to report data on the number of absentee ballots transmitted and received, and that FVAP is to store the data collected. In order to evaluate the MOVE Act's reforms and perform the actions prescribed in 52 U.S.C. 20301 (b [6,11]) and 20308 (b [1]), FVAP requires transaction-level data that can associate specific UOCAVA ballot business process transactions with the ultimate outcome on whether the ballot was received and accepted for counting in each Federal election.

Affected Public: Individuals or Households.

Annual Burden Hours: 69.

Number of Respondents: 827.

Responses per Respondent: 1.

Annual Responses: 827.

Average Burden per Response: 5 minutes.

Frequency: Semi-Annually.

To help better assist UOCAVA voters, FVAP and the Council of State Governments worked to refine a transformative new data schema called the Election Administration and Voting Survey (EAVS) Section B (ESB) Data Standard. The ESB Data Standard builds on other data standardization efforts and allows FVAP to analyze the three key parts of the voting process: (1) Ballot request; (2) ballot transmission; and (3) ballot return.

The ESB Data Standard collects transactional data from the absentee voter's experience in the election process that, when aggregated, align to the post-election survey questions administered by the EAC's Administration and Voting Survey (EAVS) data specifically focused on administration of UOCAVA. To that

end, under FVAP's guidance, states now have the option of making transactional-level data on UOCAVA ballots available through the ESB Data Standard, and the Council of State Governments is assisting with securing standardized feeds of these transactional data from members of the Overseas Voting Initiative.

This standard captures data from state databases, a process that has the advantage of more accurately assessing when ballot transactions occurred and whether ballot requests and returns were returned. The EAVS survey, as administered by the EAC, aggregates totals at the state and jurisdiction levels on ballot receipt and transmission time, but this blurs the effects experienced by voters into a single statewide estimate. Further, these data do not isolate how much timing and transmission type can influence a successful voter transaction in the process or contrast the impacts of these across two differing populations, the overseas citizen versus the active duty military voter. The ESB Data Standard is the first approach of its kind to analyze administrative data at the transactional level and attempt to identify drivers for UOCAVA voter success.

FVAP intends to leverage the momentum created from the ESB Data Standard Analysis to secure greater levels of implementation across jurisdictions with major populations of UOCAVA voters. Doing so will drastically reduce the burden on jurisdictions from the EAVS Section B data collection to only collecting high level metrics as points of validation for the ESB Data Standard.

Dated: July 8, 2020.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2020-15082 Filed 7-10-20; 8:45 am]

BILLING CODE 5001-06-P

DEPARTMENT OF DEFENSE

Office of the Secretary

Defense Health Board; Notice of Federal Advisory Committee Meeting

AGENCY: Under Secretary of Defense for Personnel and Readiness, Department of Defense (DoD).

ACTION: Notice of Federal Advisory Committee meeting.

SUMMARY: The DoD is publishing this notice to announce that the following Federal Advisory Committee meeting of the Defense Health Board (DHB) will take place.

DATES: Open to the public Friday, August 7, 2020 from 1:00 p.m. to 5:15 p.m.

ADDRESSES: The meeting will be held by videoconference/teleconference. Participant access information will be provided after registering. (Pre-meeting registration is required. See guidance in **SUPPLEMENTARY INFORMATION**, "Meeting Accessibility.")

FOR FURTHER INFORMATION CONTACT:

CAPT Gregory H. Gorman, U.S. Navy, 703-275-6060 (Voice), 703-275-6064 (Facsimile), gregory.h.gorman.mil@mail.mil (Email). Mailing address is 7700 Arlington Boulevard, Suite 5101, Falls Church, Virginia 22042. Website: <http://www.health.mil/dhb>. The most up-to-date changes to the meeting agenda can be found on the website.

SUPPLEMENTARY INFORMATION: This meeting is being held under the provisions of the Federal Advisory Committee Act (FACA) (5 U.S.C., Appendix), the Government in the Sunshine Act (5 U.S.C. 552b), and 41 CFR 102-3.140 and 102-3.150.

Availability of Materials for the Meeting: Additional information, including the agenda, is available at the DHB website, <http://www.health.mil/dhb>. A copy of the agenda or any updates to the agenda for the August 7, 2020 meeting will be available on the DHB website. Any other materials presented in the meeting may be obtained at the meeting.

Purpose of the Meeting: The DHB provides independent advice and recommendations to maximize the safety and quality of, as well as access to, health care for DoD health care beneficiaries. The purpose of the meeting is to provide progress updates on specific taskings before the DHB. In addition, the DHB will receive an information briefing on current issues related to military medicine.

Agenda: The DHB anticipates receiving a decision briefing from the Neurological/Behavioral Health Subcommittee on the Examination of Mental Health Accession Screening: Predictive Value of Current Measures and Processes review, a TRICARE briefing, and a progress update from the Health Care Delivery Subcommittee on the Active Duty Women's Health Care Services review. Any changes to the agenda can be found at the link provided in this **SUPPLEMENTARY INFORMATION** section.

Meeting Accessibility: Pursuant to 5 U.S.C. 552b and 41 CFR 102-3.140 through 102-3.165, this meeting is open to the public from 1:00 p.m. to 5:15 p.m. on August 7, 2020. The meeting will be held by videoconference/teleconference.

The number of participants is limited and is on a first-come basis. All members of the public who wish to participate must register by emailing their name, rank/title, and organization/company to dha.ncr.dhb.mbx.defense-health-board@mail.mil or by contacting Ms. Michele Porter at (703) 275-6012 no later than Friday, July 31, 2020. Once registered, the web address and audio number will be provided.

Special Accommodations: Individuals requiring special accommodations to access the public meeting should contact Ms. Michele Porter at least five (5) business days prior to the meeting so that appropriate arrangements can be made.

Written Statements: Any member of the public wishing to provide comments to the DHB related to its current taskings or mission may do so at any time in accordance with section 10(a)(3) of the Federal Advisory Committee Act, 41 CFR 102-3.105(j) and 102-3.140, and the procedures described in this notice. Written statements may be submitted to the DHB Designated Federal Officer (DFO), Captain Gorman, at gregory.h.gorman.mil@mail.mil.

Supporting documentation may also be included, to establish the appropriate historical context and to provide any necessary background information. If the written statement is not received at least five (5) business days prior to the meeting, the DFO may choose to postpone consideration of the statement until the next open meeting. The DFO will review all timely submissions with the DHB President and ensure they are provided to members of the DHB before the meeting that is subject to this notice. After reviewing the written comments, the President and the DFO may choose to invite the submitter to orally present their issue during an open portion of this meeting or at a future meeting.

Dated: July 7, 2020.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2020-14986 Filed 7-10-20; 8:45 am]

BILLING CODE 5001-06-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG20-205-000.

Applicants: Sanford Airport Solar, LLC.

Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Sanford Airport Solar, LLC.

Filed Date: 7/6/20.

Accession Number: 20200706–5175.

Comments Due: 5 p.m. ET 7/27/20.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER20–1395–000.

Applicants: ND OTM LLC.

Description: Third Supplement to March 26, 2020 ND OTM LLC tariff filing.

Filed Date: 7/1/20.

Accession Number: 20200701–5527.

Comments Due: 5 p.m. ET 7/22/20.

Docket Numbers: ER20–1905–001.

Applicants: Southwest Power Pool, Inc.

Description: Tariff Amendment: 3651 Arkansas Electric Cooperative Corp NITSA NOA Amended to be effective 7/1/2020.

Filed Date: 7/7/20.

Accession Number: 20200707–5060.

Comments Due: 5 p.m. ET 7/28/20.

Docket Numbers: ER20–2156–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: Amendment to June 26, 2020 Request for Waiver Tariff Provisions, et al. of Midcontinent Independent System Operator, Inc.

Filed Date: 7/2/20.

Accession Number: 20200702–5338.

Comments Due: 5 p.m. ET 7/7/20.

Docket Numbers: ER20–2330–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: Compliance filing: 2020–07–07_SA 2925 ITC Midwest-MEC 1st Rev GIA (J344) to be effective 6/30/2020.

Filed Date: 7/7/20.

Accession Number: 20200707–5027.

Comments Due: 5 p.m. ET 7/28/20.

Docket Numbers: ER20–2331–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: Compliance filing: 2020–07–07_SA 3511 ITC Midwest-MEC FSA (J344) to be effective 9/6/2020.

Filed Date: 7/7/20.

Accession Number: 20200707–5029.

Comments Due: 5 p.m. ET 7/28/20.

Docket Numbers: ER20–2332–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: Compliance filing: 2020–07–07_SA 3052 ITC–IPL 1st Rev FCA (J438) to be effective 6/30/2020.

Filed Date: 7/7/20.

Accession Number: 20200707–5032.

Comments Due: 5 p.m. ET 7/28/20.

Docket Numbers: ER20–2333–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: Compliance filing: 2020–07–07_SA 3523 ITC–IPL FSA (J438) to be effective 6/30/2020.

Filed Date: 7/7/20.

Accession Number: 20200707–5037.

Comments Due: 5 p.m. ET 7/28/20.

Docket Numbers: ER20–2334–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: Revisions to Establish Zonal Planning Criteria to be effective 9/7/2020.

Filed Date: 7/7/20.

Accession Number: 20200707–5046.

Comments Due: 5 p.m. ET 7/28/20.

Docket Numbers: ER20–2335–000.

Applicants: Idaho Power Company.

Description: Tariff Cancellation: Cancellation of SA 358 to be effective 9/21/2020.

Filed Date: 7/7/20.

Accession Number: 20200707–5118.

Comments Due: 5 p.m. ET 7/28/20.

Docket Numbers: ER20–2336–000.

Applicants: Idaho Power Company.

Description: Tariff Cancellation: Cancellation of SA 365 to be effective 9/7/2020.

Filed Date: 7/7/20.

Accession Number: 20200707–5120.

Comments Due: 5 p.m. ET 7/28/20.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES20–48–000.

Applicants: Ameren Illinois Company.

Description: Application Under Section 204 of the Federal Power Act for Authorization to Issue Securities of Ameren Illinois Company.

Filed Date: 7/6/20.

Accession Number: 20200706–5206.

Comments Due: 5 p.m. ET 7/27/20.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 7, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–15041 Filed 7–10–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 553–238]

City of Seattle, Washington; 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. *Application Type:* Non-capacity License Amendment.

b. *Project No:* 553–238.

c. *Date Filed:* June 11, 2020.

d. *Applicant:* City of Seattle, Washington.

e. *Name of Project:* Skagit River Hydroelectric Project.

f. *Location:* Skagit River, in Whatcom, Snohomish, and Skagit Counties, Washington.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791a–825r.

h. *Applicant Contact:* Shelly Adams, Project Environmental Lead, Seattle City Light, 700 Fifth Avenue, Suite 3200, Seattle, Washington, 98124–4023, (206) 684–3117, shelly.adams@seattle.gov.

i. *FERC Contact:* Mark Ivy, (202) 502–6156, mark.ivy@ferc.gov

j. *Deadline for filing comments, motions to intervene, and protests:* August 6, 2020.

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/docs-filing/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). The first page of any filing should include docket number P–553–238. Comments emailed to Commission staff are not considered part of the Commission record.

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 whose name appears 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:* City of Seattle is requesting Commission approval to replace an existing fuel dock on Diablo Lake with a new fuel dock. The applicant proposes to remove the existing 234-square-foot wooden fuel float, ten-foot-tall access ladder, and onshore fuel dispenser, and replace them with a 600-square-foot float (made of wooden beams, fiberglass grating deck and steel pontoon floats), a gangway, and a fuel dispenser on the float. The existing failing riprap bulkhead on the shoreline at the proposed fuel dock location (25–80 feet northeast of the existing fuel dock) would be replaced with a prefabricated crib wall.

l. *Locations of the Application:* 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 document 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) 208–3673 or TYY, (202) 502–8659. Agencies may obtain copies of the application directly from the applicant.

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, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214, respectively. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the

proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Documents:* Any filing must (1) bear in all capital letters the title "COMMENTS", "PROTEST", or "MOTION TO INTERVENE" as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person commenting, protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis. Any filing made by an intervenor 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: July 7, 2020.

Kimberly D. Bose,

Secretary.

[FR Doc. 2020–15021 Filed 7–10–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2299–082; Project No. 14581–002]

Turlock Irrigation District; Modesto Irrigation District; Notice of Availability of the Final Environmental Impact Statement for the Don Pedro and La Grange Projects

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission) regulations, 18 CFR part 380, the Office of Energy Projects has reviewed the applications for new license for the Don Pedro Project (FERC No. 2299) and for an original license for the La Grange Project (FERC No. 14581) and has prepared a final environmental impact statement (EIS) for the projects. The Don Pedro Project is located on the Tuolumne River in Tuolumne County, California. It occupies 4,802 acres of federal land administered by the U.S. Department of Interior, Bureau of Land Management. The La Grange Project is located on the Tuolumne River immediately downstream of the Don Pedro Project in Stanislaus and Tuolumne Counties, California. It

occupies 14 acres of federal land administered by BLM.

The final EIS contains staff's evaluations of the applicant's proposals and the alternatives for relicensing the Don Pedro Project and licensing the La Grange Project. The final EIS documents the views of governmental agencies, non-governmental organizations, affected Indian tribes, the public, the license applicants, and Commission staff.

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://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 the Federal Energy Regulatory Commission at FERCOnlineSupport@ferc.gov or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the "eFiling" link at <http://www.ferc.gov>. Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

Dated: July 7, 2020.

Kimberly D. Bose,

Secretary.

[FR Doc. 2020–15023 Filed 7–10–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY**Federal Energy Regulatory Commission**

[Docket Nos. CP20–68–000; CP20–70–000]

Enable Gas Transmission, LLC; Enable Gulf Run Transmission, LLC; Notice of Revised Schedule for Environmental Review of The Gulf Run and Line CP Modifications Project

This notice identifies the Federal Energy Regulatory Commission staff's revised schedule for the completion of the environmental assessment (EA) for Enable Gas Transmission, LLC and Enable Gulf Run Transmission, LLC (collectively, Enable) Gulf Run and Line CP Modifications Project. The first notice of schedule, issued on April 28, 2020, identified July 31, 2020 as the EA issuance date. However, Enable filed supplemental information on June 23, 2020 related to certain modifications to its project. In addition, the U.S. Army Corps of Engineers (USACE) recently requested cooperating agency status for the project to ensure that the EA addresses the USACE National Environmental Policy Act requirements for processing Enable's June 4, 2020 USACE application for a Clean Water Act Section 404 Individual Permit for the project. This change is in response to the court vacatur, in April 2020, of the Nationwide Permit 12 Program. As a result, Commission staff has revised the schedule for issuance of the EA.

Schedule for Environmental Review

Issuance of the EA October 29, 2020
90-day Federal Authorization Decision
Deadline January 27, 2021

If a schedule change becomes necessary, an additional notice will be provided so that the relevant agencies are kept informed of the project's progress.

Additional Information

In order to receive notification of the issuance of the EA and to keep track of all formal issuances and submittals in specific dockets, the Commission offers a free service called eSubscription. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. Go to <https://www.ferc.gov/ferc-online/overview> to register for eSubscription.

Additional information about the Project is available from the Commission's Office of External Affairs at (866) 208–FERC or on the FERC website (www.ferc.gov). Using the

eLibrary link, enter the "Docket Number" excluding the last three digits (i.e., CP20–68 or –70), select a date range, and follow the instructions. For assistance with access to eLibrary, the helpline can be reached at (866) 208–3676, TTY (202) 502–8659, or at FERCOnlineSupport@ferc.gov. The eLibrary link on the FERC website also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rule makings.

Dated: July 7, 2020.

Kimberly D. Bose,
Secretary.

[FR Doc. 2020–15025 Filed 7–10–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY**Federal Energy Regulatory Commission**

[Project No. 12532–006]

Pine Creek Mine, LLC; Notice of Petition for Declaratory Order

Take notice that on June 3, 2020, pursuant to Rule 207 of the Federal Energy Regulatory Commission's Rules of Practice and Procedure, 18 CFR 385.207(2019), Pine Creek Mine, LLC (PCM or Petitioner), filed a petition for declaratory order (Petition) requesting that the Commission issue a declaratory order finding that the California State Water Resources Control Board has waived its authority to issue a certification for the Pine Creek Mine Tunnel Hydroelectric Project under section 401 of the Clean Water Act, 33 U.S.C. 1341(a)(1), as more fully explained in the petition.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. Anyone filing a motion to intervene or protest must serve a copy of that document on the Petitioner.

Any person wishing to comment on PCM's petition may do so.¹ The

¹ PCM's request is part of its licensing proceeding in Project No. 12532–006. Thus, any person that intervened in the relicensing proceeding is already a party. Generally, the filing of a petition for a

deadline for filing comments is 30 days from the issuance of this notice. The Commission encourages electronic submission of comments in lieu of paper using the "eFiling" link at <http://www.ferc.gov>. Persons unable to file electronically should send comments to the following address: Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852. Be sure to reference the project docket number (P–12532–006) with your submission.

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 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, (866) 208–3676 or TYY, (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on August 6, 2020.

Dated: July 7, 2020.

Kimberly D. Bose,
Secretary.

[FR Doc. 2020–15024 Filed 7–10–20; 8:45 am]

BILLING CODE 6717–01–P

declaratory order involving an issue arising from the relicensing proceeding does not trigger a new opportunity to intervene. Accordingly, at this point in this proceeding, any person seeking to become a party to the proceeding must file a motion to intervene out-of-time pursuant to Rule 214(b)(3) and (d) of the Commission's Rules of Practice and Procedures that provides justification by reference to the factors set forth in Rule 214(d). The Commission may limit a late intervenor's participation to the issues raised in the petition for declaratory order. 18 CFR 385.214(d)(3)(i).

DEPARTMENT OF ENERGY**Federal Energy Regulatory Commission**

[Project No. 2206–089]

Duke Energy Carolinas, LLC; Notice of Availability of Environmental Assessment

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission (Commission) regulations, 18 CFR part 380 (Order No. 486, 52 FR 47897), the Office of Energy Projects has reviewed an application submitted by Duke Energy Carolinas, LLC (licensee) to grant easements to the Town of Norwood, North Carolina and Union County, North Carolina (co-applicants) to allow the use of Yadkin-Pee Dee Hydroelectric Project No. 2206, project lands and waters on Lake Tillery for municipal water supply. The Yadkin Pee-Dee Project is located on the Yadkin and Pee Dee Rivers in Anson, Montgomery, Richmond, and Stanly counties, North Carolina. The project does not occupy federal land.

An Environmental Assessment (EA) has been prepared as part of Commission staff's review of the proposal. In the application, the licensee proposes to grant easements to the co-applicants to construct and operate a raw water intake facility (facility) on Lake Tillery, one of the project's two storage reservoir. The easement area would total 0.34 acres of land within the project boundary. The intake structure and intake piping would require a 0.25 acre easement and an adjacent boathouse and pier for use in servicing the withdrawal facility would require an additional 0.09 acre easement. The facility would withdraw a maximum annual average of 19.6 million gallons per day (MGD) and an instantaneous maximum of 49.0 MGD. A maximum monthly average of up to 23.3 MGD of the water withdrawn would be transferred out of the Yadkin River Basin into the Rocky River Basin, for consumptive use. A portion of the transferred water would be returned via treated wastewater effluent back through the Rocky River into the Pee Dee River approximately five miles downstream from the Lake Tillery Dam.

The EA contains Commission staff's analysis of the potential environmental impacts of the construction and operation of the facility and the proposed water withdrawal volume and concludes that approval of the proposal would not constitute a major federal action significantly affecting the quality of the human environment.

The EA may be viewed on the Commission's website at <http://www.ferc.gov> using the "eLibrary" link. Enter the docket number (P–2206) in the docket number field to access the document. For assistance, contact FERC Online Support at FERCOnlineSupport@ferc.gov or toll-free at (866) 208–3372 or for TTY, (202) 502–8659.

For further information, contact Robert Ballantine at (202) 502–6289 or by email at robert.ballantine@ferc.gov.

Dated: July 7, 2020.

Kimberly D. Bose,
Secretary.

[FR Doc. 2020–15022 Filed 7–10–20; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2020–0351; FRL–10011–83–OAR]

Ozone Transport Commission; Recommendation That EPA Require Daily Limits for Emissions of Nitrogen Oxides from Certain Sources in Pennsylvania

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability and public hearing.

SUMMARY: The Environmental Protection Agency (EPA) is announcing that on June 8, 2020, the Ozone Transport Commission (OTC) submitted a recommendation to EPA for additional control measures at certain coal-fired electricity generating units (EGUs) in Pennsylvania. Specifically, the OTC has recommended that EPA require Pennsylvania to revise the Pennsylvania State Implementation Plan (SIP) to include additional control measures which would establish daily nitrogen oxides (NO_x) emission limits for all coal-fired EGUs with already-installed selective catalytic reduction (SCR) or selective non-catalytic reduction (SNCR) control technology to ensure that these technologies are optimized to minimize NO_x emissions each day of the ozone season. EPA is also announcing a public hearing on the recommendation as discussed under **DATES** below. EPA is commencing a review of the recommendation to determine whether to approve, disapprove, or partially approve and partially disapprove it. Prior to the public hearing, EPA plans to publish another document in the **Federal Register** providing further discussion of the recommendation and

the framework the Agency intends to apply in reaching a decision.

DATES: EPA will hold a virtual public hearing within 90 days of the OTC recommendation or by September 4, 2020. Further information on the date and time of the virtual public hearing will be available at <https://www.epa.gov/interstate-air-pollution-transport/ozone-transport-commission-otc-section-184c-petition>.

ADDRESSES: Materials related to this action, including the recommendation and supporting materials submitted to EPA by the OTC, can be viewed online at [regulations.gov](https://www.epa.gov/regulations.gov) under Docket No. EPA–HQ–OAR–2020–0351. To reduce the risk of COVID–19 transmission, the EPA Docket Center and Reading Room is closed to the public with limited exceptions. Visitors must complete docket material requests in advance and then make an appointment to retrieve the material. Visitors will be allowed entrance to the Reading Room by appointment only, and no walk-ins will be allowed. Additional information on the exception procedures, location and hours of the Reading Room is available at <https://www.epa.gov/dockets>. Please call or email the contact listed in **FOR FURTHER INFORMATION CONTACT** if you need alternative access to material indexed but not electronically available in the docket at [regulations.gov](https://www.epa.gov/regulations.gov).

FOR FURTHER INFORMATION CONTACT: Beth Murray, Clean Air Markets Division, Office of Atmospheric Programs, Office of Air and Radiation, Environmental Protection Agency, 202–343–9115, murray.beth@epa.gov.

SUPPLEMENTARY INFORMATION: Ground-level ozone is a secondary air pollutant created by chemical reactions between the ozone precursor pollutants NO_x and volatile organic compounds in the presence of sunlight. Precursor pollutant emissions can be transported downwind directly or, after transformation in the atmosphere, as ozone. Studies have established that ozone formation, atmospheric residence, and transport can occur on a regional scale (*i.e.*, across hundreds of miles) over much of the eastern U.S.¹ Starting more than two decades ago, EPA has issued multiple rules requiring reductions in NO_x emissions to address the interstate transport of NO_x and ozone, including the NO_x SIP Call, 63 FR 57356 (October 27, 1998), the Clean Air Interstate Rule (CAIR), 70 FR 25162 (May 12, 2005), the Cross-State Air

¹ For example, Bergin, M.S. et al. (2007). Regional air quality: Local and interstate impacts of NO_x and SO₂ emissions on ozone and fine particulate matter in the eastern United States. *Environmental Sci. & Tech.* 41: 4677–4689.

Pollution Rule (CSAPR), 76 FR 48208 (August 8, 2011), and the CSAPR Update, 81 FR 74504 (October 26, 2016). These actions were all taken under the authority of section 110(a)(2)(D)(i)(I) of the Clean Air Act (CAA or the Act), often referred to as the “good neighbor provision.”

The Ozone Transport Region (OTR) was established by operation of law under CAA section 184 and comprises the states of Connecticut, Delaware, Maine, Massachusetts, Maryland, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, and Vermont, the District of Columbia, and the portion of Virginia that is within the Consolidated Metropolitan Statistical Areas that includes the District of Columbia. Congress established the OTR in the 1990 Clean Air Act Amendments based on the recognition that the transport of ozone and ozone precursors throughout the region may render the states’ attainment strategies interdependent.

Under section 184(a), the Administrator established a commission for the OTR, the OTC, consisting of the Governor of each state or their designees, the Administrator or their designee, the Regional Administrators for the EPA regional offices affected (or the Administrator’s designees), and an air pollution control official representing each state in the region, appointed by the Governor. Section 184(b) sets forth certain control measures that OTR states are required to include in their SIPs.

Section 184(c) specifies a procedure for the OTC to develop recommendations for additional control measures to be applied within all or a part of the OTR if the OTC determines that such measures are necessary to bring any area in the OTR into attainment for ozone by the applicable attainment deadlines. Section 184(c)(1) provides that:

Upon petition of any states within a transport region for ozone, and based on a majority vote of the Governors on the Commission (or their designees), the Commission may, after notice and opportunity for public comment, develop recommendations for additional control measures to be applied within all or a part of such transport region if the Commission determines such measures are necessary to bring any area in such region into attainment by the dates provided by [subpart II of part D of CAA title I].

Section 184(c) also lays out procedures the Administrator is to follow in responding to recommendations from the OTC. Upon receipt of the recommendations, the Administrator is to publish a **Federal**

Register notice stating that the recommendations are available and providing an opportunity for a public hearing within 90 days. The Administrator is also to “commence a review of the recommendations to determine whether the control measures in the recommendations are necessary to bring any area in such region into attainment by the dates provided by [subpart II] and are otherwise consistent with [the Act].” Finally, in undertaking the review, the Administrator is to consult with members of the OTC and is to consider the data, views, and comments received pursuant to the public hearing.

Last, sections 184(c)(4) and (5) govern EPA’s response to the OTC recommendations. The Administrator is to determine whether to approve, disapprove, or partially approve and partially disapprove the recommendations within nine months of receipt. For any disapproval, the Administrator is to specify:

(i) Why any disapproved additional control measures are not necessary to bring any area in such region into attainment by the dates provided by [subpart II] or are otherwise not consistent with the Act; and

(ii) Recommendations concerning equal or more effective actions that could be taken by the commission to conform the disapproved portion of the recommendations to the requirements of [section 184].

Section 184(c)(5) provides that, upon approval or partial approval of any recommendations, the Administrator is to issue to each state in the OTR to which an approved requirement applies a finding under section 110(k)(5) that the SIP for that state is inadequate to meet the requirements of section 110(a)(2)(D). Section 110(a)(2)(D) provides, in pertinent part, that each state’s SIP shall contain adequate provisions:

(i) Prohibiting, consistent with the provisions of [CAA title I], any source or other type of emissions activity within the state from emitting any air pollutant in amounts which will—

(I) Contribute significantly to nonattainment in, or interfere with maintenance by, any other state with respect to any national primary or secondary ambient air quality standard [NAAQS].

Under section 184(c)(5), the Administrator’s finding of inadequacy under section 110(a)(2)(D) is to require that each affected state revise its SIP to include the approved additional control measures within one year after the finding is issued.

In 2015, EPA revised the NAAQS for ozone to 70 parts per billion (ppb). 80 FR 65292 (October 28, 2015). In 2018, EPA designated certain areas as

nonattainment with respect to this NAAQS and identified each area’s classification according to the severity of its air quality problems. 83 FR 25776 (June 4, 2018). Five areas within the OTR were designated as nonattainment: Baltimore, MD; Greater Connecticut, CT; Philadelphia-Wilmington-Atlantic City, PA–NJ–MD–DE; Washington, DC–MD–VA; and New York-Northern New Jersey-Long Island, NY–NJ–CT. *Id.* The first four of these areas were classified as Marginal and the fifth area was classified as Moderate. *Id.* The attainment deadlines for the Marginal and Moderate areas are three and six years after the effective date of their nonattainment designations, or August 3, 2021 and August 3, 2024, respectively. 83 FR 10376 (March 9, 2018).

On May 30, 2019, Maryland petitioned the OTC to adopt recommendations calling for additional control measures to be applied within part of the OTR. The Maryland petition asserted that daily limits on NO_x emissions from coal-fired EGUs in Pennsylvania are necessary to bring areas in the OTR into attainment by the dates mandated by the CAA. On June 26, 2019, the OTC voted to proceed with the initial steps associated with the CAA Section 184(c) recommendation process, including analyzing recent operations of coal-fired EGUs in Pennsylvania. The OTC held a public hearing on August 16, 2019 to receive comment on Maryland’s petition. After considering the comments, on October 4, 2019, the OTC voted to evaluate a modified recommendation that Pennsylvania adopt daily emissions limits for certain coal-fired EGUs at least as stringent as those in Delaware, Maryland, or New Jersey. The OTC held a second hearing on November 21, 2019, to receive comment on its modified recommendation. Finally, at its meeting on June 3, 2020, a majority of the OTC’s voting members voted to recommend that EPA require Pennsylvania to revise its SIP to include NO_x limits for coal-fired EGUs with SCR and SNCR as stringent as the limits in Delaware, Maryland, or New Jersey to ensure that the controls are operated optimally each day of the ozone season. The OTC members voting in favor of the recommendation were Connecticut, Delaware, Maryland, Massachusetts, New Hampshire, New Jersey, Rhode Island, Vermont, and the District of Columbia. Pennsylvania and Virginia voted against the recommendation, and Maine and New York abstained.

The OTC’s recommendation contains the following specific elements:

(1) That EPA require Pennsylvania to revise the Pennsylvania SIP to include additional control measures to establish daily NO_x emission limits for all coal-fired EGUs with already-installed SCR or SNCR control technology to ensure that these technologies are optimized to minimize NO_x emissions each day of the ozone season.

(2) That these requirements must be as stringent as any one of three rules adopted by Delaware, Maryland, and New Jersey that establish daily limits designed to optimize the use of SCR and SNCR control technologies to minimize NO_x emissions each day of the ozone season.

(3) That EPA require Pennsylvania to adopt and implement daily NO_x limits as expeditiously as practicable in a timeframe to help downwind OTC states attain the 2015 ozone standard by the dates required in the Act.

(4) That Pennsylvania implement these requirements in time to reduce ozone levels during the summers of 2020 and 2021, because the recommendation does not involve the purchase or installation of new control technologies.

As required by the Act, EPA will hold a public hearing on the OTC's recommendation and will undertake consultations with the affected states before reaching a decision on whether to approve, disapprove, or partially approve and partially disapprove the OTC's recommendation. The Agency also plans to publish another **Federal Register** notice prior to the date of the public hearing in order to provide further discussion of the OTC's recommendation and the framework the Agency intends to apply in reaching a decision.

Dated: July 7, 2020.

Hans Christopher Grundler,

Director, Office of Atmospheric Programs.

[FR Doc. 2020-15005 Filed 7-10-20; 8:45 am]

BILLING CODE 6560-50-P

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

Agency Information Collection Activities; Comment Request

AGENCY: Equal Employment Opportunity Commission.

ACTION: Final notice of information collection under review; ADEA waivers.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (PRA), the Equal Employment Opportunity Commission (EEOC or Commission) gives notice that it has

submitted to the Office of Management and Budget (OMB) a request for extension without change of the information collection described below. No public comments were received in response to the EEOC's May 5, 2020 60 day notice soliciting comments on the proposed extension of this collection.

DATES: Written comments on this notice must be submitted on or before August 12, 2020.

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 "Currently under 30-day Review—Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT:

Kathleen Oram, Assistant Legal Counsel, (202) 663-4668, or Savannah Marion Felton, Senior Attorney, (202) 663-4909, Office of Legal Counsel, 131 M Street NE, Washington, DC 20507. Requests for this notice in an alternative format should be made to the Office of Communications and Legislative Affairs at 1-800-669-4000 (voice), 1-800-669-6820 (TTY), or 1-800-234-5122 (ASL Video Phone).

SUPPLEMENTARY INFORMATION:

Overview of This Information Collection

Collection Title: Waivers of Rights and Claims Under the ADEA; Informational Requirements.

OMB Number: 3046-0042.

Type of Respondent: Business, state or local governments, not for profit institutions.

Description of Affected Public: Any employer with 20 or more employees that seeks waiver agreements in connection with an exit incentive or other employment termination program.

Number of Respondents: 2,425.

Burden Hours per Respondent: 16.19 hours.

Total Annual Burden Hours: 39,260.75.

Number of Forms: None.

Abstract: The EEOC enforces the Age Discrimination in Employment Act (ADEA) which prohibits discrimination against employees and applicants for employment who are age 40 or older. The Older Workers Benefit Protection Act (OWBPA), enacted in 1990, amended the ADEA to require employers to disclose certain information to employees (but not to the EEOC) in writing when they ask employees to waive their rights under the ADEA in connection with an exit

incentive program or other employment termination program. The regulation at 29 CFR 1625.22 reiterates those disclosure requirements. The EEOC seeks an extension without change for the third-party disclosure requirements contained in this regulation. On May 5, 2020, the Commission published a 60-Day Notice informing the public of its intent to request an extension of the information collection requirements from the Office of Management and Budget. 85 FR 26687-89 (May 5, 2020). No comments were received.

For the Commission.

Janet Dhillon,

Chair.

[FR Doc. 2020-15026 Filed 7-10-20; 8:45 am]

BILLING CODE 6570-01-P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060-0512; FRS 16921]

Information Collection Being Reviewed by the Federal Communications Commission Under Delegated Authority

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the

PRA that does not display a valid Office of Management and Budget (OMB) control number.

DATES: Written PRA comments should be submitted on or before September 11, 2020. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicole Ongele, FCC, via email PRA@fcc.gov and to Nicole.Ongele@fcc.gov.

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Nicole Ongele at (202) 418-2991.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060-0512.

Title: ARMIS Annual Summary

Report.

Form Number: FCC Report 43-01.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents and Responses: 90 respondents; 90 responses.

Estimated Time per Response: 8 hours.

Frequency of Response: Annual reporting requirement.

Obligation to Respond: Mandatory. Statutory authority for this information collection is contained in 47 U.S.C. 219 and 220 of the Communications Act of 1934, as amended.

Total Annual Burden: 720 hours.

Total Annual Cost: No cost.

Privacy Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: Ordinarily questions of a sensitive nature are not involved in the ARMIS Report 43-01. The Commission contends that areas in which detailed information is required are fully subject to regulation and the issue of data being regarded as sensitive will arise in special circumstances only. In such circumstances, respondents may request materials or information submitted to the Commission be withheld from public inspection under 47 CFR 0.459 of the Commission's rules.

Needs and Uses: The information contained in FCC Report 43-01 helps the Commission fulfill its regulatory responsibilities regarding pole attachment rates. The Commission has granted all carriers forbearance from ARMIS 43-01 with the exception that carriers are still required to file pole attachment cost data. These data are required to allow the Commission to fulfill its responsibilities under Section

224 of the Communications Act of 1934, as amended.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2020-14969 Filed 7-10-20; 8:45 am]

BILLING CODE 6712-01-P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060-0430; FRS 16919]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act of 1995 (PRA), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before September 11, 2020. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicole Ongele, FCC, via email PRA@fcc.gov and to Nicole.Ongele@fcc.gov.

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Nicole Ongele, (202) 418-2991.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060-0430.

Title: Section 1.1206, Permit-but-Disclose Proceedings.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Individuals or households; Business or other for-profit; Not-for-profit institutions; Federal Government; and State, local, or tribal governments.

Number of Respondent and Responses: 11,500 respondents; 34,500 responses.

Frequency of Response: On occasion reporting requirement.

Obligation to Respond: Required to obtain benefits. Statutory authority for this collection of information is contained in sections 4(i) and (j), 303(r), and 409 of the Communications Act of 1934, as amended, 47 U.S.C. 154(i) and (j), 303(r), and 409.

Estimated Time per Response: 45 minutes (0.75 hours).

Total Annual Burden: 25,875 hours.

Total Annual Costs: No cost.

Nature and Extent of Confidentiality: Consistent with the Commission's rules on confidential treatment of submissions, under 47 CFR 0.459, a presenter may request confidential treatment of *ex parte* presentations. In addition, the Commission will permit parties to remove metadata containing confidential or privileged information, and the Commission will also not require parties to file electronically *ex parte* notices that contain confidential information. The Commission will, however, require a redacted version to be filed electronically at the same time the paper filing is submitted, and that the redacted version must be machine-readable whenever technically possible.

Privacy Act Impact Assessment: No impact(s).

Needs and Uses: The Commission's rules, under 47 CFR 1.1206, require that a public record be made of *ex parte* presentations (*i.e.*, written presentations not served on all parties to the proceeding or oral presentations as to which all parties have not been given notice and an opportunity to be present) to decision-making personnel in "permit-but-disclose" proceedings, such as notice-and-comment rulemakings and declaratory ruling proceedings.

On February 2, 2011, the FCC released a *Report and Order and Further Notice*

of Proposed Rulemaking, GC Docket Number 10–43, FCC 11–11, which amended and reformed the Commission's rules on *ex parte* presentations (47 CFR 1.1206(b)(2)) made in the course of Commission rulemakings and other permit-but-disclose proceedings. The modifications to the existing rules adopted in this Report and Order require that parties file more descriptive summaries of their *ex parte* contacts, by ensuring that other parties and the public have an adequate opportunity to review and respond to information submitted *ex parte*, and by improving the FCC's oversight and enforcement of the *ex parte* rules. The modified *ex parte* rules which contain information collection requirements which OMB approved on December 6, 2011, are as follows: (1) *Ex parte* notices will be required for all oral *ex parte* presentations in permit-but-disclose proceedings, not just for those presentations that involve new information or arguments not already in the record; (2) If an oral *ex parte* presentation is limited to material already in the written record, the notice must contain either a succinct summary of the matters discussed or a citation to the page or paragraph number in the party's written submission(s) where the matters discussed can be found; (3) Notices for all *ex parte* presentations must include the name of the person(s) who made the *ex parte* presentation as well as a list of all persons attending or otherwise participating in the meeting at which the presentation was made; (4) Notices of *ex parte* presentations made outside the Sunshine period must be filed within two business days of the presentation; (5) The Sunshine period will begin on the day (including business days, weekends, and holidays) after issuance of the Sunshine notice, rather than when the Sunshine Agenda is issued (as the current rules provide); (6) If an *ex parte* presentation is made on the day the Sunshine notice is released, an *ex parte* notice must be submitted by the next business day, and any reply would be due by the following business day. If a permissible *ex parte* presentation is made during the Sunshine period (under an exception to the Sunshine period prohibition), the *ex parte* notice is due by the end of the same day on which the presentation was made, and any reply would need to be filed by the next business day. Any reply must be in writing and limited to the issues raised in the *ex parte* notice to which the reply is directed; (7) Commissioners and agency staff may continue to request *ex parte* presentations during the Sunshine

period, but these presentations should be limited to the specific information required by the Commission; (8) *Ex parte* notices must be submitted electronically in machine-readable format. PDF images created by scanning a paper document may not be submitted, except in cases in which a word-processing version of the document is not available. Confidential information may continue to be submitted by paper filing, but a redacted version must be filed electronically at the same time the paper filing is submitted. An exception to the electronic filing requirement will be made in cases in which the filing party claims hardship. The basis for the hardship claim must be substantiated in the *ex parte* filing; (9) To facilitate stricter enforcement of the *ex parte* rules, the Enforcement Bureau is authorized to levy forfeitures for *ex parte* rule violations; (10) Copies of electronically filed *ex parte* notices must also be sent electronically to all staff and Commissioners present at the *ex parte* meeting so as to enable them to review the notices for accuracy and completeness. Filers may be asked to submit corrections or further information as necessary for compliance with the rules; and (11) Parties making permissible *ex parte* presentations in restricted proceedings must conform and clarify rule changes when filing an *ex parte* notice with the Commission.

The information is used by parties to permit-but-disclose proceedings, including interested members of the public, to respond to the arguments made and data offered in the presentations. The responses may then be used by the Commission in its decision-making.

The availability of the *ex parte* materials ensures that the Commission's decisional processes are fair, impartial, and comport with the concept of due process in that all interested parties can know of and respond to the arguments made to the decision-making officials.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2020–14971 Filed 7–10–20; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0208; FRS 16917]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

DATES: Written comments should be submitted on or before September 11, 2020. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contacts below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email PRA@fcc.gov and to Cathy.Williams@fcc.gov.

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION: The FCC may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

As part of its continuing effort to reduce paperwork burdens, and as required by the PRA of 1995 (44 U.S.C.

3501–3520), the FCC invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

OMB Control Number: 3060–0208.

Title: Section 73.1870, Chief Operators.

Form Number: Not applicable.

Type of Review: Extension of a currently approved collection.

Respondents: Business and other for-profit; Not-for-profit institutions.

Number of Respondents and

Responses: 18,498 respondents; 36,996 responses.

Estimated Time per Response: 0.166–26 hours.

Frequency of Response:

Recordkeeping requirement; Third party disclosure requirement.

Total Annual Burden: 484,019 hours.

Total Annual Cost: None.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this collection of information is contained in Sections 154(i) of the Communications Act of 1934, as amended.

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Privacy Impact Assessment(s): No impact(s).

Needs and Uses: The information collection requirements contained in 47 CFR 73.1870 require that the licensee of an AM, FM, or TV broadcast station designate a chief operator of the station. Section 73.1870(b)(3) requires that this designation must be in writing and posted with the station license. Section 73.1870(c)(3) requires that the chief operator, or personnel delegated and supervised by the chief operator, review the station records at least once each week to determine if required entries are being made correctly, and verify that the station has been operated in accordance with FCC rules and the station authorization. Upon completion of the review, the chief operator must date and

sign the log, initiate corrective action which may be necessary and advise the station licensee of any condition which is repetitive. The posting of the designation of the chief operator is used by interested parties to readily identify the chief operator. The review of the station records is used by the chief operator, and FCC staff in investigations, to ensure that the station is operating in accordance with its station authorization and the FCC rules and regulations.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2020–14970 Filed 7–10–20; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–1039 and OMB 3060–1089; FRS 16918]

Information Collections Being Submitted for Review and Approval to Office of Management and Budget

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal Agencies to take this opportunity to comment on the following information collection. Pursuant to the Small Business Paperwork Relief Act of 2002, the FCC seeks specific comment on how it can further reduce the information collection burden for small business concerns with fewer than 25 employees.

DATES: Written comments and recommendations for the proposed information collection should be submitted on or before August 12, 2020.

ADDRESSES: Comments should be sent to 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. Your comment must be submitted into www.reginfo.gov per the above instructions for it to be considered. In addition to submitting in www.reginfo.gov also send a copy of your comment on the proposed information collection to Cathy Williams, FCC, via email to PRA@fcc.gov and to Cathy.Williams@fcc.gov.

Include in the comments the OMB control number as shown in the **SUPPLEMENTARY INFORMATION** below.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection, contact Cathy Williams at (202) 418–2918. To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to the web page <http://www.reginfo.gov/public/do/PRAMain>, (2) look for the section of the web page called “Currently Under Review,” (3) click on the downward-pointing arrow in the “Select Agency” box below the “Currently Under Review” heading, (4) select “Federal Communications Commission” from the list of agencies presented in the “Select Agency” box, (5) click the “Submit” button to the right of the “Select Agency” box, (6) when the list of FCC ICRs currently under review appears, look for the Title of this ICR and then click on the ICR Reference Number. A copy of the FCC submission to OMB will be displayed.

SUPPLEMENTARY INFORMATION: The Commission may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

As part of its continuing effort to reduce paperwork burdens, as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the FCC invited the general public and other Federal Agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimates; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology. Pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, see 44 U.S.C. 3506(c)(4), the FCC seeks specific comment on how it might “further reduce the information collection burden for small business concerns with fewer than 25 employees.”

OMB Control No.: 3060–1039.

Title: Nationwide Programmatic Agreement Regarding the Section 106 National Historic Preservation Act—Review Process, WT Docket No. 03–128.

Form No.: FCC Form 620 and 621, TCNS E-filing.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities; not-for-profit institutions; State, Local or Tribal Government.

Number of Respondents and Responses: 70,152 respondents and 70,152 responses.

Estimated Time per Response: 1–5 hours.

Frequency of Response:

Recordkeeping requirement; on occasion reporting requirement; third party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this collection of information is contained in sections 1, 4(i), 303(q), 303(r), 309(a), 309(j) and 319 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154(i), 303(q), 303(r), 309(a), 309(j) and 319, sections 101(d)(6) and 106 of the National Historic Preservation Act (NHPA) of 1966, 16 U.S.C. 470a(d)(6) and 470f, and section 800.14(b) of the rules of the Advisory Council on Historic Preservation, 36 CFR 800.14(b).

Total Annual Burden: 97,929 hours.

Annual Cost Burden: \$13,087,425.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: In general there is no need for confidentiality. On a case by case basis, the Commission may be required to withhold from disclosure certain information about the location, character, or ownership of a historic property, including traditional religious sites.

Needs and Uses: FCC staff, State Historic Preservation Officers (SHPO), Tribal Historic Preservation Officers (THPO) and the Advisory Council of Historic Preservation (ACHP) use the data to take such action as may be necessary to ascertain whether a proposed action may affect sites of cultural significance to tribal nations and historic properties that are listed or eligible for listing on the National Register as directed by section 106 of the National Historic Preservation Act (NHPA) and the Commission's rules.

FCC Form 620, New Tower (NT) Submission Packet is to be completed by or on behalf of applicants to construct new antenna support structures by or for the use of licensees of the FCC. The form is to be submitted to the State Historic Preservation Office (“SHPO”) or to the Tribal Historic

Preservation Office (“THPO”), as appropriate, and the Commission before any construction or other installation activities on the site begins. Failure to provide the form and complete the review process under section 106 of the NHPA prior to beginning construction may violate section 110(k) of the NHPA and the Commission's rules.

FCC Form 621, Collocation (CO) Submission Packet is to be completed by or on behalf of applicants who wish to collocate an antenna or antennas on an existing communications tower or non-tower structure by or for the use of licensees of the FCC. The form is to be submitted to the State historic Preservation Office (“SHPO”) or to the Tribal Historic Preservation Office (“THPO”), as appropriate, and the Commission before any construction or other installation activities on the site begins. Failure to provide the form and complete the review process under section 106 of the NHPA prior to beginning construction or other installation activities may violate section 110(k) of the NHPA and the Commission's rules.

The Tower Construction Notification System (TCNS) is used by or on behalf of Applicants proposing to construct new antenna support structures, and some collocations, to ensure that Tribal Nations have the requisite opportunity to participate in review prior to construction. To facilitate this coordination, Tribal Nations have designated areas of geographic preference, and they receive automated notifications based on the site coordinates provided in the filing. Applicants complete TCNS before filing a 620 or 621 and all the relevant data is pre-populated on the 620 and 621 when the forms are filed electronically.

OMB Control No.: 3060–1089.

Title: Structure and Practices of the Video Relay Service Program; Telecommunications Relay Services and Speech-to-Speech Services for Individuals with Hearing and Speech Disabilities, CG Docket Nos. 10–51 & 03–123.

Form No.: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit entities; Individuals or households; Not-for-profit institutions; State, Local or Tribal Government.

Number of Respondents and Responses: 202,021 respondents; 1,846,406 responses.

Estimated Time per Response: .05 hours (3 minutes) to 300 hours.

Frequency of Response: Annual, monthly, on occasion, on-going, one-time, and quarterly reporting

requirements; Recordkeeping requirement; and Third-Party Disclosure requirements.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for the collection is contained in section 225 of the Communications Act, 47 U.S.C. 225. The law was enacted on July 26, 1990, as Title IV of the Americans with Disabilities Act of 1990 (ADA), Public Law 101–336, 104 Stat. 327,366–69, and amended by the Twenty-First Century Communications and Video Accessibility Act of 2010, Public Law 111–260, 103(a), 124 Stat. 2751, 2755 (2010) (CVAA); Public Law 111–265 (technical amendments to CVAA).

Total Annual Burden: 329,582 hours.

Annual Cost Burden: \$261,000.

Nature and Extent of Confidentiality: Confidentiality is an issue to the extent that individuals and households provide personally identifiable information, which is covered under the FCC's updated system of records notice (SORN), FCC/CGB–4, “internet-based Telecommunications Relay Service-User Registration Database (ITRS–URD).” As required by the Privacy Act, 5 U.S.C. 552a, the Commission also published a SORN, FCC/CGB–4 “internet-based Telecommunications Relay Service-User Registration Database (ITRS–URD),” in the **Federal Register** on February 9, 2015 (80 FR 6963) which became effective on March 23, 2015.

Privacy Act Impact Assessment: This information collection affects individuals or households. As required by the Office of Management and Budget Memorandum M–03–22 (September 26, 2003), the FCC is in the process of completing the Privacy Impact Assessment.

Needs and Uses: The telecommunications relay service (TRS) program enables access to the nation's telephone network by persons with hearing and speech disabilities. In 1991, as required by the Americans with Disabilities Act and codified at 47 U.S.C. 225, the Commission adopted rules governing the telecommunications relay services (TRS) program and procedures for each state TRS program to apply for initial Commission certification and renewal of Commission certification of each state program. Telecommunications Services for Individuals with Hearing and Speech Disabilities, and the Americans with Disabilities Act of 1990, Report and Order and Request for Comments, document FCC 91–213, published at 56 FR 36729, August 1, 1991 (1991 TRS Implementation Order).

Between 2008 and 2011, to integrate internet-based TRS into the North

American Numbering plan and facilitate interoperability, universal calling, and 911 emergency services, the Commission adopted rules in three separate orders related to the telephone numbering system and enhanced 911 (E911) services for users of two forms of internet-based TRS: Video Relay Service (VRS) and internet Protocol Relay service (IP Relay). See document FCC 08–151, Report and Order and Further Notice of Proposed Rulemaking, published at 73 FR 41286, July 18, 2008 (First Numbering Order); document FCC 08–275, Second Report and Order and Order on Reconsideration, published at 73 FR 79683, December 30, 2008 (Second Numbering Order); and document FCC 11–123, Report and Order, published at 76 FR 59551, September 27, 2011 (iTRS Toll Free Order).

The rules adopted in these three orders have information collection requirements that include requiring VRS and IP Relay providers to: Register each user who selects the provider as his or her default provider, including obtaining a self-certification from each user; verify the accuracy of each user's; provision and maintain their registered users' routing information to the TRS Numbering Directory; place their users' Registered Location and certain callback information in Automatic Location Information (ALI) databases across the country and provide a means for their users to update their Registered Locations; include advisories on their websites and in any promotional materials addressing numbering and E911 services for VRS or IP Relay; verify in the TRS Numbering Directory whether each dial-around user is registered with another provider; and if they provide equipment to a consumer, make available to other VRS providers enough information about that equipment to enable another VRS provider selected as the consumer's default provider to perform all of the functions of a default provider.

On July 28, 2011, the Commission released Structure and Practices of the Video Relay Service Program, document FCC 11–118, published at 76 FR 47469, August 5, 2011, and at 76 FR 47476, August 5, 2011 (VRS Certification Order), adopting final and interim rules—designed to help prevent waste, fraud, and abuse, and ensure quality service, in the provision of internet-based forms of Telecommunications Relay Services (iTRS). On October 17, 2011, the Commission released Structure and Practices of the Video Relay Service Program, Memorandum Opinion and Order, Order, and Further Notice of Proposed Rulemaking,

document FCC 11–155, published at 76 FR 67070, October 31, 2011 (VRS Certification Reconsideration Order), modifying two aspects of information collection requirements contained in the VRS Certification Order. On June 10, 2013, the Commission made permanent the interim rule adopted in the VRS Certification Order. Structure and Practices of the Video Relay Service Program; Telecommunications Relay Services and Speech-to-Speech Services for Individuals with Hearing and Speech Disabilities, Report and Order and Further Notice of Proposed Rulemaking, document FCC 13–82, published at 78 FR 40582, July 5, 2013 (2013 VRS Reform Order).

The VRS Certification Order as modified by the VRS Certification Reconsideration and, as applicable, made permanent by the (2013 VRS Reform Order), amended the Commission's process for certifying internet-based TRS (iTRS) providers as eligible for payment from the Interstate TRS Fund (Fund) for their provision of iTRS to ensure that iTRS providers receiving certification are qualified to provide iTRS in compliance with the Commission's rules and to eliminate waste, fraud and abuse through improved oversight of such providers. They contain information collection requirements including: Submission of detailed information in an application for certification that shows the applicant's ability to comply with the Commission's rules; submission of annual reports that include updates to the provider's information on file with the Commission or a certification that there are no changes to the information; requirements for a senior executive of an applicant for iTRS certification or an iTRS provider, when submitting an annual compliance report, to certify under penalty of perjury that all information required under the Commission's rules and orders has been provided and all statements of fact, as well as all documentation contained in the submission, are true, accurate, and complete; requirements for VRS providers to obtain prior authorization from the Commission for planned interruptions of service, to report to the Commission unforeseen interruptions of service, and to provide notification of temporary service outages, including updates, to consumers on their websites; and requirements for iTRS providers that will no longer be providing service to give their customers at least 30-days notice.

In the 2013 VRS Reform Order, the Commission also adopted further measures to improve the structure, efficiency, and quality of the video relay

service (VRS) program, reducing the noted inefficiencies in the program, as well as reducing the risk of waste, fraud, and abuse, and ensuring that the program makes full use of advances in commercially-available technology. The Commission required reporting of unauthorized and unnecessary use of VRS; established a central telecommunications relay services (TRS) user registration database (TRS–URD) for VRS, which incorporates a centralized eligibility verification requirement to ensure accurate registration and verification of users, as well as per-call validation, to achieve more effective prevention of waste, fraud, and abuse; established procedures to prevent unauthorized changes of a user's default TRS provider; and established procedures to protect TRS users' customer proprietary network information (CPNI) from disclosure.

On March 23, 2017, the Commission released Structure and Practices of the Video Relay Services Program et al., FCC 17–26, published at 82 FR 17754, April 13, 2017 (2017 VRS Improvements Order), which among other things, allows VRS providers to assign TRS Numbering Directory 10-digit telephone numbers to hearing individuals for the limited purpose of making point-to-point video calls, and gives VRS providers the option to participate in an at-home call handling pilot program, subject to certain limitations, as well as recordkeeping and reporting requirements.

On May 15, 2019, the Commission released Structure and Practices of the Video Relay Service Program; Telecommunications Relay Services and Speech-to-Speech Services for Individuals with Hearing and Speech Disabilities, FCC 19–39, published at 84 FR 26364, June 6, 2019 (2019 VRS Program Management Order). The Commission further improved the structure, efficiency, and quality of the VRS program, reduced the risk of waste, fraud, and abuse, and ensured that the program makes full use of advances in commercially-available technology. These improvements include information collection requirements, including: The establishment of procedures to register enterprise and public videophones to the TRS–URD; and permitting Qualified Direct Video Calling (DVC) Entities to access the TRS Numbering Directory and establishing an application procedure to authorize such access, including rules governing DVC entities and entry of information in the TRS Numbering Directory and the TRS–URD.

On August 2, 2019, the Commission released Implementing Kari's Law and Section 506 of RAY BAUM'S Act; Inquiry Concerning 911 Access, Routing, and Location in Enterprise Communications Systems; Amending the Definition of Interconnected VoIP Service in Section 9.3 of the Commission's Rules, FCC 19–76, published at 84 FR 66716, December 5, 2019 (MLTS 911 and Dispatchable Location Order). The Commission amended its rules to ensure that the dispatchable location is conveyed to a Public Safety Answering Point (PSAP) with a 911 call, regardless of the technological platform used. Based on the directive in section 506 of RAY BAUM'S Act, the Commission adopted dispatchable location requirements that in effect modified the existing information collection requirements applicable to VRS, IP Relay and covered IP CTS by improving the options for providing accurate location information to PSAPs as part of 911 calls.

Fixed internet-based TRS devices must provide automated dispatchable location. For non-fixed devices, when dispatchable location is not technically feasible, internet-based TRS providers may fall back to Registered Location or provide alternative location information. As a last resort, internet-based providers may route calls to Emergency Relay Calling Centers, after making a good faith effort to obtain location data from all available alternative location sources. Dispatchable location means a location delivered to the PSAP with a 911 call that consists of the validated street address of the calling party, plus additional information such as suite, apartment or similar information necessary to adequately identify the location of the calling party. Automated dispatchable location means automatic generation of dispatchable location. Alternative location information is location information (which may be coordinate-based) sufficient to identify the caller's civic address and approximate in-building location, including floor level, in large buildings.

On January 31, 2020, the Commission released Structure and Practices of the Video Relay Service Program; Telecommunications Relay Services and Speech-to-Speech Services for Individuals with Hearing and Speech Disabilities, FCC 20–7 (VRS At-Home Call Handling Order). The Commission amended its rules to convert the VRS at-home call handling pilot program into a permanent one, thereby allowing CAs to work from home. To ensure user privacy and call confidentiality and to help prevent waste, fraud, and abuse, the

modified information collections include requirements for VRS providers to apply for certification to allow their communications assistants to handle calls while working at home; monitoring and oversight requirements; and reporting requirements.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2020–14963 Filed 7–10–20; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0678; FRS 16916]

Information Collections Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

DATES: Written comments should be submitted on or before September 11, 2020. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contacts below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email PRA@fcc.gov and to Cathy.Williams@fcc.gov.

FOR FURTHER INFORMATION CONTACT: For additional information about the

information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION: The FCC may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

As part of its continuing effort to reduce paperwork burdens, and as required by the PRA of 1995 (44 U.S.C. 3501–3520), the FCC invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

OMB Control No.: 3060–0678.

Title: Part 25 of the Commission's Rules Governing the Licensing of, and Spectrum Usage by, Satellite Network Stations and Space Station.

Form Nos.: FCC Form 312, FCC Form 312–EZ, FCC Form 312–R and Schedules A, B and S.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit entities and Not-for-profit institutions.

Number of Respondents: 6,501 respondents; 6,550 responses.

Estimated Time per Response: 0.5–80 hours.

Frequency of Response: On occasion, one time, and annual reporting requirements; third-party disclosure requirement; recordkeeping requirement.

Obligation to Respond: Required to obtain or retain benefits. The Commission has statutory authority for the information collection requirements under 47 U.S.C. 154, 301, 302, 303, 307, 309, 310, 319, 332, 605, and 721.

Total Annual Burden: 42,854 hours.

Total Annual Cost: \$16,863,793.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: There is no need for confidentiality pertaining to the information collection requirements in this collection.

Needs and Uses: First, on September 27, 2019, the Commission released a Report and Order, FCC 19–93, in IB Docket No. 06–160, titled “Amendment of the Commission’s Policies and Rules for Processing Applications in the Direct Broadcast Satellite Service” (DBS Licensing Report and Order). In this Report and Order, the Commission adopted a new licensing process for space stations in the Direct Broadcast Satellite Service (DBS). This new process allows applicants for DBS space station licenses to take advantage of a licensing process that parallels the Commission’s streamlined Part 25 satellite licensing rules for geostationary orbit (GSO) space stations in the fixed-satellite service (FSS). The Commission limited the regulatory burdens borne by applicants, while promoting new opportunities for efficient use of orbital spacing and spectrum by DBS licensees. The Commission’s action supports and encourages the increasing innovation in the DBS sector and helps to preserve U.S. leadership in space-based services and operations. This information collection will provide the Commission and the public with necessary information about this area of satellite operations. While this information collection represents an overall increase in the burden hours, the increase is due to an anticipated overall increase in number of applications as a result of additional applications being filed under the process adopted in the DBS Licensing Report and Order. This information collection serves the public interest by streamlining the collection of information and allowing the Commission to authorize DBS space stations under the new process established in the Report and Order.

Specifically, FCC 19–93 contains the new or modified information collection requirement listed below: Space station applications for GSO space stations operating in the frequencies of the International Telecommunication Union (ITU) Appendices 30 and 30A (incorporated by reference, see § 25.108) must include a statement that the proposed operation will take into account the applicable requirements of these Appendices of the ITU Radio Regulations and a demonstration that it is compatible with other U.S. ITU filings under Appendices 30 and 30A or, for any affected filings, a letter signed by the affected operator indicating that it consents to the new application.

Second, on March 3, 2020, the Commission released a Report and

Order and Order of Proposed Modification, FCC 20–22, GN Docket No. 18–122, titled “Expanding Flexible Use of the 3.7 to 4.2 GHz Band.” In this Report and Order of Proposed Modification, the Commission updated its rules by reforming the use of the 3.7–4.2 GHz band, also known as the C-Band. The new rules repack existing satellite operations into the upper 200 megahertz of the band (and reserve a 20 megahertz guard band), making a significant amount of spectrum—280 megahertz or more than half of the band—available for flexible use throughout the contiguous United States. The relevant rule revisions for purposes of this information collection are the addition of sections 25.138 and 25.147 of the Commission’s rules. In updating this information collection, we are not accounting for any changes to the number of respondents, burden hours, and annual cost related to these rule revisions since the addition of sections 25.138 and 25.147 set forth rules for transition of operations from one frequency band to another.

Third, on April 24, 2020, the Commission released a Report and Order, FCC 20–54, IB Docket No. 18–313, titled “Mitigation of Orbital Debris in the New Space Age” (Orbital Debris Report and Order). In this Report and Order, the Commission updated its rules related to orbital debris mitigation, including application requirements. The new rules are designed to ensure that the Commission’s actions concerning radio communications, including licensing U.S. spacecraft and granting access to the U.S. market for non-U.S. spacecraft, mitigate the growth of orbital debris, while at the same time not creating undue regulatory obstacles to new satellite ventures. The action will help to ensure that Commission decisions are consistent with the public interest in space remaining viable for future satellites and systems and the many services that those systems provide to the public. The rule revisions also provide additional detail to applicants on what information is expected under the Commission’s rules, which can help to increase certainty in the application filing process. While this information collection represents an overall increase in the burden hours, the information collection serves the public interest by ensuring that the Commission and public have necessary information about satellite applicants’ plans for mitigation of orbital debris.

Specifically, FCC 20–54 contains the new or modified information collection requirements listed below.

The following are new or modified information collection requirements

contained in FCC 20–54 and applicable to non-streamlined space station applicants submitting orbital debris mitigation plans under part 25 of the Commission’s rules:

(1) Existing application disclosure requirements have been revised to include specific metrics in several areas, including: Probability that the space stations will become a source of debris by collision with small debris and meteoroids that would cause loss of control and prevent disposal; probability of collision between any non-geostationary orbit (NGSO) space station and other large objects; and casualty risk associated with any individual spacecraft that will be disposed by atmospheric re-entry.

(2) Where relevant, applicants must disclose the following: Use of separate deployment devices, distinct from the space station launch vehicle, that may become a source of orbital debris; potential release of liquids that will persist in droplet form; and any planned proximity operations and debris generation that will or may result from the proposed operations, including any planned release of debris, the risk of accidental explosions, the risk of accidental collision, and measures taken to mitigate those risks.

(3) The existing application disclosure requirement to analyze potential collision risk associated with space station(s) orbits has been modified to specify that the disclosure identify characteristics of the space station(s)’ orbits that may present a collision risk, including any planned and/or operational space stations in those orbits, and indicate what steps, if any, have been taken to coordinate with the other spacecraft or system, or what other measures the operator plans to use to avoid collision.

(4) Applicants for NGSO space stations that will transit through the orbits used by any inhabitable spacecraft, including the International Space Station, must disclose as part of the application the design and operational strategies, if any, that will be used to minimize the risk of collision and avoid posing any operational constraints to the inhabitable spacecraft.

(5) The application disclosure must include a certification that upon receipt of a space situational awareness conjunction warning, the operator will review and take all possible steps to assess the collision risk, and will mitigate the collision risk if necessary. As appropriate, steps to assess and mitigate the collision risk should include, but are not limited to: Contacting the operator of any active spacecraft involved in such a warning;

sharing ephemeris data and other appropriate operational information with any such operator; and modifying space station attitude and/or operations.

(6) Applicants for NGSO space stations must describe the extent of satellite maneuverability.

(7) Applicants must address trackability of the space station(s). NGSO space station applicants must also disclose: (a) How the operator plans to identify the space station(s) following deployment and whether the space station tracking will be active or passive; (b) whether, prior to deployment the space station(s) will be registered with the 18th Space Control Squadron or successor entity; and (c) the extent to which the space station operator plans to share information regarding initial deployment, ephemeris, and/or planned maneuvers with the 18th Space Control Squadron or successor entity, other entities that engage in space situational awareness or space traffic management functions, and/or other operators.

(8) NGSO space station applicants must provide additional disclosures regarding spacecraft disposal, including, for some applicants, a demonstration that the probability of success of the chosen disposal method is 0.9 or greater for any individual space station, and for multi-satellite systems, a demonstration including additional information regarding efforts to achieve a higher probability of success

The following are new or modified information collection requirements contained in FCC 20–54 and applicable to those space station applicants qualifying for small satellite streamlined processing under part 25 of the Commission's rules:

(1) Applicants must certify that the probability that any individual space station will become a source of debris by collision with small debris or meteoroids that would cause loss of control and prevent disposal is 0.01 (1 in 100) or less.

(2) Applicants must certify that upon receipt of a space situational awareness conjunction warning, the licensee or operator will review and take all possible steps to assess the collision risk, and will mitigate the collision risk if necessary. As appropriate, steps to assess and mitigate the collision risk should include, but are not limited to: contacting the operator of any active spacecraft involved in such a warning; sharing ephemeris data and other appropriate operational information with any such operator; and modifying space station attitude and/or operations.

(3) If at any time during the space station(s)' mission or de-orbit phase the

space station(s) will transit through the orbits used by any inhabitable spacecraft, including the International Space Station, applicants must provide a description of the design and operational strategies, if any, that will be used to minimize the risk of collision and avoid posing any operational constraints to the inhabitable spacecraft shall be furnished at the time of application.

(4) Applicants must provide a statement identifying characteristics of the space station(s)' orbits that may present a collision risk, including any planned and/or operational space stations in those orbits, and indicating what steps, if any, have been taken to coordinate with the other spacecraft or system, or what other measures the licensee plans to use to avoid collision. This requirement also applies to applicants for streamlined small spacecraft authorizations.

(5) Applicants must provide a statement disclosing how the licensee or operator plans to identify the space station(s) following deployment and whether space station tracking will be active or passive; whether the space station(s) will be registered with the 18th Space Control Squadron or successor entity prior to deployment; and the extent to which the space station licensee or operator plans to share information regarding initial deployment, ephemeris, and/or planned maneuvers with the 18th Space Control Squadron or successor entity, other entities that engage in space situational awareness or space traffic management functions, and/or other operators.

(6) If the applicant's space station(s) will undertake any planned proximity operations, the applicant must provide a statement disclosing those planned operations, and addressing debris generation that will or may result from the proposed operations, including any planned release of debris, the risk of accidental explosions, the risk of accidental collision, and measures taken to mitigate those risks.

(7) Applicants must provide a demonstration that the probability of success of disposal is 0.9 or greater for any individual space station. Space stations deployed to orbits in which atmospheric drag will, in the event of a space station failure, limit the lifetime of the space station to less than 25 years do not need to provide this additional demonstration.

Additionally, the following new or modified information collection requirements contained in FCC 20–54 are applicable to applicants requesting a modification of an existing licensee for a GSO space station to extend the space

station license term under part 25 of the Commission's rules:

GSO space station licensees seeking a license term extension through a license modification application must provide a statement that includes the requested duration of the license extension; the estimated total remaining space station lifetime; a description of any single points of failure or other malfunctions, defects, or anomalies during the space station operation that could affect its ability to conduct end-of-life procedures as planned, and an assessment of the associated risk; a certification that remaining fuel reserves are adequate to complete de-orbit as planned; and a certification that telemetry, tracking, and command links are fully functional.

This collection is used by the Commission's staff in carrying out its statutory duties to regulate satellite communications in the public interest, as generally provided under 47 U.S.C. 154, 301, 302, 303, 307, 309, 310, 319, 332, 605, and 721. This collection is also used by staff in carrying out United States treaty obligations under the World Trade Organization (WTO) Basic Telecom Agreement. The information collected is used for the practical and necessary purposes of assessing the legal, technical, and other qualifications of applicants; determining compliance by applicants, licensees, and other grantees with Commission rules and the terms and conditions of their grants; and concluding whether, and under what conditions, grant of an authorization will serve the public interest, convenience, and necessity.

As technology advances and new spectrum is allocated for satellite use, applicants for satellite service will continue to submit the information required in 47 CFR part 25 of the Commission's rules. Without such information, the Commission could not determine whether to permit respondents to provide telecommunication services in the United States. Therefore, the Commission would be unable to fulfill its statutory responsibilities in accordance with the Communications Act of 1934, as amended, and the obligations imposed on parties to the WTO Basic Telecom Agreement.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2020–14964 Filed 7–10–20; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION**FDIC Advisory Committee on Community Banking; Notice of Meeting**

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice of open meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, notice is hereby given of a meeting of the FDIC Advisory Committee on Community Banking. The Advisory Committee will provide advice and recommendations on a broad range of policy issues that have particular impact on small community banks throughout the United States and the local communities they serve, with a focus on rural areas. The meeting is open to the public. Out of an abundance of caution related to current and potential coronavirus developments, the public's means to observe this Community Banking Advisory Committee meeting will be via a Webcast live on the internet. In addition, the meeting will be recorded and subsequently made available on-demand approximately two weeks after the event. To view the live event, visit <http://fdic.windrosemedia.com>. To view the recording, visit <http://fdic.windrosemedia.com/index.php?category=Community+Banking+Advisory+Committee>. Observers requiring auxiliary aids (e.g., sign language interpretation) for this meeting should call 703-562-2404 (Voice) or 703-649-4354 (Video Phone) to make necessary arrangements.

DATES: Tuesday, July 28, 2020, from 1:00 p.m. to 5:30 p.m.

FOR FURTHER INFORMATION CONTACT: Requests for further information concerning the meeting may be directed to Mr. Robert E. Feldman, Committee Management Officer of the FDIC, at (202) 898-7043.

SUPPLEMENTARY INFORMATION:

Agenda: The agenda will include a discussion of current issues affecting community banking. The agenda is subject to change. Any changes to the agenda will be announced at the beginning of the meeting.

Type of Meeting: This meeting of the Advisory Committee on Community Banking will be Webcast live via the internet <http://fdic.windrosemedia.com>. For optimal viewing, a high-speed internet connection is recommended.

Federal Deposit Insurance Corporation.

Dated at Washington, DC, on July 8, 2020.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2020-15008 Filed 7-10-20; 8:45 am]

BILLING CODE 6714-01-P

GENERAL SERVICES ADMINISTRATION

[Notice-MA-2020-06; Docket No. 2020-0002; Sequence No.18]

Cancellation of FMR Bulletins B-37 and B-39

AGENCY: Office of Government-Wide Policy (OGP), General Services Administration (GSA).

ACTION: Notice of cancellation of FMR Bulletins B-37 and B-39.

SUMMARY: This notice announces the cancellation of GSA Federal Management Regulation (FMR) Bulletins B-37 and B-39.

DATES: *Applicability Date:* July 13, 2020

FOR FURTHER INFORMATION CONTACT: For clarification of content, contact Mr. William Garrett, Director, Personal Property Management Policy, Office of Government-Wide Policy, Office of Asset and Transportation Management, at 202-368-8163, or by email at william.garrett@gsa.gov. Please cite Notice of Cancellation of FMR Bulletins B-37 and B-39.

SUPPLEMENTARY INFORMATION:

Background: In 2013, GSA issued FMR Bulletin B-37: Federal Print Management Practices. In 2014, GSA issued FMR Bulletin B-39: Federal Sustainable Print Management Policy Template. As Executive Order (E.O.) 13514 "Federal Leadership in Environmental, Energy, and Economic Performance," that precipitated this guidance, has been revoked, GSA is posting this **Federal Register** Notice, which cancels Bulletins B-37 and B-39.

Jessica Salmoiraghi,

Associate Administrator, Office of Government-wide Policy.

[FR Doc. 2020-14999 Filed 7-10-20; 8:45 am]

BILLING CODE 6820-14-P

DEPARTMENT OF DEFENSE**GENERAL SERVICES ADMINISTRATION****NATIONAL AERONAUTICS AND SPACE ADMINISTRATION**

[OMB Control No. 9000-0182; Docket No. 2020-0053; Sequence No. 4]

Submission for OMB Review; Privacy Training

AGENCY: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division has submitted to the Office of Management and Budget (OMB) a request to review and approve a revision and renewal of a previously approved information collection requirement regarding privacy training.

DATES: Submit comments on or before August 12, 2020.

ADDRESSES: Written comments and recommendations for this 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 "Currently under Review—Open for Public Comments" or by using the search function.

Additionally submit a copy to GSA through <http://www.regulations.gov> and follow the instructions on the site. This website provides the ability to type short comments directly into the comment field or attach a file for lengthier comments.

Instructions: All items submitted must cite Information Collection 9000-0182, Privacy Training. Comments received generally will be posted without change to <http://www.regulations.gov>, including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check www.regulations.gov, approximately two to three days after submission to verify posting. If there are difficulties submitting comments, contact GSA Regulatory Secretariat Division at 202-501-4755 or GSARegSec@gsa.gov.

FOR FURTHER INFORMATION CONTACT: Bryon Boyer, Procurement Analyst, at telephone 817-707-6671, or bryon.boyer@gsa.gov.

SUPPLEMENTARY INFORMATION:

A. OMB control number, Title, and any Associated Form(s): OMB Control No. 9000–0182, Privacy Training

B. Needs and Uses

This clearance covers the information that contractors must submit to comply with the following Federal Acquisition Regulation (FAR) requirement:

- 52.224–3(d). This clause requires contractors to:
 - (1) Maintain a record of initial and annual privacy training, for the contractor's employees that have: (a) Have access to a system of records; (b) create, collect, use, process, store, maintain, disseminate, disclose, dispose, or otherwise handle personally identifiable information on behalf of an agency; or (c) design, develop, maintain, or operate a system of records; and
 - (2) provide the above information to the contracting officer if requested.

The contracting officer will use the information in contract administration and to establish that all applicable contractor and subcontractor employees comply with the privacy training requirements.

C. Annual Burden

Recordkeeping Burden:

Recordkeepers: 33,162.

Hours per Recordkeeper: 3.0.

Total Recordkeeping Burden Hours: 99,483 hours.

Reporting Burden:

Respondents: 829.

Total Annual Responses: 829.

Total Burden Hours: 207 hours.

D. Public Comment

A 60-day notice was published in the **Federal Register** at 85 FR 26690, on May 05, 2020. No comments were received.

OBTAINING COPIES: Requesters may obtain a copy of the information collection documents from the GSA Regulatory Secretariat Division, by calling 202–501–4755 or emailing GSARegSec@gsa.gov. Please cite OMB Control No. 9000–0182, Privacy Training.

Dated: July 7, 2020.

Janet Fry,

Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2020–14962 Filed 7–10–20; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0113; Docket No. 2020–0053; Sequence No. 3]

Submission for OMB Review; Acquisition of Helium

AGENCY: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division has submitted to the Office of Management and Budget (OMB) a request to review and approve a revision and renewal of a previously approved information collection requirement regarding acquisition of helium.

DATES: Submit comments on or before August 12, 2020.

ADDRESSES: Written comments and recommendations for this 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 “Currently under Review—Open for Public Comments” or by using the search function. Additionally submit a copy to GSA through <http://www.regulations.gov> and follow the instructions on the site. This website provides the ability to type short comments directly into the comment field or attach a file for lengthier comments.

Instructions: All items submitted must cite Information Collection 9000–0113, Acquisition of Helium. Comments received generally will be posted without change to <http://www.regulations.gov>, including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check www.regulations.gov, approximately two to three days after submission to verify posting. If there are difficulties submitting comments, contact GSA Regulatory Secretariat Division at 202–501–4755 or GSARegSec@gsa.gov.

FOR FURTHER INFORMATION CONTACT: Bryon Boyer, Procurement Analyst, at telephone 817–850–5580, or bryon.boyer@gsa.gov.

SUPPLEMENTARY INFORMATION:

A. OMB Control Number, Title, and Any Associated Form(s)

9000–0113, Acquisition of Helium.

B. Needs and Uses

This clearance covers the information that contractors must submit to comply with the Federal Acquisition Regulation (FAR) clause 52.208–8, Required Sources for Helium and Helium Usage Data. This clause implements the requirements of the Helium Act (50 U.S.C. 167, *et seq.*) and 43 CFR 3195. The clause, in paragraph(b)(2), requires contractors to: Purchase major helium requirements, to be used in performance of a contract, from Federal helium suppliers to the extent supplies are available; and submit (within 10 days of such acquisition) the following information to the contracting officer: (1) The name of the supplier; (2) the amount of helium purchased; (3) the delivery date(s); and (4) the location where the helium was used.

The contracting officer will use the information to ensure compliance with contract clauses and will forward the information to the Department of the Interior, Bureau of Land Management. Without the information, Federal and contractor compliance with the applicable statutory requirements cannot be monitored effectively.

C. Annual Burden

Respondents: 26.

Total Annual Responses: 26.

Total Burden Hours: 26.

D. Public Comment

A 60-day notice was published in the **Federal Register** at 85 FR 26690, on May 05, 2020. No comments were received.

Obtaining Copies: Requesters may obtain a copy of the information collection documents from the GSA Regulatory Secretariat Division, by calling 202–501–4755 or emailing GSARegSec@gsa.gov. Please cite OMB Control No. 9000–0113, Acquisition of Helium, in all correspondence.

Dated: July 7, 2020.

Janet Fry,

Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2020–14961 Filed 7–10–20; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Disease Control and Prevention****Board of Scientific Counselors, National Center for Injury Prevention and Control**

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, the CDC announces the following meeting for the Board of Scientific Counselors, National Center for Injury Prevention and Control (BSC, NCIPC). This meeting is partially open to the public. There will be 15 minutes allotted for public comments at the end of the open session from 12:30 p.m. to 12:45 p.m. on August 20, 2020.

DATES: The meeting will be held on August 20, 2020, from 10:00 a.m. to 1:00 p.m., EST (OPEN) and August 20, 2020, from 1:30 p.m. to 5:00 p.m., EST (CLOSED).

ADDRESSES: Teleconference 1-800-369-3110; Participant Code 7563795

FOR FURTHER INFORMATION CONTACT: Gwendolyn H. Cattledge, Ph.D., M.S.E.H., Deputy Associate Director for Science, NCIPC, CDC, 4770 Buford Highway NE, Mailstop S106-9, Atlanta, GA 30341, Telephone (770) 488-3953, Email address: NCIPCBSC@cdc.gov.

SUPPLEMENTARY INFORMATION: Portions of the meeting as designated above will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, CDC, pursuant to Public Law 92-463.

Purpose: The Board will: (1) Conduct, encourage, cooperate with, and assist other appropriate public health authorities, scientific institutions, and scientists in the conduct of research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases, and other impairments; (2) assist States and their political subdivisions in preventing and suppressing communicable and non-communicable diseases and other preventable conditions and in promoting health and well-being; and (3) conduct and assist in research and control activities related to injury. The BSC, NCIPC makes recommendations

regarding policies, strategies, objectives, and priorities; reviews progress toward injury prevention goals; and provides evidence in injury prevention-related research and programs. The Board also provides advice on the appropriate balance of intramural and extramural research, and the structure, progress and performance of intramural programs. The Board is designed to provide guidance on extramural scientific program matters, including the: (1) Review of extramural research concepts for funding opportunity announcements; (2) conduct of Secondary Peer Review of extramural research grants, cooperative agreements, and contracts applications received in response to funding opportunity announcements as they relate to the Center's programmatic balance and mission; (3) submission of secondary review recommendations to the Center Director of applications to be considered for funding support; (4) review of research portfolios, and (5) review of program proposals.

Matters to be Considered: The open portion of the agenda will include discussions on Health Equity, Violence, and Racism. All presentations will be followed by discussion by the BSC.

The closed portion of the agenda will focus on the Secondary Peer Review of extramural research grant applications received in response to three (3) Notice of Funding Opportunities (NOFOs): RFA-CE-20-002—"Grants to Support New Investigators in Conducting Research Related to Preventing Interpersonal Violence Impacting Children and Youth"; RFA-CE-20-005—"Rigorously Evaluating Approaches to Prevent Adult-Perpetrated Child Sex Abuse (CSA)"; and RFA-CE-20-006—"Research Grants to Prevent Firearm-Related Violence and Injuries (R01)", as well as PA-19-272/273-PHS 2019-02 "Omnibus Solicitation of the NIH, CDC, and FDA for Small Business Innovation Research Grant Applications" (Parent SBIR [R43/R44]). Agenda items are subject to change as priorities dictate.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and

Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2020-15029 Filed 7-10-20; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Disease Control and Prevention**

[Docket No. CDC-2020-0081]

Advisory Committee on Immunization Practices (ACIP)

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting and request for comment.

SUMMARY: In accordance with the Federal Advisory Committee Act, the CDC, announces the following meeting of the Advisory Committee on Immunization Practices (ACIP). This meeting is open to the public. Time will be available for public comment. The meeting will be webcast live via the World Wide Web.

DATES: The meeting will be held on July 29, 2020, from 10 a.m. to 4 p.m., EDT (times subject to change).

Written comments must be received on or before July 30, 2020.

ADDRESSES: For more information on ACIP please visit the ACIP website: <http://www.cdc.gov/vaccines/acip/index.html>.

You may submit comments, identified by Docket No. CDC-2020-0081, by either of the following methods below. CDC does not accept comment by email.

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments.

- **Mail:** Docket No. CDC-2020-0081, c/o Attn: July ACIP Meeting, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H24-8, Atlanta, GA 30329-4027.

Instructions: All submissions received must include the Agency name and Docket Number. All relevant comments received in conformance with the <https://www.regulations.gov> suitability policy will be posted without change to <https://www.regulations.gov>, including any personal information provided. For access to the docket to read background documents or comments received, go to <https://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT:

Stephanie Thomas, ACIP Committee Management Specialist, Centers for Disease Control and Prevention, National Center for Immunization and Respiratory Diseases, 1600 Clifton Road, NE, MS-H24-8, Atlanta, GA 30329-4027; Telephone: 404-639-8367; Email: ACIP@cdc.gov.

SUPPLEMENTARY INFORMATION:

Purpose: The committee is charged with advising the Director, CDC, on the use of immunizing agents. In addition, under 42 U.S.C. 1396s, the committee is mandated to establish and periodically review and, as appropriate, revise the list of vaccines for administration to vaccine-eligible children through the Vaccines for Children (VFC) program, along with schedules regarding dosing interval, dosage, and contraindications to administration of vaccines. Further, under provisions of the Affordable Care Act, section 2713 of the Public Health Service Act, immunization recommendations of the ACIP that have been approved by the Director of the Centers for Disease Control and Prevention and appear on CDC immunization schedules must be covered by applicable health plans.

Matters To Be Considered: The agenda will include discussions on COVID-19 vaccines. No recommendation votes are scheduled. Agenda items are subject to change as priorities dictate. For more information on the meeting agenda visit <https://www.cdc.gov/vaccines/acip/meetings/meetings-info.html>.

Meeting Information: The meeting will be webcast live via the World Wide Web; for more information on ACIP please visit the ACIP website: <http://www.cdc.gov/vaccines/acip/index.html>.

Public Participation

Interested persons or organizations are invited to participate by submitting written views, recommendations, and data. Comments received are part of the public record and are subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. CDC will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign. CDC will carefully consider

all comments submitted into the docket. CDC does not accept comment by email.

Oral Public Comment: This meeting will include time for members of the public to make an oral comment. Oral public comment will occur before any scheduled votes including all votes relevant to the ACIP's Affordable Care Act and Vaccines for Children Program roles. Priority will be given to individuals who submit a request to make an oral public comment before the meeting according to the procedures below.

Procedure for Oral Public Comment: All persons interested in making an oral public comment at the July ACIP meeting must submit a request at <http://www.cdc.gov/vaccines/acip/meetings/> no later than 11:59 p.m., EDT, July 22, 2020 according to the instructions provided.

If the number of persons requesting to speak is greater than can be reasonably accommodated during the scheduled time, CDC will conduct a lottery to determine the speakers for the scheduled public comment session. CDC staff will notify individuals regarding their request to speak by email by July 23, 2020. To accommodate the significant interest in participation in the oral public comment session of ACIP meetings, each speaker will be limited to 3 minutes, and each speaker may only speak once per meeting.

Written Public Comment: Written comments must be received on or before July 30, 2020. Written public comments submitted by 72 hours prior to the ACIP meeting will be provided to ACIP members before the meeting.

This notice is being published less than 15 days prior to the meeting due to the public health emergency declared on January 27, 2020. There is a critical need for this committee to discuss urgent matters related to discussions on COVID-19 vaccines and be actively engaged in the national response efforts as dictated by circumstances and events. In the interest of promoting openness and transparency, we are publishing a late notice in the **Federal Register** to inform the public.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and

Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2020-15178 Filed 7-9-20; 3:00 pm]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Disease Control and Prevention**

[Docket No. CDC-2020-0077]; [Docket No. NIOSH 338]

Advisory Board on Radiation and Worker Health, National Institute for Occupational Safety and Health

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting and request for comment.

SUMMARY: In accordance with the Federal Advisory Committee Act, the CDC, announces the following meeting of the Advisory Board on Radiation and Worker Health (ABRWH). This meeting is open to the public, limited only by the space available. The audio conference line has 150 ports for callers. The public is welcome to submit written comments in advance of the meeting, to the contact person below. Written comments received in advance of the meeting will be included in the official record of the meeting. The public is also welcome to listen to the meeting by joining the teleconference (information below).

DATES: The meeting will be held on August 26, 2020 from 1:15 p.m. to 6:15 p.m., EDT and August 27, 2020 from 1:15 p.m. to 6:30 p.m., EDT. An oral public comment session will be held on August 26, 2020 at 5:15 p.m. and conclude at 6:15 p.m., or following the final call for public comment, whichever comes first.

Written comments must be received on or before August 21, 2020.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2020-0077, Docket No. NIOSH-338 by either of the following methods listed below. CDC does not accept comment by email.

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *Mail:* Docket No. CDC-2020-0077, Docket number NIOSH-338 c/o Sherri Diana, NIOSH Docket Office, National Institute for Occupational Safety and

Health, 1090 Tusculum Avenue, MS C-34, Cincinnati, Ohio 45226.

Instructions: All submissions received must include the Agency name and Docket Number. All relevant comments received in conformance with the <https://www.regulations.gov> suitability policy will be posted without change to <https://www.regulations.gov>, including any personal information provided. For access to the docket to read background documents or comments received, go to <https://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Rashaun Roberts, Ph.D., Designated Federal Officer, NIOSH, CDC, 1090 Tusculum Avenue, Mailstop C-24, Cincinnati, Ohio 45226, Telephone (513) 533-6800, Toll Free 1(800)CDC-INFO, Email ocas@cdc.gov.

SUPPLEMENTARY INFORMATION:

Background: The Advisory Board was established under the

Energy Employees Occupational Illness Compensation Program Act of 2000 to advise the President on a variety of policy and technical functions required to implement and effectively manage the new compensation program. Key functions of the Advisory Board include providing advice on the development of probability of causation guidelines which have been promulgated by the Department of Health and Human Services (HHS) as a final rule, advice on methods of dose reconstruction which have also been promulgated by HHS as a final rule, advice on the scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program, and advice on petitions to add classes of workers to the Special Exposure Cohort (SEC). In December 2000, the President delegated responsibility for funding, staffing, and operating the Advisory Board to HHS, which subsequently delegated this authority to the CDC. NIOSH implements this responsibility for CDC.

The Advisory Board's charter was issued on August 3, 2001, renewed at appropriate intervals, rechartered on March 22, 2020, and will terminate on March 22, 2022.

Purpose: This Advisory Board is charged with (a) providing advice to the Secretary, HHS, on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS, on the scientific validity and quality of dose reconstruction efforts performed for this program; and (c) upon request by the Secretary, HHS, advising the Secretary on whether there is a class of employees at any Department of Energy facility

who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood that such radiation doses may have endangered the health of members of this class.

Matters to Be Considered: The agenda will include discussions on the following: NIOSH Program Update; Department of Labor Program Update; Department of Energy Program Update; SEC Petitions Update; Completed Site Profile Review for W.R Grace Company (Erwin, Tennessee); Update on Site Profile Review for Idaho National Laboratory Site (Burial Ground and other Exposure Scenarios), and Hanford (Richland, Washington); SEC Petition Reviews for Superior Steel (Carnegie, Pennsylvania; 1952-2957), and Reduction Pilot Plant (Huntington, West Virginia; 1976-1978), and a Board Work Session. Agenda items are subject to change as priorities dictate.

Meeting Information: The USA toll-free dial-in number is 1-866-659-0537; the pass code is 9933701. Web conference by Skype: meeting Connection: <https://webconf.cdc.gov/zab6/yzdq02pl?sl=1>.

Public Participation

Comments received are part of the public record and are subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. CDC will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign. CDC will carefully consider all comments submitted into the docket. CDC does not accept comment by email.

Oral Public Comment: An oral public comment session will be held on August 26, 2020 at 5:15 p.m., EDT and conclude at 6:15 p.m., EDT or following the final call for public comment, whichever comes first.

Written Public Comment: Written comments will also be accepted from those unable to attend the public session per the instructions provided in the address section above. Written comments received in advance of the meeting will be included in the official record of the meeting.

The Director, Strategic Business Initiatives Unit, Office of the Chief

Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2020-15028 Filed 7-10-20; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-D-2494]

Select Updates for Peripheral Vascular Atherectomy Devices—Premarket Notification Submissions; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled “Select Updates for Peripheral Vascular Atherectomy Devices—Premarket Notification (510(k)) Submissions.” FDA has developed this draft guidance to propose select updates to certain sections of the existing FDA guidance document “Peripheral Vascular Atherectomy Devices—Premarket Notification (510(k)) Submissions.” This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by September 11, 2020 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are

solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2018-D-2494 for "Select Updates for Peripheral Vascular Atherectomy Devices—Premarket Notification (510(k)) Submissions." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management

Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled "Select Updates for Peripheral Vascular Atherectomy Devices—Premarket Notification (510(k)) Submissions" to the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT:

Jhumur Banik, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2223, Silver Spring, MD 20993-0002, 240-402-5239.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has developed this draft guidance to propose select updates to the FDA guidance document "Peripheral Vascular Atherectomy Devices—Premarket Notification (510(k)) Submissions." The existing guidance on atherectomy devices remains in effect, in its current form, until this draft guidance is finalized. FDA intends to incorporate this draft

guidance into one final guidance document after obtaining and considering public comment on these select updates. FDA does not intend to substantively change the sections of the existing atherectomy guidance that are not affected by this select update.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on "Select Updates for Peripheral Vascular Atherectomy Devices—Premarket Notification (510(k)) Submissions." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products>. This guidance document is also available at <https://www.regulations.gov>. Persons unable to download an electronic copy of "Select Updates for Peripheral Vascular Atherectomy Devices—Premarket Notification (510(k)) Submissions" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 19047 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521). The collections of information in the following FDA regulations have been approved by OMB as listed in the following table:

21 CFR part or guidance	Topic	OMB control No.
807, subpart E	Premarket notification.	0910-0120
820	Quality System Regulations.	0910-0073

Dated: July 8, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–15081 Filed 7–10–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–0358]

Cancer Clinical Trial Eligibility Criteria: Minimum Age Considerations for Inclusion of Pediatric Patients; Guidance for Industry and Institutional Review Boards; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry and institutional review boards (IRBs) entitled “Cancer Clinical Trial Eligibility Criteria: Minimum Age Considerations for Inclusion of Pediatric Patients.” This guidance is one in a series of guidances that provide recommendations regarding eligibility criteria for clinical trials of drugs or biological products regulated by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) for the treatment of cancer. Specifically, this guidance includes recommendations on the inclusion of pediatric patients (*i.e.*, children and adolescents) in clinical trials for cancer treatments. This guidance finalizes the draft guidance entitled “Cancer Clinical Trial Eligibility Criteria: Minimum Age for Pediatric Patients” that published on March 13, 2019.

DATES: The announcement of the guidance is published in the **Federal Register** on July 13, 2020.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your

comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions
Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2019–D–0358 for “Cancer Clinical Trial Eligibility Criteria: Minimum Age Considerations for Inclusion of Pediatric Patients.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Julia Beaver, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2100, Silver Spring, MD 20993–0002, 240–402–0489; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry and IRBs entitled “Cancer Clinical Trial Eligibility Criteria: Minimum Age Considerations for Inclusion of Pediatric Patients.” This guidance provides

recommendations on the inclusion of pediatric patients in clinical trials of drugs or biological products regulated by CDER and CBER for the treatment of cancer.

A clinical trial's eligibility criteria (for inclusion and exclusion) are essential components of the trial, defining the characteristics of the study population. Because there is variability in investigational drugs and trial objectives, eligibility criteria should be developed, taking into consideration the mechanism of action of the drug, the targeted disease or patient population, the anticipated safety of the investigational drug, the availability of adequate safety data, and the ability to recruit trial participants from the patient population to meet the objectives of the clinical trial. However, some eligibility criteria have become commonly accepted over time or used as a template across trials without clear scientific or clinical rationale. Unnecessarily restrictive eligibility criteria may slow patient accrual, limit patients' access to clinical trials, and lead to trial results that do not fully represent treatment effects in the patient population that will ultimately use the drug. Broadening cancer trial eligibility criteria can maximize the generalizability of trial results and the ability to understand the therapy's benefit-risk profile across the patient population likely to use the drug in clinical practice and should be considered to avoid jeopardizing patient safety. Early evaluation and development of potentially effective drugs, particularly targeted drugs, in pediatric patients may provide information on safe and effective use, therefore reducing risks associated with off label use, and accelerate the development of effective, innovative therapies for pediatric patients.

The guidance includes recommendations regarding minimum age eligibility criteria and addresses specific situations in which the inclusion of children (for the purposes of this guidance, ages 2 years to younger than 12 years) and adolescents (for the purposes of this guidance, ages 12 years to 17 years) is appropriate in cancer trials (*i.e.*, based on disease biology and clinical course, molecular target of the investigational drug, and/or its molecular mechanism). In addition, the guidance includes ethical and regulatory considerations for including pediatric patients in such trials.

In the **Federal Register** of March 13, 2019 (84 FR 9130), FDA announced the availability of the draft guidance entitled "Cancer Clinical Trial Eligibility Criteria: Minimum Age for Pediatric Patients." FDA received

comments and considered those comments as the guidance was finalized. The final guidance recommends specific issues to discuss with FDA and provides additional recommendations for providing care in pediatric oncology trials. In addition, the final guidance includes additional information for clarification, for example regarding types of evidence that could support inclusion of children and dosing considerations in early phase trials.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on "Cancer Clinical Trial Eligibility Criteria: Minimum Age Considerations for Inclusion of Pediatric Patients." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved FDA collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR 201.56 and 201.57 have been approved under OMB control number 0910–0572.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, or <https://www.regulations.gov>.

Dated: July 7, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–14998 Filed 7–10–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–0363]

Cancer Clinical Trial Eligibility Criteria: Patients With Human Immunodeficiency Virus, Hepatitis B Virus, or Hepatitis C Virus Infections; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled "Cancer Clinical Trial Eligibility Criteria: Patients with HIV, Hepatitis B Virus, or Hepatitis C Virus Infections." This guidance is one in a series of guidances that provide recommendations regarding eligibility criteria for clinical trials of drugs or biological products regulated by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) for the treatment of cancer. Specifically, this guidance includes recommendations on the inclusion of patients with human immunodeficiency virus (HIV), hepatitis B virus (HBV) infections, and hepatitis C virus (HCV) infections. Exclusion of patients with HIV, HBV, or HCV infections from cancer clinical trials remains common in most studies of investigational drugs. Expanding cancer clinical trial eligibility to be more inclusive of patients with HIV, HBV, or HCV infections is justified in many cases and may accelerate the development of effective therapies in cancer patients with these chronic infections. This guidance finalizes the draft guidance of the same title that published on March 13, 2019.

DATES: The announcement of the guidance is published in the **Federal Register** on July 13, 2020.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are

solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2019-D-0363 for "Cancer Clinical Trial Eligibility Criteria: Patients with HIV, Hepatitis B Virus, or Hepatitis C Virus Infections." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Julia Beaver, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2100, Silver Spring, MD 20993-0002, 240-402-0489; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Cancer Clinical Trial Eligibility Criteria: Patients with HIV, Hepatitis B Virus, or

Hepatitis C Virus Infections." This guidance provides recommendations on the inclusion of patients with HIV, HBV, and HCV infections in clinical trials of drugs or biological products regulated by CDER and CBER for the treatment of cancer.

A clinical trial's eligibility criteria (for inclusion and exclusion) are essential components of the trial, defining the characteristics of the study population. Because there is variability in investigational drugs and trial objectives, eligibility criteria should be developed taking into consideration the mechanism of action of the drug, the targeted disease or patient population, the anticipated safety of the investigational drug, the availability of adequate safety data, and the ability to recruit trial participants from the patient population to meet the objectives of the clinical trial. However, some eligibility criteria have become commonly accepted over time or used as a template across trials without clear scientific or clinical rationale. Unnecessarily restrictive eligibility criteria may slow patient accrual, limit patients' access to clinical trials, and lead to trial results that do not fully represent treatment effects in the patient population that will ultimately use the drug. Broadening cancer trial eligibility criteria can maximize the generalizability of trial results and the ability to understand the therapy's benefit-risk profile across the patient population likely to use the drug in clinical practice and should be considered to avoid jeopardizing patient safety.

The guidance recommends that eligibility criteria regarding patients with HIV, HBV, or HCV infections address requirements regarding relevant concurrent antiviral and other therapies (e.g., antibiotic prophylaxis) and degree of immunocompetence appropriate for a given cancer, investigational drug, and intended use population. The recommendations for eligibility criteria for patients with cancer and concurrent HIV infection are focused on evaluation of immune function and HIV therapy. The recommendations for eligibility criteria for cancer patients with evidence of chronic HBV or with history of chronic HCV or virologically suppressed on HCV treatment are focused on liver-related laboratories and HBV/HCV therapy.

In the **Federal Register** of March 13, 2019 (84 FR 9130), FDA announced the availability of the draft guidance of the same title. FDA received comments and considered those comments as the guidance was finalized. The final guidance includes additional detail on the recommendations regarding

eligibility criteria related to HBV and HCV therapy, additional references in the appendices for patients with HBV and HCV in cancer trials, and clarifications.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on "Cancer Clinical Trial Eligibility Criteria: Patients with HIV, Hepatitis B Virus, or Hepatitis C Virus Infections." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved FDA collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR 201.56 and 201.57 have been approved under OMB control number 0910–0572.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information/biologics/guidances>, or <https://www.regulations.gov>.

Dated: July 7, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–14995 Filed 7–10–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–0357]

Cancer Clinical Trial Eligibility Criteria: Brain Metastases; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled "Cancer

Clinical Trial Eligibility Criteria: Brain Metastases." This guidance is one in a series of guidances that provide recommendations regarding eligibility criteria for clinical trials of drugs or biological products regulated by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) for the treatment of cancer. Specifically, this guidance includes recommendations regarding the inclusion of patients with brain metastases. This guidance finalizes the draft guidance of the same title that published on March 13, 2019.

DATES: The announcement of the guidance is published in the **Federal Register** on July 13, 2020.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and

identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA–2019–D–0357 for "Cancer Clinical Trial Eligibility Criteria: Brain Metastases." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New

Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Julia Beaver, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2100, Silver Spring, MD 20993-0002, 240-402-0489; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Cancer Clinical Trial Eligibility Criteria: Brain Metastases." This guidance provides recommendations on the inclusion of patients with brain metastases in clinical trials of drugs or biological products regulated by CDER and CBER for the treatment of cancer.

A clinical trial's eligibility criteria (for inclusion and exclusion) are essential components of the trial, defining the characteristics of the study population. Because there is variability in investigational drugs and trial objectives, eligibility criteria should be developed taking into consideration the mechanism of action of the drug, the targeted disease or patient population, the anticipated safety of the investigational drug, the availability of adequate safety data, and the ability to recruit trial participants from the patient population to meet the objectives of the clinical trial. However, some eligibility criteria have become commonly accepted over time or used as a template across trials without clear scientific or clinical rationale. Unnecessarily restrictive eligibility criteria may slow patient accrual, limit patients' access to clinical trials, and lead to trial results that do not fully represent treatment effects in the patient population that will ultimately use the drug. Broadening cancer trial eligibility criteria can maximize the generalizability of trial results and the ability to understand the therapy's benefit-risk profile across the

patient population likely to use the drug in clinical practice and should be considered to avoid jeopardizing patient safety.

Patients with brain metastases have historically been excluded from clinical trials due to concerns of poor functional status, shortened life expectancy, or increased risk of toxicity. Given the prevalence of brain metastases in patients with cancer, their systematic exclusion from clinical trials may result in the assessment of an investigational drug's efficacy or safety in a trial population that is not fully representative of the patient population that will be prescribed the drug in clinical practice. The guidance includes recommendations regarding eligibility criteria for patients with brain metastases, as well as recommendations specific to patients with treated/stable metastases, active metastases, and leptomeningeal metastases.

The recommendations in this guidance do not apply to trials designed specifically to assess the safety and efficacy of investigational drugs for the treatment of primary brain cancers (e.g., glioblastoma) or brain metastases.

In the **Federal Register** of March 13, 2019 (84 FR 9127), FDA announced the availability of the draft guidance of the same title. FDA received comments and considered those comments as the guidance was finalized. The final guidance includes general considerations and general approaches for including patients with the different types of brain metastases described in the guidance. The final guidance includes clarifications, for example regarding the description of the types of metastases and the recommendations for inclusion of patients with the different types of metastases and the recommendation for exclusion of patients with brain metastases and a history of seizures in trials for drugs with the potential to lower seizure threshold.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on "Cancer Clinical Trial Eligibility Criteria: Brain Metastases." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved FDA collections of information. These collections of information are subject to review by the

Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910-0014; the collections of information in 21 CFR 201.56 and 201.57 have been approved under OMB control number 0910-0572.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, or <https://www.regulations.gov>.

Dated: July 7, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020-14997 Filed 7-10-20; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-D-0359]

Cancer Clinical Trial Eligibility Criteria: Patients With Organ Dysfunction or Prior or Concurrent Malignancies; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled "Cancer Clinical Trial Eligibility Criteria: Patients With Organ Dysfunction or Prior or Concurrent Malignancies." This guidance is one in a series of guidances that provide recommendations regarding eligibility criteria for clinical trials of drugs or biological products regulated by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) for the treatment of cancer. Specifically, this guidance includes recommendations on the inclusion of patients with organ dysfunction or with prior or concurrent malignancies. This guidance finalizes the draft guidance of the same title that published on March 13, 2019.

DATES: The announcement of the guidance is published in the **Federal Register** on July 13, 2020.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2019-D-0359 for "Cancer Clinical Trial Eligibility Criteria: Patients with Organ Dysfunction or Prior or Concurrent Malignancies." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Julia Beaver, Center for Drug Evaluation and Research, Food and Drug

Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2100, Silver Spring, MD 20993-0002, 240-402-0489; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Cancer Clinical Trial Eligibility Criteria: Patients with Organ Dysfunction or Prior or Concurrent Malignancies." This guidance provides recommendations on the inclusion of patients with organ dysfunction or prior or concurrent malignancies in clinical trials of drugs or biological products regulated by CDER and CBER for the treatment of cancer.

A clinical trial's eligibility criteria (for inclusion and exclusion) are essential components of the trial, defining the characteristics of the study population. Because there is variability in investigational drugs and trial objectives, eligibility criteria should be developed taking into consideration the mechanism of action of the drug, the targeted disease or patient population, the anticipated safety of the investigational drug, the availability of adequate safety data, and the ability to recruit trial participants from the patient population to meet the objectives of the clinical trial. However, some eligibility criteria have become commonly accepted over time or used as a template across trials without clear scientific or clinical rationale. Unnecessarily restrictive eligibility criteria may slow patient accrual, limit patients' access to clinical trials, and lead to trial results that do not fully represent treatment effects in the patient population that will ultimately use the drug. Broadening cancer trial eligibility criteria can maximize the generalizability of trial results and the ability to understand the therapy's benefit-risk profile across the patient population likely to use the drug in clinical practice and should be considered to avoid jeopardizing patient safety.

The recommendations in this guidance for clinical trial eligibility criteria for patients with organ dysfunction focus on renal function, cardiac function, and hepatic function. This guidance also includes recommendations for eligibility criteria for patients with cancer who have prior or concurrent malignancies.

In the **Federal Register** of March 13, 2019 (84 FR 9129), FDA announced the

availability of the draft guidance of the same title. FDA received comments and considered those comments as the guidance was finalized. The final guidance clarifies the recommendations regarding eligibility criteria related to renal function, cardiac function, and hepatic function. For example, recommendations regarding the equation used to assess renal function for eligibility were clarified and recommendations regarding population pharmacokinetic analyses of patients with renal impairment were added. In addition, recommendations regarding QTc prolongation were clarified and the recommendation on patients with asymptomatic elevations in unconjugated bilirubin was removed because it is out of the scope of organ dysfunction.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on "Cancer Clinical Trial Eligibility Criteria: Patients with Organ Dysfunction or Prior or Concurrent Malignancies." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved FDA collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR 201.56 and 201.57 have been approved under OMB control number 0910–0572.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, or <https://www.regulations.gov>.

Dated: July 7, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–14996 Filed 7–10–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1500]

Food and Drug Administration Hiring and Retention Interim Assessment; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is holding a virtual meeting entitled "FDA Hiring and Retention Interim Assessment" and an opportunity for public comment. The topic to be discussed is FDA's hiring and retention interim assessment which was an independent assessment performed by Booz Allen Hamilton, published on June 5, 2020. This public meeting will take place virtually due to extenuating circumstances and will be held by webcast only.

DATES: The public meeting will be held on July 30, 2020, from 9 a.m. to noon. Submit either electronic or written comments on this public meeting by September 30, 2020. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or by September 30, 2020. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 30, 2020. 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–2020–N–1500 "FDA Hiring and Retention Interim Assessment; Public Meeting; Request for 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, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Patricia Stewart, Office of Operations, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993; 301-796-4735, patricia.stewart@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is holding a public meeting to share high-level findings from a recently-completed interim assessment of FDA’s hiring process, conducted by a qualified, independent contractor with expertise in assessing transformation of human resources operations. FDA recognizes that the critical work to protect public health is made possible in part by the Agency’s ability to attract and retain a talented, diverse, and dedicated workforce. As FDA continues to fulfil its strategic mission, it is imperative that the Agency identify and leverage the talent, skills, and diversity within—and outside of—the Agency.

These priorities are reflected in FDA’s plan to enhance its hiring and retention programs; recruit qualified candidates with diverse backgrounds, experiences, and talents; provide internal development opportunities; and further enhance the Agency’s ability to nurture a supportive and fair work environment. The public meeting will provide an update on FDA’s progress toward PDUFA (Prescription Drug User Fee Act) and BsUFA (Biosimilar User Fee Act) user fee hiring and retention commitments and solicit input on actions with regards to the hiring process. To view the evaluation assessment report, please visit here: <https://www.fda.gov/industry/prescription-drug-user-fee-amendments/>

fda-interim-hiring-and-retention-assessment-report.

This public meeting is intended to meet performance commitments included in PDUFA VI and BsUFA II. These user fee programs were reauthorized as part of the FDA Reauthorization Act of 2017 (FDARA) (Pub. L. 115-52) signed by the President on August 18, 2017. The complete set of performance goals for each program are available at:

- PDUFA VI program: <https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM511438.pdf> and
- BsUFA II program: <https://www.fda.gov/downloads/forindustry/userfees/biosimilaruserfeeactsufaf/ucm521121.pdf>.

II. Topics for Discussion at the Public Meeting

This public meeting will provide FDA the opportunity to update interested public stakeholders on topics related to the FDA hiring and retention programs. Booz Allen Hamilton will present their findings and recommendations that are outlined in the Interim Hiring and Retention Assessment report and FDA will provide an update on the Agency’s progress in addressing the findings from the independent third-party evaluation that was published June 5, 2020. To view the evaluation assessment report, please visit here: <https://www.fda.gov/industry/prescription-drug-user-fee-amendments/fda-interim-hiring-and-retention-assessment-report>

III. Participating in the Public Meeting

Registration: To register for the public meeting, please visit the following website to register: <https://www.eventbrite.com/e/fda-hiring-and-retention-interim-assessment-public-meeting-registration-106125275556>. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Persons interested in attending this public meeting must register by July 28, 2020, 11:59 p.m. Eastern Time.

If you need special accommodations due to a disability (e.g. Closed Captioning), please contact Patricia Stewart (see **FOR FURTHER INFORMATION CONTACT**) no later than July 22, 2020.

Requests for Oral Presentations: During online registration you may indicate if you wish to present during a public comment session, and which topic(s) you wish to address. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their

presentations and request time for a joint presentation. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by July 27, 2020. All requests to make oral presentations must be received by July 22, 2020, 11:59 p.m. Eastern Time. If selected for presentation, any presentation materials must be emailed to Patricia Stewart (see **FOR FURTHER INFORMATION CONTACT**) no later than July 28, 2020. No commercial or promotional material will be permitted to be presented at the public meeting.

Streaming Webcast of the Public Meeting: The webcast for this public meeting is at <https://collaboration.fda.gov/fdapublicmeeting073020/>.

If you have never attended a Connect Pro event before, test your connection at https://collaboration.fda.gov/common/help/en/support/meeting_test.htm. To get a quick overview of the Connect Pro program, visit https://www.adobe.com/go/connectpro_overview. FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at <https://www.regulations.gov>. It may be viewed at the Dockets Management Staff (see **ADDRESSES**).

Dated: July 7, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020-14980 Filed 7-10-20; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-E-4463]

Determination of Regulatory Review Period for Purposes of Patent Extension; XEPI

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for XEPI and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S.

Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by September 11, 2020. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by January 11, 2021. See “Petitions” in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before September 11, 2020. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 11, 2020. 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–2018–E–4463 for “Determination of Regulatory Review Period for Purposes of Patent Extension; XEPI.” 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 § 10.20 (21 CFR 10.20) and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.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: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product’s regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA’s determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product, XEPI (ozenoxacin). XEPI is indicated for topical treatment of impetigo due to *Staphylococcus aureus* or *Streptococcus pyogenes* in adult and pediatric patients 2 months of age and older. Subsequent to this approval, the USPTO received a patent term restoration application for XEPI (U.S. Patent No. 6,335,447) from Toyama Chemical Co., Ltd., and the USPTO requested FDA’s assistance in determining the patent’s eligibility for patent term restoration. In a letter dated

May 13, 2019, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of XEPI represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for XEPI is 2,819 days. Of this time, 2,282 days occurred during the testing phase of the regulatory review period, while 537 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* March 26, 2010. FDA has verified the applicant's claim that the date the investigational new drug application became effective was March 26, 2010.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* June 23, 2016. FDA has verified the applicant's claim that the new drug application (NDA) for XEPI (NDA 208945) was initially submitted on June 23, 2016.

3. *The date the application was approved:* December 11, 2017. FDA has verified the applicant's claim that NDA 208945 was approved on December 11, 2017.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,678 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: Must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA

investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to <https://www.regulations.gov> at Docket No. FDA-2013-S-0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: July 7, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020-15013 Filed 7-10-20; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-3708]

InvaGen Pharmaceuticals, Inc.; Withdrawal of Approval of an Abbreviated New Drug Application for Trandolapril Tablets

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA or Agency) Center for Drug Evaluation and Research (CDER) is withdrawing approval of an abbreviated new drug application (ANDA) for trandolapril tablets. The basis for the withdrawal is that the holder of the ANDA has repeatedly failed to submit the required data to support a finding of bioequivalence for this ANDA. The holder of the ANDA has waived its opportunity for a hearing.

DATES: Withdrawal of approval is applicable July 13, 2020.

FOR FURTHER INFORMATION CONTACT:

Jennifer Forde, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6228, Silver Spring, MD 20993-0002, 301-348-3035.

SUPPLEMENTARY INFORMATION: FDA's Office of Generic Drugs (OGD) approved ANDA 078320, held by InvaGen Pharmaceuticals, Inc. (InvaGen), for a generic version of trandolapril tablets, 1 milligram (mg), 2 mg, and 4 mg, under the requirements of section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) and FDA's implementing regulations. OGD

approved ANDA 078320 on June 12, 2007. In a notice published in the **Federal Register** of October 28, 2019 (84 FR 57736), CDER notified InvaGen of CDER's proposal to issue an order, under section 505(e) of the FD&C Act and § 314.150 (21 CFR 314.150), withdrawing approval of ANDA 078320 and all amendments and supplements to it on the grounds that InvaGen has failed to submit the required bioequivalence data necessary to demonstrate the bioequivalence of its drug product. In its October 28, 2019, notice of opportunity for a hearing (NOOH), CDER provided InvaGen with an opportunity to request a hearing to show why approval of ANDA 078320 should not be withdrawn.

As noted in the October 28, 2019, NOOH, FDA issued a letter to InvaGen on August 9, 2011, regarding ANDA 078320 because this drug product application was supported by bioequivalence studies with the bioanalytical analysis conducted by Cetero Research at the Houston, TX, site between April 1, 2005, and June 15, 2010. As FDA noted in its August 9, 2011, correspondence, inspection findings regarding Cetero Research's bioequivalence studies raised significant concerns about the validity of the reported results of the analytical studies conducted between April 2005 and June 2010 in support of drug applications, and as such, steps needed to be taken to demonstrate the bioequivalence of InvaGen's drug product approved under ANDA 078320. FDA informed InvaGen that ANDA 078320 needed to be supplemented by conducting new bioequivalence studies or re-assaying the samples from the original bioequivalence study. FDA recommended to InvaGen that the results of the requested bioequivalence studies or re-assays be submitted to ANDA 078320 within 6 months of the date of the August 9, 2011, letter.

Although the October 28, 2019, NOOH states that FDA did not receive a response from InvaGen to the August 9, 2011, letter from FDA, upon further review, additional correspondence between InvaGen and FDA has been identified. In a letter to FDA dated August 12, 2011, InvaGen requested a 6-month extension for submitting bioequivalence study data for ANDA 078320. On September 21, 2011, FDA issued a letter to InvaGen acknowledging InvaGen's August 12, 2011, request for an extension. In a letter to FDA dated September 6, 2012, InvaGen requested an additional 6-month extension to submit bioequivalence study data; and in a letter to FDA dated October 4, 2012,

InvaGen requested that FDA consider and grant InvaGen's request for an extension. On October 23, 2012, FDA issued a letter to InvaGen granting InvaGen an extension until March 2013 to submit bioequivalence study data. InvaGen has not submitted the bioequivalence study data.

The additional correspondence noted above that was not identified in the October 28, 2019, NOOH does not alter the underlying basis of the October 28, 2019, NOOH. In the absence of information showing bioequivalence between the generic drug at issue and the reference listed drug (RLD), there is no basis for concluding that the Agency's finding of safety and efficacy supporting approval of the RLD can be used as a basis to support approval of the generic drug. Section 505(e) of the FD&C Act provides FDA the authority to withdraw approval of an ANDA in these circumstances.

In correspondence dated November 7, 2019, InvaGen requested withdrawal of the approval of ANDA 078320 under § 314.150(d). Because this application withdrawal is effectuated through the NOOH process (see 84 FR 57736), InvaGen's request to withdraw approval under § 314.150(d) is moot. In the November 7, 2019, correspondence, InvaGen also waived its opportunity for a hearing under § 314.150(a).

FDA finds that InvaGen has repeatedly failed to submit the required data to support a finding of bioequivalence for ANDA 078320. In addition, under 21 CFR 314.200, FDA finds that InvaGen has waived any contentions concerning the legal status of the drug product. Therefore, under section 505(e) of the FD&C Act, approval of ANDA 078320, and all amendments and supplements thereto, is withdrawn (see **DATES**). Introduction or delivery for introduction of this drug product into interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the FD&C Act (21 U.S.C. 355(a), 331(d))).

Dated: July 7, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020-14981 Filed 7-10-20; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-E-4404]

Determination of Regulatory Review Period for Purposes of Patent Extension; **CARTIVA**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for **CARTIVA** and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that medical device.

DATES: Anyone with knowledge that any of the dates as published (in **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by September 11, 2020. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by January 11, 2021. See "Petitions" in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before September 11, 2020. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 11, 2020. 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-2018-E-4404 for "Determination of Regulatory Review Period for Purposes of Patent Extension; **CARTIVA**." 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 § 10.20 (21 CFR 10.20) and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.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: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301-796-3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product’s regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award

(half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA’s determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA has approved for marketing the medical device CARTIVA. CARTIVA is approved for use in the treatment of patients with painful degenerative or post-traumatic arthritis (hallux limitus or hallux rigidus) in the first metatarsophalangeal joint with or without the presence of mild hallux valgus. Subsequent to this approval, the USPTO received a patent term restoration application for CARTIVA (U.S. Patent No. 5,981,826) from Cartiva, Inc., and the USPTO requested FDA’s assistance in determining this patent’s eligibility for patent term restoration. In a letter dated June 12, 2019, FDA advised the USPTO that this medical device had undergone a regulatory review period and that the approval of CARTIVA represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product’s regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for CARTIVA is 2,407 days. Of this time, 1,979 days occurred during the testing phase of the regulatory review period, while 428 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date a clinical investigation on humans involving the device was begun:* November 30, 2009. The applicant claims that the date of the beginning of the testing phase of the regulatory review period was October 27, 2009. However, records indicate that the period beginning on the date a clinical investigation on humans involving the device was begun was November 30, 2009, which represents the beginning of the testing phase of the regulatory review period.

2. *The date an application was initially submitted with respect to the device under section 515 of the FD&C Act (21 U.S.C. 360e):* May 1, 2015. The applicant claims May 13, 2015, as the date the premarket approval application (PMA) for CARTIVA (PMA 150017) was initially submitted. However, FDA records indicate that PMA 150017 was submitted on May 1, 2015.

3. *The date the application was approved:* July 1, 2016. FDA has verified the applicant’s claim that PMA 150017

was approved on July 1, 2016. This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,429 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: Must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to <https://www.regulations.gov> at Docket No. FDA-2013-S-0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: July 7, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020-15011 Filed 7-10-20; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. FDA-2016-N-2836]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Donor Risk Assessment Questionnaire for the Food and Drug Administration/National Heart, Lung, and Blood Institute-Sponsored Transfusion-Transmissible Infections Monitoring System—Risk Factor Elicitation**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 August 12, 2020.

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 0910-0841. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRASStaff@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.

Donor Risk Assessment Questionnaire for FDA/National Heart, Lung, and Blood Institute (NHLBI)-Sponsored Transfusion-Transmissible Infections Monitoring System (TTIMS)—Risk Factor Elicitation (RFE)*OMB Control Number 0910-0841—Revision*

FDA intends to interview blood donors to collect risk factor information associated with testing positive for a TTI. This collection of information is part of a larger initiative called TTIMS, which is a collaborative project funded by FDA, the NHLBI of the National Institutes of Health (NIH), and the Department of Health and Human Services (HHS) Office of the Assistant Secretary of Health with input from other Agencies in HHS, including the Centers for Disease Control and Prevention (CDC). FDA will use these scientific data collected through such interview-based risk factor elicitation of blood donors to monitor and help ensure the safety of the U.S. blood supply.

Previous assessments of risk factor profiles among blood donors found to be positive for human immunodeficiency virus (HIV) were funded by CDC for approximately 10 years after implementation of HIV serologic screening of blood donors in the mid-1980s, whereas studies of Hepatitis C virus (HCV) seropositive donors, funded by NIH, were conducted in the early 1990s. Information on current risk factors in blood donors as assessed using analytical study designs was next evaluated by the Transfusion-Transmitted Retrovirus and Hepatitis Virus Rates and Risk Factors Study conducted by the NHLBI Retrovirus Epidemiology Donor Study-II (REDS-II) approved under OMB control number 0925-0630. Through a risk factor questionnaire, this study elicited risk factors in blood donors who tested confirmed positive for one of four transfusion-transmissible infections: HIV, HCV, Hepatitis B virus (HBV), and Human T-cell Lymphotropic virus. The study also elicited risk factors from donors who did not have any infections (controls) and compared their responses to those of the donors with confirmed infection (cases). Results from the REDS-II study were published in 2015.

FDA recently revised the currently approved collection instrument for the collection of information and have included recently issued Agency guidance. On April 2, 2020, FDA issued a revised guidance document entitled “Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission

by Blood and Blood Products; Guidance for Industry” dated April 2020 (available at: <https://www.fda.gov/media/92490/download>), which changed the blood donor criterion for men who have sex with men (MSM) from a 12-month deferral to a 3-month deferral since last MSM contact. The impact of this change in the deferral criteria requires a national monitoring effort as part of TTIMS to assess if the relative proportions of risk factors for infection in blood donors have changed following the adoption of the 3-month donor deferral for MSM. We also made a change to the Risk Factor Assessment interview questionnaire to keep the TTIMS interview relevant with the current deferral. TTIMS will use similar procedures as the ones used in the REDS-II study to monitor and evaluate risk factors among HIV-positive donors and recently HCV or HBV infected donors as well as controls.

This study will help identify the specific risk factors for TTI and their prevalence in blood donors and help inform FDA on the proportion of incident (new) infections among all HIV positive blood donors. Donations with incident infections have the greatest potential transmission risk because they could be missed during routine blood screening. The study will help FDA evaluate the effectiveness of screening strategies in reducing the risk of HIV transmission from at-risk donors and to evaluate if there are unexpected consequences associated with the recent change in donor deferral policy such as an increase in HIV incidence among donors. These data also will inform FDA regarding future blood donor deferral policy options to reduce the risk of HIV transmission, including the feasibility of moving from the existing time-based deferrals related to risk behaviors to alternate deferral options, such as the use of individual risk assessments, and to inform the design of potential studies to evaluate the feasibility and effectiveness of such alternative deferral options.

TTIMS will include a comprehensive interview-based epidemiological study of risk factor information for viral infection-positive blood donors at the American Red Cross (ARC), Blood Systems, Inc. (BSI), New York Blood Center (NYBC), and OneBlood that will identify the current predominant risk factors and reasons for virus-positive donations. The TTIMS program establishes a new, ongoing donor hemovigilance capacity that currently does not exist in the United States. Using procedures developed by the REDS-II study, TTIMS will establish this capacity in greater than 50 percent

of all blood donations collected in the country.

As part of the TTIMS project, a comprehensive hemovigilance database will be created that integrates the risk factor information collected through interviews of blood donors with the resulting data from disease marker testing and blood components collected by participating organizations into a research database. Following successful initiation of the risk factor interviews, the TTIMS network is poised to be expanded to include additional blood centers and/or refocused on other safety threats as warranted. In this way, the TTIMS program will maintain standardized, statistically, and scientifically robust processes for applying hemovigilance information across blood collection organizations.

The specific objectives are to:

- Determine current behavioral risk factors associated with all HIV infections, incident HBV, and incident HCV infections in blood donors (including parenteral and sexual risks)

across the participating blood collection organizations using a case-control study design.

- Determine infectious disease marker prevalence and incidence for HIV, HBV, and HCV overall and by demographic characteristics of donors in the majority of blood donations collected in the country. This will be accomplished by forming epidemiological databases consisting of harmonized operational data from ARC, BSI, NYBC, and OneBlood.

- Analyze integrated risk factor and infectious marker testing data concurrently because when taken together these may suggest that blood centers are not achieving the same degree of success in educational efforts to prevent donation by donors with risk behaviors across all demographic groups.

The respondents will be persons who donated blood in the United States and these participants will be defined as cases and controls. The estimated number of respondents is based on an

overall expected participation in the risk factor survey. We estimate a case-to-control ratio of 1:2 (200 to 400) with a 50 percent case enrollment.

In the **Federal Register** of January 8, 2020 (85 FR 922), we published a 60-day notice requesting public comment on the proposed collection of information. We received two comments that were generally supportive of the collection. One comment also contained a specific suggestion that, in analyzing the data after it is collected, we utilize an “underreporting correction factor” identified by the commenter. The comment did not suggest that we make any changes to the Donor Risk Assessment Questionnaire or the information collection requirements. We appreciate the commenter’s interest in the accuracy of the TTIMS and will consider the “underreporting correction factor” identified by the commenter when analyzing the data.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Questionnaire/survey	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Cases and controls ²	600	1	600	0.5 (30 minutes)	300

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

² Cases consist of virus-positive donations and controls represent uninfected donors.

We have adjusted our burden estimate, which has resulted in a decrease to the currently approved burden. Based on experience with this survey, we decreased the average burden per response from 45 to 30 minutes, resulting in a change from 450 to 300 total hours.

Dated: July 7, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–15009 Filed 7–10–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1253 (formerly FDA–1987–N–0054)]

Pentaerythritol Tetranitrate; Final Decision on Proposal To Withdraw Approval From New Drug Applications and Abbreviated New Drug Applications; Availability of Final Decision

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the initial decision of the Administrative Law Judge (ALJ), to withdraw approval of new drug applications (NDAs) and abbreviated new drug applications (ANDAs) for pentaerythritol tetranitrate (PETN), is the final decision of the Commissioner of Food and Drugs (the Commissioner) by operation of law. In the initial decision, the ALJ found that PETN had not been shown to be supported by

substantial evidence consisting of adequate and well-controlled studies to be effective for prophylactic treatment of angina pectoris and ordered the withdrawal of approval for all NDAs and ANDAs. Several parties to the hearing filed exceptions to the ALJ’s initial decision; however, all parties who submitted exceptions have since voluntarily withdrawn them, or FDA has deemed them withdrawn after their associated NDA or ANDA was withdrawn. Consequently, the proceeding is in the same procedural position as if no exceptions to the ALJ’s initial decision had been filed. Therefore, the ALJ’s initial decision has become the final decision of the Commissioner by operation of law.

Applicable Date: This notice is applicable July 13, 2020.

ADDRESSES: For access to the docket, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852 between 9 a.m. and 4 p.m., Monday

through Friday. Publicly available submissions may be seen in the docket.

FOR FURTHER INFORMATION CONTACT:

Rachael Vieder Linowes, Office of the Chief Scientist, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4206, Silver Spring, MD 20993, 240-402-5931.

SUPPLEMENTARY INFORMATION:

I. Background

In 1962, the Federal Food, Drug, and Cosmetic Act (FD&C Act) was amended by the Drug Amendments of 1962 (Pub. L. 87-781), and these amendments provided that new drugs could no longer be approved unless both safety and efficacy had been established for them. As amended, the FD&C Act also required FDA to evaluate drugs approved as safe between 1938 and 1962 to determine whether such drugs were effective and to withdraw approval for any applications where there was not substantial evidence of the drug's effectiveness. The person contesting the withdrawal of the approval had the burden of coming forward with evidence of effectiveness for the drug. FDA's review of these pre-1962 drugs is known as the Drug Efficacy Study Implementation program.

In a notice published in the **Federal Register** of February 25, 1972 (37 FR 4001) available at <https://www.govinfo.gov/content/pkg/FR-1972-02-25/pdf/FR-1972-02-25.pdf>, after evaluating reports received from the National Academy of Sciences/National Research Council, Drug Efficacy Study Group, and other available evidence, FDA classified certain coronary vasodilators containing PETN as "possibly effective" for the management, prophylaxis, or treatment of angina attacks. Parke-Davis, a Division of Warner Lambert Co. (Parke-Davis) submitted data intended to support the effectiveness of single-entity coronary vasodilator drugs containing PETN in the treatment of angina pectoris.

In a notice published in the **Federal Register** of October 15, 1984 (49 FR 40213, available at <https://www.govinfo.gov/content/pkg/FR-1984-10-15/pdf/FR-1984-10-15.pdf>), the Center for Drugs and Biologics (the Center) concluded that, after reviewing all the data previously submitted to support the effectiveness of single-entity coronary vasodilator drugs containing PETN in the treatment of angina pectoris, the data did not constitute substantial evidence of effectiveness for the listed drug products in the treatment of angina pectoris. Further, the Center issued a notice of opportunity for

hearing on a proposal to withdraw approval of 15 total NDAs and ANDAs for certain coronary vasodilators containing PETN.

Multiple manufacturers responded to the notice for opportunity of hearing and submitted requests for hearings. By a notice published in the **Federal Register** of August 26, 1987 (52 FR 32170), available at <https://www.govinfo.gov/content/pkg/FR-1987-08-26/pdf/FR-1987-08-26.pdf>, the Office of the Commissioner granted requests for hearing with respect to seven NDAs and two ANDAs. Following the submission of written testimony and documentary evidence, an ALJ, Daniel J. Davidson, conducted a hearing from October 5-26, 1988. He issued his initial decision on May 10, 1989. The ALJ found that the effectiveness of PETN had not been shown to be supported by substantial evidence and, as a result, ordered that the approval of all affected NDAs and ANDAs be withdrawn.

On July 10, 1989, three parties, Parke-Davis, Jones Medical Industries, Inc. (Jones Medical) (formerly Marion Laboratories, Inc.), and Bolar Pharmaceutical Co., Inc., appealed the ALJ's initial decision by filing exceptions with the Commissioner under 21 CFR 12.125. However, since the three parties submitted their exceptions, FDA has withdrawn approval of all applications held by the three parties, either through withdrawal requests or, after notice and opportunity for hearing, for failure to file annual reports.

The Commissioner now finds that all exceptions have either been withdrawn upon the party's request or are deemed withdrawn. For these reasons, the Commissioner concludes that there are no pending appeals of the ALJ's initial decision. Parke-Davis, by a letter dated June 11, 1996, requested withdrawal of its exceptions. Watson Laboratories (successor to Bolar Pharmaceutical Co.) also submitted a letter dated November 9, 1999, requesting the withdrawal of its exceptions as to its NDA. The letter did not reference its ANDA, but the ANDA was withdrawn under a plea agreement with the United States pursuant to which Bolar Pharmaceutical Co. pled guilty to fraud and admitted to falsifying drug testing records (see July 6, 2016, 56 FR 43928), available at <https://www.govinfo.gov/content/pkg/FR-1991-09-05/pdf/FR-1991-09-05.pdf>). In light of those circumstances, the Commissioner interprets Watson Laboratories' request to withdraw exceptions to apply to both the NDA and the ANDA. When the Center for Drug Evaluation and Research (CDER) withdrew approval of Jones Medical's

NDAs, CDER notified Jones Medical that its appeal in this proceeding was also regarded as withdrawn (see 62 FR 61338, available at <https://www.govinfo.gov/content/pkg/FR-1997-11-17/pdf/97-30148.pdf#page=1>). Given that Jones Medical has never filed an objection to CDER's determination that its appeal and exceptions are regarded as withdrawn, the Commissioner affirms that Jones Medical's appeal and exceptions are deemed withdrawn.

II. Conclusion and Order

Given that the exceptions have all been withdrawn or deemed withdrawn, this proceeding is now in the same procedural posture as if no exceptions had ever been filed. When parties do not file exceptions to the ALJ's initial decision, and the Commissioner does not file a notice of review, the ALJ's initial decision becomes the final decision of the Commissioner (see 21 CFR 12.120(e)). FDA will publish a notice in the **Federal Register** when an initial decision becomes the final decision of the Commissioner without appeal to or review by the Commissioner (see 21 CFR 12.120(f)).

Therefore, the ALJ's initial decision is the final decision of the Commissioner. Pursuant to the findings in the ALJ's initial decision, under section 505(e) of the FD&C Act (21 U.S.C. 355(e)) and under the authority delegated by the Secretary of Health and Human Services, there is a lack of substantial evidence that PETN will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in its labeling for prophylactic treatment of angina pectoris. Distribution of products subject to the initial decision in interstate commerce without an approved application is prohibited and subject to regulatory action (see, e.g., sections 505(a) and 301(d) of the FD&C Act (21 U.S.C. 355(a) and 331(d)).

The full text of the ALJ's initial decision may be seen in the Dockets Management Staff and in this docket (see **ADDRESSES**).

Dated: July 7, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.
[FR Doc. 2020-15010 Filed 7-10-20; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF THE INTERIOR**Fish and Wildlife Service**

[FWS-R2-ES-2020-N069;
FXES11140200000-201-FF02ENEH00]

Receipt of Application for an Incidental Take Permit and Draft Habitat Conservation Plan for Five Species; Texas Parks and Wildlife Department, Balmorhea State Park, Texas; Low-Effect Screening Form for a Categorical Exclusion

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for public comments.

SUMMARY: We, the U.S. Fish and Wildlife Service, have received an application from the Texas Parks and Wildlife Department (TPWD) for an incidental take permit (ITP), accompanied by TPWD's habitat conservation plan (HCP) for the Balmorhea State Park Management Plan. The ITP, which would be granted under the Endangered Species Act, would authorize incidental take of five federally endangered species. A low-effect screening form supporting a categorical exclusion is also available for public review. We request public comment on the ITP application, HCP, and low-effect screening form.

DATES: To ensure consideration, written comments must be received or postmarked on or before August 12, 2020.

ADDRESSES: *Accessing Documents:*
Internet: Low effect screening form and HCP: <https://www.fws.gov/southwest/es/AustinTexas/>.

U.S. Mail: You may obtain the documents at the following addresses. In your request for documents, please reference Balmorhea State Park HCP.

- *Low-effect screening form and HCP:* A limited number of CD-ROM and printed hardcopies are available from Mr. Adam Zerrenner, Field Supervisor, Austin Ecological Services Field Office, Austin, TX, 78758; telephone 512-490-0057.

- *ITP application:* Hardcopies are available from the Regional Director, U.S. Fish and Wildlife Service, P.O. Box 1306, Room 6034, Albuquerque, NM 87103, Attention: Environmental Review Branch.

Submitting Comments: Regarding any of the documents available for review, you may submit written comments by one of the following methods. In your comments, please reference Balmorhea State Park HCP.

- *Email:* FW2_AUES_Consult@fws.gov.

- *U.S. Mail:* Field Supervisor, Austin Ecological Services Field Office, 10711 Burnet Road, Suite 200, Austin, TX 78758; telephone 512-490-0057.

We request that you send comments by only one of the methods described above.

FOR FURTHER INFORMATION CONTACT:

Adam Zerrenner, Field Supervisor, by mail (see above), via phone at 512-490-0057, or via the Federal Relay Service at 800-877-8339.

SUPPLEMENTARY INFORMATION: Under the Endangered Species Act (ESA; 16 U.S.C 1531 *et seq.*), we, the U.S. Fish and Wildlife Service (Service), have received an application from the Texas Parks and Wildlife Department (TPWD) for an incidental take permit (ITP), along with an accompanying habitat conservation plan (HCP) for the Balmorhea State Park Management Plan. If granted, the ITP would authorize incidental take of five federally endangered species resulting from the ongoing management of Balmorhea State Park.

The HCP included with the ITP application is for five endangered species that occur at San Solomon Springs, located at Balmorhea State Park, Balmorhea, Texas. The HCP describes TPWD's plans to minimize and mitigate the effects of the operation and maintenance of the pool at Balmorhea State Park. We have made a preliminary determination that the HCP is eligible for categorical exclusion under the National Environmental Policy Act. The basis for this determination is contained in a low-effect screening form for a categorical exclusion (low-effect screening form), which evaluates the impacts of implementation of the proposed HCP.

We request public comment on the ITP application, HCP, and low-effect screening form.

Background

Section 9 of the ESA and its implementing regulations prohibit the "take" of animal species listed as endangered or threatened. Take is defined under the ESA as to "harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect listed animal species, or to attempt to engage in such conduct" (16 U.S.C. 1538). However, under section 10(a) of the ESA, we may issue permits to authorize the incidental take of threatened and endangered species. "Incidental take" is defined by the ESA as take that is incidental to, and not the purpose of, carrying out an otherwise lawful activity. Regulations governing such take of endangered and threatened species, respectively, are found in the Code of Federal

Regulations at 50 CFR 17.22 and 50 CFR 17.32.

Application

The TPWD has applied to the Service for an ITP under section 10(a)(1)(B) of the ESA. The requested ITP, which would be in effect for a period of 10 years, if granted, would authorize incidental take of the Comanche Springs pupfish (*Cyprinodon elegans*), Pecos gambusia (*Gambusia nobilis*), Phantom tryonia (*Tryonia cheatumi*), diminutive amphipod (*Gammarus hyalleloides*), and Phantom springsnail (*Pyrgulopsis texana*). The proposed incidental take would result from activities associated with otherwise lawful activities, including the ongoing operation and maintenance of the swimming pool at Balmorhea State Park. The HCP and associated permit would implement a voluntary conservation plan to protect and conserve five aquatic endangered species occurring at Balmorhea State Park. The conservation strategy includes conservation measures to minimize and mitigate direct and indirect impacts to the five species and their aquatic habitat and an adaptive management program. If approved, the ITP would be for a 10-year period following permit issuance and would authorize incidental take of the five species, all of which are listed as endangered under the ESA.

Proposed Action

The proposed action involves the issuance of an ITP by the Service for the covered activities in the permit area, under section 10(a)(1)(B) of the ESA. The ITP would cover "take" of the covered species associated with operation and maintenance of the Balmorhea State Park including the swimming pool, pupfish refugium, and Hubbs Ciénega. The applicant will fully implement the HCP if approved by the Service. The terms of the HCP and ITP will also ensure that incidental take will not appreciably reduce the likelihood of the survival and recovery of the species in the wild.

Next Steps

We will evaluate the HCP and comments we receive on the low-effect screening form to determine whether the ITP application meets the requirements of section 10(a) of the ESA. We will also evaluate whether issuance of a section 10(a)(1)(B) permit would comply with section 7 of the ESA by conducting an intra-Service section 7 consultation. We will use the results of this consultation, in combination with the above findings, in our final analysis to determine whether to issue an ITP. If

all necessary requirements are met, we will issue the ITP to the applicant.

Public Availability of Comments

Written comments we receive become part of the public record associated with this action. 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 request in your comment that we withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so. We will not consider anonymous comments. All submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public disclosure in their entirety.

Authority

We provide this notice under section 10(c) of the ESA and its implementing regulations (50 CFR 17.22 and 17.32) and the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) and its implementing regulations (40 CFR 1506.6).

Amy L. Lueders,

Regional Director, Albuquerque, New Mexico.

[FR Doc. 2020-14982 Filed 7-10-20; 8:45 am]

BILLING CODE 4333-15-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[20X.LLAZ921000

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Notice of Filing of Plats of Survey; Arizona

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of official filing.

SUMMARY: The plats of survey of the following described land are scheduled to be officially filed 30 days after the date of this publication in the Bureau of Land Management (BLM), Arizona State Office, Phoenix, Arizona. The surveys announced in this notice are necessary for the management of lands administered by the agency indicated.

ADDRESSES: These plats will be available for inspection in the Arizona State Office, Bureau of Land Management, One North Central Avenue, Suite 800, Phoenix, Arizona, 85004-4427. Protests

of any of these surveys should be sent to the Arizona State Director at the above address.

FOR FURTHER INFORMATION CONTACT:

Geoffrey Graham, Chief Cadastral Surveyor of Arizona; (623) 580-5579; ggraham@blm.gov. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1-800-877-8339 to contact the above individual during normal business hours. The FRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION:

The Gila and Salt River Meridian, Arizona:

The plat, in four sheets, representing the dependent resurvey of a portion of the east boundary, portions of the subdivisional lines, portions of Mineral Survey Nos. 4352, 4360, 4417A, 4417B, 4448 and 4449, and the subdivision of certain sections, Township 11 North, Range 14 East, accepted April 27, 2020, for Group 1188, Arizona.

This plat was prepared at the request of the United States Forest Service.

The plat, in two sheets, representing the dependent resurvey of a portion of the subdivisional lines, and portions of Mineral Survey Nos. 4360, 4361 and 4448, and the subdivision of sections 18 and 19, fractional Township 11 North, Range 15 East, accepted April 27, 2020, for Group 1188, Arizona.

This plat was prepared at the request of the United States Forest Service.

A person or party who wishes to protest against any of these surveys must file a written notice of protest within 30 calendar days from the date of this publication with the Arizona State Director, Bureau of Land Management, stating that they wish to protest.

A statement of reasons for a protest may be filed with the notice of protest to the State Director, or the statement of reasons must be filed with the State Director within 30 days after the protest is filed. Before including your address, or other personal information in your protest, please be aware that your entire protest, 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.

Authority: 43 U.S.C. Chap. 3.

Geoff A. Graham,

Chief Cadastral Surveyor of Arizona.

[FR Doc. 2020-14976 Filed 7-10-20; 8:45 am]

BILLING CODE 4310-32-P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 731-TA-1014 and 1016 (Third Review)]

Polyvinyl Alcohol From China and Japan; Notice of Commission Determination To Conduct Full Five-Year Reviews

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice that it will proceed with full reviews pursuant to the Tariff Act of 1930 to determine whether revocation of the antidumping duty orders on polyvinyl alcohol from China and Japan would be likely to lead to continuation or recurrence of material injury within a reasonably foreseeable time. A schedule for the reviews will be established and announced at a later date.

DATES: July 6, 2020.

FOR FURTHER INFORMATION CONTACT:

Mary Messer (202-205-3193), 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 these reviews may be viewed on the Commission's electronic docket (EDIS) at <https://edis.usitc.gov>.

For further information concerning the conduct of these reviews and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207).

SUPPLEMENTARY INFORMATION: On July 6, 2020, the Commission determined that it should proceed to full reviews in the subject five-year reviews pursuant to section 751(c) of the Tariff Act of 1930

(19 U.S.C. 1675(c)). The Commission found that the domestic interested party group response to its notice of institution (85 FR 18271, April 1, 2020) was adequate and that the respondent interested party group response with respect to Japan was adequate and decided to conduct a full review with respect to the antidumping duty order concerning polyvinyl alcohol from Japan. The Commission found that the respondent interested party group response with respect to China was inadequate. However, the Commission determined to conduct a full review concerning the antidumping duty order on polyvinyl alcohol from China to promote administrative efficiency in light of its decision to conduct a full review with respect to the order concerning polyvinyl alcohol from Japan. A record of the Commissioners' votes will be available from the Office of the Secretary and at the Commission's website.

Authority: These reviews are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.62 of the Commission's rules.

By order of the Commission.

Issued: July 8, 2020.

William Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2020-15007 Filed 7-10-20; 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 Wrapping Material and Methods For Use in Agricultural Applications, DN 3468*; 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 Tama Group and Tama USA Inc. on July 7, 2020. 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 wrapping material and methods for use in agricultural applications. The complaint names as respondents: Zhejiang Yajia Cotton Picker Parts Co., Ltd. of China; Southern Marketing Affiliates, Inc. of Jonesboro, AR; Hai'an Xin Fu Yuan of Agricultural Science and Technology Co., Ltd. of China, and Gosun Business Development Co. Ltd. of Canada. The complainant requests that the Commission issue a limited exclusion order, cease and desist orders, and impose a bond upon the respondent alleged infringing articles during the 60-day Presidential review period pursuant to 19 U.S.C. 1337(j).

Proposed respondent, 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. 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. 3468") in a prominent place on the cover page and/or the first page. (See Handbook for Electronic Filing Procedures, Electronic Filing Procedures¹). 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

¹ Handbook for Electronic Filing Procedures: https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.

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 personnel², 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: July 8, 2020.

William Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2020-15012 Filed 7-10-20; 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 Movable Barrier Operator Systems and Components Thereof, DN 3467*; 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 Overhead Door Corporation and GMI Holdings Inc. on July 6, 2020. 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 movable barrier operator systems and components thereof. The complainant names as respondent: The Chamberlain Group, Inc. of Oak Brook, IL. The complainant requests that the Commission issue a limited exclusion order, cease and desist orders, and impose a bond upon the respondent alleged infringing articles during the 60-day Presidential review period pursuant to 19 U.S.C. 1337(j).

Proposed respondent, 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. 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. 3467") 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

² All contract personnel will sign appropriate nondisclosure agreements.

³ Electronic Document Information System (EDIS): <https://edis.usitc.gov>

¹ Handbook for Electronic Filing Procedures: https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.

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 personnel², solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS³.

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: July 7, 2020.

William Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2020-14979 Filed 7-10-20; 8:45 am]

BILLING CODE 7020-02-P

DEPARTMENT OF JUSTICE

[OMB Number 1125-0012]

Agency Information Collection Activities; Proposed Collection; Comments Requested; Request for New Recognition, Renewal of Recognition, Extension of Recognition of a Non-Profit Religious, Charitable, Social Service, or Similar Organization (Form EOIR-31)

AGENCY: Executive Office for Immigration Review, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Department of Justice (DOJ), Executive Office for Immigration Review, will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until September 11, 2020.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Lauren Alder Reid, Assistant Director, Office of Policy, Executive Office for Immigration Review, 5107 Leesburg Pike, Suite 2500, Falls Church, VA 22041, telephone: (703) 305-0289.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Executive Office for Immigration Review, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic,

mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection:* Revision of a currently approved collection.

2. *The Title of the Form/Collection:* Request for New Recognition, Renewal of Recognition, Extension of Recognition of a Non-profit Religious, Charitable, Social Service, or Similar Organization.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* Form EOIR-31. The applicable component within the Department of Justice is the Office of Legal Access Programs, Executive Office for Immigration Review.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:* Non-profit organizations seeking new recognition, renewal of recognition, or extension of recognition to be recognized as legal service providers by the Office of Legal Access Programs of the Executive Office for Immigration Review (EOIR). Abstract: This information collection will allow an organization to new recognition, renewal of recognition, or extension of recognition to appear before EOIR and/or the Department of Homeland Security. This information collection is necessary to determine whether a organization meets the eligibility requirements for recognition.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* It is estimated that 129 respondents will complete the form for new recognition annually with an average of 2 hours per response. It is estimated that 131 respondents will complete the form for renewal of recognition annually with an average of 7 hours per response.

6. *An estimate of the total public burden (in hours) associated with the collection:* There are an estimated 1,175 (258 for new + 917 for renewals) total annual burden hours associated with this collection.

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405B, Washington, DC 20530.

² All contract personnel will sign appropriate nondisclosure agreements.

³ Electronic Document Information System (EDIS): <https://edis.usitc.gov>.

Dated: July 7, 2020.

Melody D. Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2020-14953 Filed 7-10-20; 8:45 am]

BILLING CODE 4410-30-P

DEPARTMENT OF JUSTICE

[OMB Number 1121-0184]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Revision of a Currently Approved Collection: 2021 School Crime Supplement (SCS) to the National Crime Victimization Survey (NCVS)

AGENCY: Bureau of Justice Statistics, Department of Justice.

ACTION: 60-Day Notice.

SUMMARY: The Department of Justice (DOJ), Office of Justice Programs, Bureau of Justice Statistics, will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until September 11, 2020.

FOR FURTHER INFORMATION CONTACT: If you have comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Rachel Morgan (email: Rachel.Morgan@usdoj.gov; telephone: 202-616-1707) or Alexandra Thompson (email: Alexandra.Thompson@usdoj.gov; telephone: 202-598-2032), Bureau of Justice Statistics, 810 Seventh Street NW, Washington, DC 20531.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Bureau of Justice Statistics, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether and if so how the quality, utility, and clarity of the

information to be collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection:* Revision of a currently approved collection.

2. *Title of the Form/Collection:* 2021 School Crime Supplement (SCS) to the National Crime Victimization Survey (NCVS).

3. *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* The form number for the questionnaire is SCS-1. The applicable component within the Department of Justice is the Bureau of Justice Statistics (BJS), in the Office of Justice Programs.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:* The survey will be administered to persons ages 12 to 18 in NCVS sample households in the United States from January through June 2021. The SCS collects, analyzes, publishes, and disseminates statistics on the students' victimization, perceptions of school environment, and safety at school.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimate of the total number of respondents is 7,010 persons ages 12 to 18. Of the 7,010 SCS respondents, 87% or 6,071 are expected to complete the long SCS interview (entire SCS questionnaire) which takes an estimated 17 minutes (0.28 hours) to complete. The remaining 13% or 939 SCS respondents are expected to complete the short interview (i.e. will be screened out for not being in school), which takes an estimated 2 minutes (0.03 hours) to complete. There are an estimated 1,728 annual burden hours associated with this collection. Respondents will be asked to respond to this survey only once during the six month period. The burden estimates are based on data from the prior administration of the SCS.

If additional information is required, contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution

Square, 145 N Street NE, 3E.405A, Washington, DC 20530.

Dated: July 8, 2020.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2020-15030 Filed 7-10-20; 8:45 am]

BILLING CODE 4410-18-P

DEPARTMENT OF JUSTICE

[OMB Number 1125-0013]

Agency Information Collection Activities; Proposed Collection; Comments Requested; Request by Organization for Accreditation or Renewal of Accreditation of Non-Attorney Representative (Form EOIR-31A)

AGENCY: Executive Office for Immigration Review, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Department of Justice (DOJ), Executive Office for Immigration Review, will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until September 11, 2020.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Lauren Alder Reid, Assistant Director, Office of Policy, Executive Office for Immigration Review, 5107 Leesburg Pike, Suite 2500, Falls Church, VA 22041, telephone: (703) 305-0289.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Executive Office for Immigration Review, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information,

including the validity of the methodology and assumptions used;—Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection:* Revision of a currently approved collection.
2. *The Title of the Form/Collection:* Request by Organization for Accreditation or Renewal Accreditation of Non-Attorney Representative.
3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* Form EOIR-31A. The applicable component within the Department of Justice is the Office of Legal Access Programs, Executive Office for Immigration Review.
4. *Affected public who will be asked or required to respond, as well as a brief abstract:* Non-profit organizations seeking accreditation or renewal of accreditation of its representatives by the Office of Legal Access Programs of the Executive Office for Immigration Review (EOIR). Abstract: This information collection will allow an organization to seek accreditation or renewal of accreditation of a non-attorney representatives to appear before EOIR and/or the Department of Homeland Security. This information collection is necessary to determine whether a representatives meet the eligibility requirements for accreditation.
5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* It is estimated that 818 respondents will complete the form annually with an average of 2 hours per response.
6. *An estimate of the total public burden (in hours) associated with the collection:* There are an estimated 1,636 total annual burden hours associated with this collection.

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution

Square, 145 N Street NE, 3E.405B, Washington, DC 20530.

Dated: July 7, 2020.
Melody D. Braswell,
Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2020-14954 Filed 7-10-20; 8:45 am]
BILLING CODE 4410-30-P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under The Clean Water Act

On July 7, 2020, the Department of Justice lodged a proposed Consent Decree with the United States District Court for the District of Nebraska in the lawsuit entitled *United States and State of Nebraska v. Henningsen Foods, Inc.*, Civil Action No. 8:20-cv-00269.

The United States filed this lawsuit under the Clean Water Act. The United States’ complaint seeks penalties and injunctive relief for violations of the Clean Water Act’s pre-treatment regulations and the defendant’s Nebraska Pre-Treatment Program Permit at the defendant’s David City, Iowa egg-processing facility from January 2014 to the date of lodging. The proposed Consent Decree requires the defendant to pay a civil penalty of \$827,500 and to implement injunctive relief measures including operation and maintenance of an upgraded pH basin, increased monitoring of and limits on pH in effluent discharges, continued funding of a new anaerobic lagoon at the David City POTW, and implementation of an operations, maintenance, and training program for the defendant’s employees. The proposed Consent Decree resolves the United States’ claims alleged in the complaint through the date of lodging.

The publication of this notice opens a period for public comment on the proposed Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States and State of Nebraska v. Henningsen Foods, Inc.*, D.J. Ref. No. 90-5-1-1-11936. 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:

<i>To submit comments:</i>	<i>Send them to:</i>
By email	<i>pubcomment-ees.enrd@usdoj.gov.</i>

<i>To submit comments:</i>	<i>Send them to:</i>
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044-7611.

During the public comment period, the Consent Decree 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 Decree upon written request and payment of reproduction costs. Please mail your request and payment to:

Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044-7611.

Please enclose a check or money order for \$24.75 (25 cents per page reproduction cost) payable to the United States Treasury. For a paper copy without the exhibits and signature pages, the cost is \$9.75.

Susan M. Akers,
Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2020-14975 Filed 7-10-20; 8:45 am]
BILLING CODE 4410-15-P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA-2009-0025]

UL LLC: Request for Renewal of Recognition

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice.

SUMMARY: In this notice, OSHA announces the application of UL LLC (UL), requesting renewal of recognition as a Nationally Recognized Testing Laboratory (NRTL).

DATES: Submit comments, information, and documents in response to this notice, or requests for an extension of time to make a submission, on or before July 28, 2020.

ADDRESSES: Submit comments by any of the following methods:

Electronically: You may submit comments and attachments electronically at: <https://www.regulations.gov>, which is the Federal eRulemaking Portal. Follow the instructions online for submitting comments.

Facsimile: If your comments, including attachments, are not longer

than 10 pages, you may fax them to the OSHA Docket Office at (202) 693-1648.

Mail, hand delivery, express mail, messenger, or courier service: When using this method, you must submit a copy of your comments and attachments to the OSHA Docket Office, Docket No. OSHA-2009-0025, Occupational Safety and Health Administration, U.S. Department of Labor, Room N-3653, 200 Constitution Avenue NW, Washington, DC 20210. Deliveries (hand, express mail, messenger, and courier service) are accepted during the Docket Office's normal business hours, 10:00 a.m. to 3:00 p.m., ET.

Instructions: All submissions must include the agency name and the OSHA docket number (OSHA-2009-0025). OSHA places comments and other materials, including any personal information, in the public docket without revision, and these materials will be available online at <http://www.regulations.gov>. Therefore, the agency cautions commenters about submitting statements they do not want made available to the public, or submitting comments that contain personal information (either about themselves or others) such as Social Security numbers, birth dates, and medical data.

Docket: To read or download comments or other material in the docket, go to <https://www.regulations.gov> or the OSHA Docket Office at the above address. All documents in the docket (including this **Federal Register** notice) are listed in the <https://www.regulations.gov> index; however, some information (e.g., copyrighted material) is not publicly available to read or download through the website. All submissions, including copyrighted material, are available for inspection at the OSHA Docket Office. Contact the OSHA Docket Office for assistance in locating docket submissions.

Extension of comment period: Submit requests for an extension of the comment period on or before July 28, 2020 to the Office of Technical Programs and Coordination Activities, Directorate of Technical Support and Emergency Management, Occupational Safety and Health Administration, U.S. Department of Labor, 200 Constitution Avenue NW, Room N-3653, Washington, DC 20210, or by fax to (202) 693-1644.

FOR FURTHER INFORMATION CONTACT: Information regarding this notice is available from the following sources:

Press inquiries: Contact Mr. Frank Meilinger, Director, OSHA Office of Communications, U.S. Department of

Labor, telephone: (202) 693-1999; email: meilinger.francis2@dol.gov.

General and technical information: Contact Mr. Kevin Robinson, Director, Office of Technical Programs and Coordination Activities, Directorate of Technical Support and Emergency Management, Occupational Safety and Health Administration, U.S. Department of Labor, phone: (202) 693-2110 or email: robinson.kevin@dol.gov.

SUPPLEMENTARY INFORMATION:

I. Background

OSHA recognition of a NRTL signifies that the organization meets the requirements in Section 1910.7 of Title 29, Code of Federal Regulations (29 CFR 1910.7). Recognition is an acknowledgment that the organization can perform independent safety testing and certification of the specific products covered within its scope of recognition and is not a delegation or grant of government authority. As a result of recognition, employers may use products properly approved by the NRTL to meet OSHA standards that require testing and certification. OSHA maintains an informational web page for each NRTL that details its scope of recognition available at <http://www.osha.gov/dts/otpca/nrtl/index.html>.

OSHA processes applications by a NRTL for renewal of recognition following requirements in Appendix A to 29 CFR 1910.7. OSHA conducts renewals in accordance with the procedures in 29 CFR 1910.7, Appendix A, paragraph II.C. In accordance with these procedures, NRTLs submit a renewal request to OSHA, not less than nine months or no more than one year, before the expiration date of its current recognition. The submission includes a request for renewal and any additional information the NRTL wishes to submit to demonstrate its continued compliance with the terms of its recognition and 29 CFR 1910.7. If OSHA has not conducted an on-site assessment of the NRTL's headquarters and key sites within the past 18 to 24 months, it will schedule the necessary on-site assessments prior to the expiration date of the NRTL's recognition. Upon review of the submitted material and, as necessary, the successful completion of the on-site assessment, OSHA announces its preliminary decision to grant or deny renewal in the **Federal Register** and solicit comments from the public. OSHA then publishes a final **Federal Register** notice responding to any comments and renewing the NRTL's recognition for a period of five years, or denying the renewal of recognition.

UL initially received OSHA recognition as a NRTL on June 13, 1988, referenced in a **Federal Register** notice dated June 29, 1995 (60 FR 33852). UL's most recent renewal was granted on July 14, 2014, for a five-year period ending on July 14, 2019. UL submitted a timely request for renewal, dated September 4, 2018 (OSHA-2009-0025-0028), and retains its recognition pending OSHA's final decision in this renewal process. The current addresses of the UL facilities recognized by OSHA and included as part of the renewal request are:

- (1) UL Northbrook, 333 Pflingsten Road, Northbrook, Illinois 60062;
- (2) UL International Netherlands B.V., Westervoortsedijk 60, Arnhem, Netherlands 6827 AT;
- (3) UL International Italia S.r.l., Via Delle Industrie 1&6, Carugate, Milano, Italy 20061;
- (4) UL International Services, Ltd. Taiwan, 1st Floor, 260 Da-Yeh Road, Pei Tou District AND 4th/5th Floor, No. 35, Sec 2, Zhongyang S Rd, Pei Tou, Taipei City, Taiwan 112;
- (5) UL Japan, 4383-326 Asama-cho and 3600-18 Asama-cho, Ise-shi, Japan 516-0021;
- (6) UL Melville, 1285 Walt Whitman Road, Melville, New York 11747;
- (7) UL International Germany GmbH, Admiral-Rosendahl-Strasse 9, 23, Neu-Isenburg 63263;
- (8) UL Canada, 7 Underwriters Road, Toronto, Ontario, Canada M1R 3A9;
- (9) UL Research Triangle Park, 12 Laboratory Drive, P.O. Box 13995, Research Triangle Park, North Carolina 27709;
- (10) UL International Denmark A/S, Borupvang 5A, Ballerup, Denmark DK-2750;
- (11) UL International Limited Hong Kong, 18th Floor, Delta House, 3 On Yiu Street, Shatin, Hong Kong; and
- (12) UL Korea, 26th Floor Gangnam Finance Center, 737 Yeoksam-dong Gangnam-gu, Seoul, Korea 132-984.
- (13) Underwriters Laboratories International UK Ltd, Womersley House, The Guildway, Old Portsmouth Road, Guildford, Surrey GU3 1LR, United Kingdom

II. Notice of Preliminary Findings

OSHA is providing notice that UL is applying for renewal of its recognition as a NRTL. This renewal covers UL's existing NRTL scope of recognition. OSHA evaluated UL's application for renewal and preliminarily determined that UL can continue to meet the requirements prescribed by 29 CFR 1910.7 for recognition. Accordingly, OSHA is making a determination that it does not need to conduct an additional

on-site review of UL's facilities based on its evaluations of UL's application and all other available information. This information includes OSHA's audits of UL's recognized NRTL sites during this recognition period, and the satisfactory resolution of non-conformances with the requirements of 29 CFR 1910.7. This preliminary finding does not constitute an interim or temporary approval of the request.

OSHA welcomes public comment as to whether UL meets the requirements of 29 CFR 1910.7 for renewal of their recognition as a NRTL. Comments should consist of pertinent written documents and exhibits. Commenters needing more time to comment must submit a request in writing, stating the reasons for the request. OSHA must receive the written request for an extension by the due date for comments. OSHA will limit any extension to 30 days unless the requester justifies a longer period. OSHA may deny a request for an extension if it is not adequately justified. To obtain or review copies of the publicly available information in UL's application and other pertinent documents (including exhibits), as well as all submitted comments, contact the Docket Office, Room N-3653, Occupational Safety and Health Administration, U.S. Department of Labor, at the above address; these materials also are available online at <http://www.regulations.gov> under Docket No. OSHA-2009-0025.

The NRTL Program staff will review all comments to the docket submitted in a timely manner and, after addressing the issues raised by these comments, will make a recommendation to the Assistant Secretary on whether to grant UL's application for renewal. The Assistant Secretary will make the final decision on granting the application and, in making this decision, may undertake other proceedings prescribed in Appendix A to 29 CFR 1910.7.

OSHA will publish a public notice of this final decision in the **Federal Register**.

III. Authority and Signature

Loren Sweatt, Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, Washington, DC 20210, authorized the preparation of this notice. Accordingly, the agency is issuing this notice pursuant to 29 U.S.C. 657(g)(2), Secretary of Labor's Order No. 1-2012 (77 FR 3912, Jan. 25, 2012), and 29 CFR 1910.7.

Signed at Washington, DC, on July 7, 2020.

Loren Sweatt,

Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2020-15072 Filed 7-10-20; 8:45 am]

BILLING CODE 4510-26-P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA-2006-0028]

MET Laboratories, Inc.: Request for Renewal of Recognition

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice.

SUMMARY: In this notice, OSHA announces MET Laboratories, Inc.'s (MET), application requesting renewal of recognition as a Nationally Recognized Testing Laboratory (NRTL). **DATES:** Submit comments, information, and documents in response to this notice, or requests for an extension of time to make a submission, on or before July 28, 2020.

ADDRESSES: Submit comments by any of the following methods:

Electronically: You may submit comments and attachments electronically at: <https://www.regulations.gov>, which is the Federal eRulemaking Portal. Follow the instructions online for submitting comments.

Facsimile: If your comments, including attachments, are not longer than 10 pages, you may fax them to the OSHA Docket Office at (202) 693-1648.

Mail, hand delivery, express mail, messenger, or courier service: When using this method, you must submit a copy of your comments and attachments to the OSHA Docket Office, Docket No. OSHA-2006-0028, Occupational Safety and Health Administration, U.S. Department of Labor, Room N-3653, 200 Constitution Avenue NW, Washington, DC 20210. Deliveries (hand, express mail, messenger, and courier service) are accepted during the Docket Office's normal business hours, 10:00 a.m. to 3:00 p.m., ET.

Instructions: All submissions must include the agency name and the OSHA docket number (OSHA-2006-0028). OSHA places comments and other materials, including any personal information, in the public docket without revision, and these materials will be available online at <http://www.regulations.gov>. Therefore, the agency cautions commenters about submitting statements they do not want

made available to the public, or submitting comments that contain personal information (either about themselves or others) such as Social Security numbers, birth dates, and medical data.

Docket: To read or download comments or other material in the docket, go to <https://www.regulations.gov> or the OSHA Docket Office at the above address. All documents in the docket (including this **Federal Register** notice) are listed in the <https://www.regulations.gov> index; however, some information (e.g., copyrighted material) is not publicly available to read or download through the website. All submissions, including copyrighted material, are available for inspection at the OSHA Docket Office. Contact the OSHA Docket Office for assistance in locating docket submissions.

Extension of comment period: Submit requests for an extension of the comment period on or before July 28, 2020 to the Office of Technical Programs and Coordination Activities, Directorate of Technical Support and Emergency Management, Occupational Safety and Health Administration, U.S. Department of Labor, 200 Constitution Avenue NW, Room N-3653, Washington, DC 20210, or by fax to (202) 693-1644.

FOR FURTHER INFORMATION CONTACT: Information regarding this notice is available from the following sources:

Press inquiries: Contact Mr. Frank Meilinger, Director, OSHA Office of Communications, U.S. Department of Labor, telephone: (202) 693-1999; email: meilinger.francis2@dol.gov.

General and technical information: Contact Mr. Kevin Robinson, Director, Office of Technical Programs and Coordination Activities, Directorate of Technical Support and Emergency Management, Occupational Safety and Health Administration, U.S. Department of Labor, phone: (202) 693-2110 or email: robinson.kevin@dol.gov.

SUPPLEMENTARY INFORMATION:

I. Background

OSHA recognition of a NRTL signifies that the organization meets the requirements in § 1910.7 of title 29, Code of Federal Regulations (29 CFR 1910.7). Recognition is an acknowledgment that the organization can perform independent safety testing and certification of the specific products covered within its scope of recognition and is not a delegation or grant of government authority. As a result of recognition, employers may use products properly approved by the

NRTL to meet OSHA standards that require testing and certification. OSHA maintains an informational web page for each NRTL that details its scope of recognition available at <http://www.osha.gov/dts/otpca/nrtl/index.html>.

OSHA processes applications by a NRTL for renewal of recognition following requirements in appendix A to 29 CFR 1910.7. OSHA conducts renewals in accordance with the procedures in 29 CFR 1910.7, appendix A, paragraph II.C. In accordance with these procedures, NRTLs submit a renewal request to OSHA, not less than nine months or no more than one year, before the expiration date of its current recognition. The submission includes a request for renewal and any additional information the NRTL wishes to submit to demonstrate its continued compliance with the terms of its recognition and 29 CFR 1910.7. If OSHA has not conducted an on-site assessment of the NRTL's headquarters and key sites within the past 18 to 24 months, it will schedule the necessary on-site assessments prior to the expiration date of the NRTL's recognition. Upon review of the submitted material and, as necessary, the successful completion of the on-site assessment, OSHA announces its preliminary decision to grant or deny renewal in the **Federal Register** and solicit comments from the public. OSHA then publishes a final **Federal Register** notice responding to any comments and renewing the NRTL's recognition for a period of five years, or denying the renewal of recognition.

MET initially received OSHA recognition as a NRTL on May 16, 1989 (54 FR 21136). MET's most recent renewal was granted on July 14, 2014, for a five-year period ending on July 14, 2019. MET submitted a timely request for renewal, dated September 5, 2018 (OSHA-2006-0028-0058), and retains its recognition pending OSHA's final decision in this renewal process. The current address of the MET facility recognized by OSHA and included as part of the renewal request is:

1. MET Laboratories, Inc., 914 West Patapsco Avenue, Baltimore, Maryland 21230.

II. Notice of Preliminary Findings

OSHA is providing notice that MET is applying for renewal of its recognition as a NRTL. This renewal covers MET's existing NRTL scope of recognition. OSHA evaluated MET's application for renewal and preliminarily determined that MET can continue to meet the requirements prescribed by 29 CFR 1910.7 for recognition. Accordingly, OSHA is making a determination that it

does not need to conduct an additional on-site review of MET's facility based on its evaluations of MET's application and all other available information. This information includes OSHA's most recent audit of MET's NRTL recognized site during this recognition period, and the satisfactory resolution of non-conformances with the requirements of 29 CFR 1910.7. This preliminary finding does not constitute an interim or temporary approval of the request.

OSHA welcomes public comment as to whether MET meets the requirements of 29 CFR 1910.7 for renewal of their recognition as a NRTL. Comments should consist of pertinent written documents and exhibits. Commenters needing more time to comment must submit a request in writing, stating the reasons for the request. OSHA must receive the written request for an extension by the due date for comments. OSHA will limit any extension to 30 days unless the requester justifies a longer period. OSHA may deny a request for an extension if it is not adequately justified. To obtain or review copies of the publicly available information in MET's application and other pertinent documents (including exhibits), as well as all submitted comments, contact the Docket Office, Room N-3653, Occupational Safety and Health Administration, U.S. Department of Labor, at the above address; these materials also are available online at <http://www.regulations.gov> under Docket No. OSHA-2006-0028.

OSHA staff will review all comments to the docket submitted in a timely manner and, after addressing the issues raised by these comments, will make a recommendation to the Assistant Secretary on whether to grant MET's application for renewal. The Assistant Secretary will make the final decision on granting the application and, in making this decision, may undertake other proceedings prescribed in appendix A to 29 CFR 1910.7.

OSHA will publish a public notice of this final decision in the **Federal Register**.

III. Authority and Signature

Loren Sweatt, Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, Washington, DC 20210, authorized the preparation of this notice. Accordingly, the agency is issuing this notice pursuant to 29 U.S.C. 657(g)(2), Secretary of Labor's Order No. 1-2012 (77 FR 3912, Jan. 25, 2012), and 29 CFR 1910.7.

Signed at Washington, DC, on July 7, 2020.

Loren Sweatt,

Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2020-15055 Filed 7-10-20; 8:45 am]

BILLING CODE 4510-26-P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA-2013-0017]

QAI Laboratories Ltd.: Request for Renewal of Recognition

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice.

SUMMARY: In this notice, OSHA announces the application of QAI Laboratories Ltd. (QAI) requesting renewal of recognition as a Nationally Recognized Testing Laboratory (NRTL).

DATES: Submit comments, information, and documents in response to this notice, or requests for an extension of time to make a submission, on or before July 28, 2020.

ADDRESSES: Submit comments by any of the following methods:

Electronically: You may submit comments and attachments electronically at: <https://www.regulations.gov>, which is the Federal eRulemaking Portal. Follow the instructions online for submitting comments.

Facsimile: If your comments, including attachments, are not longer than 10 pages, you may fax them to the OSHA Docket Office at (202) 693-1648.

Mail, hand delivery, express mail, messenger, or courier service: When using this method, you must submit a copy of your comments and attachments to the OSHA Docket Office, Docket No. OSHA-2013-0017, Occupational Safety and Health Administration, U.S. Department of Labor, Room N-3653, 200 Constitution Avenue NW, Washington, DC 20210. Deliveries (hand, express mail, messenger, and courier service) are accepted during the Docket Office's normal business hours, 10:00 a.m. to 3:00 p.m., ET.

Instructions: All submissions must include the agency name and the OSHA docket number (OSHA-2013-0017). OSHA places comments and other materials, including any personal information, in the public docket without revision, and these materials will be available online at <http://www.regulations.gov>. Therefore, the agency cautions commenters about submitting statements they do not want

made available to the public, or submitting comments that contain personal information (either about themselves or others) such as Social Security numbers, birth dates, and medical data.

Docket: To read or download comments or other material in the docket, go to <https://www.regulations.gov> or the OSHA Docket Office at the above address. All documents in the docket (including this **Federal Register** notice) are listed in the <https://www.regulations.gov> index; however, some information (e.g., copyrighted material) is not publicly available to read or download through the website. All submissions, including copyrighted material, are available for inspection at the OSHA Docket Office. Contact the OSHA Docket Office for assistance in locating docket submissions.

Extension of comment period: Submit requests for an extension of the comment period on or before July 28, 2020 to the Office of Technical Programs and Coordination Activities, Directorate of Technical Support and Emergency Management, Occupational Safety and Health Administration, U.S. Department of Labor, 200 Constitution Avenue NW, Room N-3653, Washington, DC 20210, or by fax to (202) 693-1644.

FOR FURTHER INFORMATION CONTACT: Information regarding this notice is available from the following sources:

Press inquiries: Contact Mr. Frank Meilinger, Director, OSHA Office of Communications, U.S. Department of Labor, telephone: (202) 693-1999; email: meilinger.francis@dol.gov.

General and technical information: Contact Mr. Kevin Robinson, Director, Office of Technical Programs and Coordination Activities, Directorate of Technical Support and Emergency Management, Occupational Safety and Health Administration, U.S. Department of Labor, phone: (202) 693-2110 or email: robinson.kevin@dol.gov.

SUPPLEMENTARY INFORMATION:

I. Background

OSHA recognition of a NRTL signifies that the organization meets the requirements in § 1910.7 of title 29, Code of Federal Regulations (29 CFR 1910.7). Recognition is an acknowledgment that the organization can perform independent safety testing and certification of the specific products covered within its scope of recognition and is not a delegation or grant of government authority. As a result of recognition, employers may use products properly approved by the

NRTL to meet OSHA standards that require testing and certification. OSHA maintains an informational web page for each NRTL that details its scope of recognition available at <http://www.osha.gov/dts/otpca/nrtl/index.html>.

The agency processes applications by a NRTL for renewal of recognition following requirements in appendix A to 29 CFR 1910.7. OSHA conducts renewals in accordance with the procedures in 29 CFR 1910.7, appendix A, paragraph II.C. In accordance with these procedures, NRTLs submit a renewal request to OSHA, not less than nine months or no more than one year, before the expiration date of its current recognition. The submission includes a request for renewal and any additional information the NRTL wishes to submit to demonstrate its continued compliance with the terms of its recognition and 29 CFR 1910.7. If OSHA has not conducted an on-site assessment of the NRTL's headquarters and key sites within the past 18 to 24 months, it will schedule the necessary on-site assessments prior to the expiration date of the NRTL's recognition. Upon review of the submitted material and, as necessary, the successful completion of the on-site assessment, OSHA announces its preliminary decision to grant or deny renewal in the **Federal Register** and solicit comments from the public. OSHA then publishes a final **Federal Register** notice responding to any comments and renewing the NRTL's recognition for a period of five years, or denying the renewal of recognition.

QAI initially received OSHA recognition as a NRTL on December 19, 2014 (79 FR 75841) for a five-year period expiring on December 19, 2019. QAI submitted a timely request for renewal, dated March 13, 2019 (OSHA-2013-0017-0011), and retains its recognition pending OSHA's final decision in this renewal process. The current addresses of the QAI facilities recognized by OSHA and included as part of the renewal request are:

1. QAI Laboratories Ltd, Coquitlam, 3980 North Fraser Way, Burnaby, British Columbia, Canada V5J 5k5; and
2. QAI Laboratories Ltd, Los Angeles, 8385 White Oak Avenue, Rancho Cucamonga, California, 91730.

II. Notice of Preliminary Findings

OSHA is providing notice that QAI is applying for renewal of its recognition as a NRTL. This renewal covers QAI's existing NRTL scope of recognition. OSHA evaluated QAI's application for renewal and preliminarily determined that QAI can continue to meet the requirements prescribed by 29 CFR

1910.7 for recognition. Accordingly, OSHA is making a determination that it does not need to conduct an additional on-site review of QAI's facilities based on its evaluations of QAI's application and all other available information. This information includes OSHA's audits of QAI's recognized NRTL sites during this recognition period, and the satisfactory resolution of non-conformances with the requirements of 29 CFR 1910.7. This preliminary finding does not constitute an interim or temporary approval of the application.

OSHA welcomes public comment as to whether QAI meets the requirements of 29 CFR 1910.7 for renewal of their recognition as a NRTL. Comments should consist of pertinent written documents and exhibits. Commenters needing more time to comment must submit a request in writing, stating the reasons for the request. OSHA must receive the written request for an extension by the due date for comments. OSHA will limit any extension to 30 days unless the requester justifies a longer period. OSHA may deny a request for an extension if it is not adequately justified. To obtain or review copies of the publicly available information in QAI's application and other pertinent documents (including exhibits), as well as all submitted comments, contact the Docket Office, Room N-3653, Occupational Safety and Health Administration, U.S. Department of Labor, at the above address; these materials also are available online at <http://www.regulations.gov> under Docket No. OSHA-2013-0017.

OSHA staff will review all comments to the docket submitted in a timely manner and, after addressing the issues raised by these comments, will make a recommendation to the Assistant Secretary on whether to grant QAI's application for renewal. The Assistant Secretary will make the final decision on granting the application and, in making this decision, may undertake other proceedings prescribed in appendix A to 29 CFR 1910.7.

OSHA will publish a public notice of this final decision in the **Federal Register**.

III. Authority and Signature

Loren Sweatt, Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, Washington, DC 20210, authorized the preparation of this notice. Accordingly, the agency is issuing this notice pursuant to 29 U.S.C. 657(g)(2), Secretary of Labor's Order No. 1-2012 (77 FR 3912, Jan. 25, 2012), and 29 CFR 1910.7.

Signed at Washington, DC, on July 7, 2020.

Loren Sweatt,

Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2020-15058 Filed 7-10-20; 8:45 am]

BILLING CODE 4510-26-P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA-2006-0041]

Southwest Research Institute: Request for Renewal of Recognition

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice.

SUMMARY: In this notice, OSHA announces Southwest Research Institute's (SWRI) application containing a request for renewal of recognition as a Nationally Recognized Testing Laboratory (NRTL).

DATES: Submit comments, information, and documents in response to this notice, or requests for an extension of time to make a submission, on or before July 28, 2020.

ADDRESSES: Submit comments by any of the following methods:

Electronically: You may submit comments and attachments electronically at: <https://www.regulations.gov>, which is the Federal eRulemaking Portal. Follow the instructions online for submitting comments.

Facsimile: If your comments, including attachments, are not longer than 10 pages, you may fax them to the OSHA Docket Office at (202) 693-1648.

Mail, hand delivery, express mail, messenger, or courier service: When using this method, you must submit a copy of your comments and attachments to the OSHA Docket Office, Docket No. OSHA-2006-0041, Occupational Safety and Health Administration, U.S. Department of Labor, Room N-3653, 200 Constitution Avenue NW, Washington, DC 20210. Deliveries (hand, express mail, messenger, and courier service) are accepted during the Docket Office's normal business hours, 10:00 a.m. to 3:00 p.m., ET.

Instructions: All submissions must include the agency name and the OSHA docket number (OSHA-2006-0041). OSHA places comments and other materials, including any personal information, in the public docket without revision, and these materials will be available online at <http://www.regulations.gov>. Therefore, the agency cautions commenters about

submitting statements they do not want made available to the public, or submitting comments that contain personal information (either about themselves or others) such as Social Security numbers, birth dates, and medical data.

Docket: To read or download comments or other material in the docket, go to <https://www.regulations.gov> or the OSHA Docket Office at the above address. All documents in the docket (including this **Federal Register** notice) are listed in the <https://www.regulations.gov> index; however, some information (e.g., copyrighted material) is not publicly available to read or download through the website. All submissions, including copyrighted material, are available for inspection at the OSHA Docket Office. Contact the OSHA Docket Office for assistance in locating docket submissions.

Extension of comment period: Submit requests for an extension of the comment period on or before July 28, 2020 to the Office of Technical Programs and Coordination Activities, Directorate of Technical Support and Emergency Management, Occupational Safety and Health Administration, U.S. Department of Labor, 200 Constitution Avenue NW, Room N-3653, Washington, DC 20210, or by fax to (202) 693-1644.

FOR FURTHER INFORMATION CONTACT: Information regarding this notice is available from the following sources:

Press inquiries: Contact Mr. Frank Meilinger, Director, OSHA Office of Communications, U.S. Department of Labor, telephone: (202) 693-1999; email: meilinger.francis2@dol.gov.

General and technical information: Contact Mr. Kevin Robinson, Director, Office of Technical Programs and Coordination Activities, Directorate of Technical Support and Emergency Management, Occupational Safety and Health Administration, U.S. Department of Labor, phone: (202) 693-2110 or email: robinson.kevin@dol.gov.

SUPPLEMENTARY INFORMATION:

I. Background

OSHA recognition of a NRTL signifies that the organization meets the requirements in Section 1910.7 of Title 29, Code of Federal Regulations (29 CFR 1910.7). Recognition is an acknowledgment that the organization can perform independent safety testing and certification of the specific products covered within its scope of recognition and is not a delegation or grant of government authority. As a result of recognition, employers may use

products properly approved by the NRTL to meet OSHA standards that require testing and certification. OSHA maintains an informational web page for each NRTL that details its scope of recognition available at <http://www.osha.gov/dts/otpca/nrtl/index.html>.

OSHA processes applications by a NRTL for renewal of recognition following requirements in Appendix A to 29 CFR 1910.7. OSHA conducts renewals in accordance with the procedures in 29 CFR 1910.7, Appendix A, paragraph I.I.C. In accordance with these procedures, NRTLs submit a renewal request to OSHA, not less than nine months or no more than one year, before the expiration date of its current recognition. The submission includes a request for renewal and any additional information the NRTL wishes to submit to demonstrate its continued compliance with the terms of its recognition and 29 CFR 1910.7. If OSHA has not conducted an on-site assessment of the NRTL's headquarters and key sites within the past 18 to 24 months, it will schedule the necessary on-site assessments prior to the expiration date of the NRTL's recognition. Upon review of the submitted material and, as necessary, the successful completion of the on-site assessment, OSHA announces its preliminary decision to grant or deny renewal in the **Federal Register** and solicit comments from the public. OSHA then publishes a final **Federal Register** notice responding to any comments and renewing the NRTL's recognition for a period of five years, or denying the renewal of recognition.

SWRI initially received OSHA recognition as a NRTL on July 13, 1993 (58 FR 37752). SWRI's most recent renewal was granted on July 30, 2014, for a five-year period ending on July 30, 2019. SWRI submitted a timely request for renewal, dated September 14, 2018 (OSHA-2006-0041-0008), and retains its recognition pending OSHA's final decision in this renewal process. The current address of the SWRI facility recognized by OSHA and included as part of the renewal request is:

1. Southwest Research Institute, 6220 Culebra Road, Post Office Drawer 28510, San Antonio, Texas 78238.

II. Notice of Preliminary Findings

OSHA is providing notice that SWRI is applying for renewal of its recognition as a NRTL. This renewal covers SWRI's existing NRTL scope of recognition. OSHA evaluated SWRI's application for renewal and preliminarily determined that SWRI can continue to meet the requirements prescribed by 29 CFR 1910.7 for recognition. Accordingly,

OSHA is making a determination that it does not need to conduct an additional on-site review of SWRI's facility based on its evaluations of SWRI's application and all other available information. This information includes OSHA's audits of SWRI's NRTL recognized site during this recognition period, and the satisfactory resolution of non-conformances with the requirements of 29 CFR 1910.7. This preliminary finding does not constitute an interim or temporary approval of the request.

OSHA welcomes public comment as to whether SWRI meets the requirements of 29 CFR 1910.7 for renewal of their recognition as a NRTL. Comments should consist of pertinent written documents and exhibits. Commenters needing more time to comment must submit a request in writing, stating the reasons for the request. OSHA must receive the written request for an extension by the due date for comments. OSHA will limit any extension to 30 days unless the requester justifies a longer period. OSHA may deny a request for an extension if it is not adequately justified. To obtain or review copies of the publicly available information in SWRI's application and other pertinent documents (including exhibits), as well as all submitted comments, contact the Docket Office, Room N-3653, Occupational Safety and Health Administration, U.S. Department of Labor, at the above address; these materials also are available online at <http://www.regulations.gov> under Docket No. OSHA-2006-0041.

OSHA staff will review all comments to the docket submitted in a timely manner and, after addressing the issues raised by these comments, will make a recommendation to the Assistant Secretary on whether to grant SWRI's application for renewal. The Assistant Secretary will make the final decision on granting the application and, in making this decision, may undertake other proceedings prescribed in Appendix A to 29 CFR 1910.7.

OSHA will publish a public notice of this final decision in the **Federal Register**.

III. Authority and Signature

Loren Sweatt, Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, Washington, DC 20210, authorized the preparation of this notice. Accordingly, the agency is issuing this notice pursuant to 29 U.S.C. 657(g)(2), Secretary of Labor's Order No. 1-2012 (77 FR 3912, Jan. 25, 2012), and 29 CFR 1910.7.

Signed at Washington, DC, on July 7, 2020.

Loren Sweatt,

Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2020-15068 Filed 7-10-20; 8:45 am]

BILLING CODE 4510-26-P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA-2007-0043]

TÜV SÜD America, Inc.: Request for Renewal of Recognition

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice.

SUMMARY: In this notice, OSHA announces the application of TÜV SÜD America, Inc. requesting renewal of recognition as a Nationally Recognized Testing Laboratory (NRTL).

DATES: Submit comments, information, and documents in response to this notice, or requests for an extension of time to make a submission, on or before July 28, 2020.

ADDRESSES: Submit comments by any of the following methods:

Electronically: You may submit comments and attachments electronically at: <https://www.regulations.gov>, which is the Federal eRulemaking Portal. Follow the instructions online for submitting comments.

Facsimile: If your comments, including attachments, are not longer than 10 pages, you may fax them to the OSHA Docket Office at (202) 693-1648.

Mail, hand delivery, express mail, messenger, or courier service: When using this method, you must submit a copy of your comments and attachments to the OSHA Docket Office, Docket No. OSHA-2007-0043, Occupational Safety and Health Administration, U.S. Department of Labor, Room N-3653, 200 Constitution Avenue NW, Washington, DC 20210. Deliveries (hand, express mail, messenger, and courier service) are accepted during the Docket Office's normal business hours, 10:00 a.m. to 3:00 p.m., ET.

Instructions: All submissions must include the agency name and the OSHA docket number (OSHA-2007-0043). OSHA places comments and other materials, including any personal information, in the public docket without revision, and these materials will be available online at <http://www.regulations.gov>. Therefore, the agency cautions commenters about submitting statements they do not want

made available to the public, or submitting comments that contain personal information (either about themselves or others) such as Social Security Numbers, birth dates, and medical data.

Docket: To read or download comments or other material in the docket, go to <https://www.regulations.gov> or the OSHA Docket Office at the above address. All documents in the docket (including this **Federal Register** notice) are listed in the <https://www.regulations.gov> index; however, some information (e.g., copyrighted material) is not publicly available to read or download through the website. All submissions, including copyrighted material, are available for inspection at the OSHA Docket Office. Contact the OSHA Docket Office for assistance in locating docket submissions.

Extension of comment period: Submit requests for an extension of the comment period on or before July 28, 2020 to the Office of Technical Programs and Coordination Activities, Directorate of Technical Support and Emergency Management, Occupational Safety and Health Administration, U.S. Department of Labor, 200 Constitution Avenue NW, Room N-3653, Washington, DC 20210, or by fax to (202) 693-1644.

FOR FURTHER INFORMATION CONTACT: Information regarding this notice is available from the following sources:

Press inquiries: Contact Mr. Frank Meilinger, Director, OSHA Office of Communications, U.S. Department of Labor, telephone: (202) 693-1999; email: meilinger.francis2@dol.gov.

General and technical information: Contact Mr. Kevin Robinson, Director, Office of Technical Programs and Coordination Activities, Directorate of Technical Support and Emergency Management, Occupational Safety and Health Administration, U.S. Department of Labor, phone: (202) 693-2110 or email: robinson.kevin@dol.gov.

SUPPLEMENTARY INFORMATION:

I. Background

OSHA recognition of a NRTL signifies that the organization meets the requirements in Section 1910.7 of Title 29, Code of Federal Regulations (29 CFR 1910.7). Recognition is an acknowledgment that the organization can perform independent safety testing and certification of the specific products covered within its scope of recognition and is not a delegation or grant of government authority. As a result of recognition, employers may use products properly approved by the

NRTL to meet OSHA standards that require testing and certification. OSHA maintains an informational web page for each NRTL that details its scope of recognition available at <http://www.osha.gov/dts/otpca/nrtl/index.html>.

The agency processes applications by a NRTL for renewal of recognition following requirements in Appendix A to 29 CFR 1910.7. OSHA conducts renewals in accordance with the procedures in 29 CFR 1910.7, Appendix A, paragraph II.C. In accordance with these procedures, NRTLs would submit a renewal request to OSHA, not less than nine months or no more than one year, before the expiration date of its current recognition. The submission would include a request for renewal and any additional information the NRTL wishes to submit to demonstrate its continued compliance with the terms of its recognition and 29 CFR 1910.7. If OSHA has not conducted an on-site assessment of the NRTL headquarters and any key sites within the past 18 months, it will schedule the necessary on-site assessments prior to the expiration date of the NRTL's recognition. Upon review of the submitted material and, as necessary, the successful completion of the on-site assessment, OSHA announces its preliminary decision to grant or deny renewal in the **Federal Register** and solicit comments from the public. OSHA then publishes a final **Federal Register** notice responding to any comments and renewing the NRTL's recognition for a period of five years, or denying the renewal of recognition.

TÜV SÜD America, Inc. (TUVAM) initially received OSHA recognition as a NRTL on January 25, 2002 (65 FR 26637), for a five-year period ending on January 25, 2007. TUVAM's most recent renewal was granted on January 30, 2014, for a five year period ending on January 20, 2019. TUVAM submitted a timely request for renewal, dated April 26, 2018 (OSHA-2007-0043-0029), and retains its recognition pending OSHA's final decision in this renewal process. The current addresses of TUVAM facilities recognized by OSHA and included as part of the renewal request are:

1. TÜV SÜD America, 10 Centennial Drive, Peabody, Massachusetts 01960;
2. TÜV SÜD America, 141 14th Street, NW, New Brighton, Minnesota 55112;
3. TÜV SÜD America, Inc., 10040 Mesa Rim Road, San Diego, California 92121;
4. TÜV SÜD Canada, 1229 Ringwell Drive, Newmarket, ON, L3Y 8T8, Canada;

5. TÜV SÜD Product Services GmbH, Ridlerstrasse 65 D-80339, Munich, Germany; and

6. TÜV SÜD Product Services GmbH, Daimlerstrasse 11 D-85748, Garching, Germany.

II. Notice of Preliminary Findings

OSHA is providing notice that TUVAM is applying for renewal of its recognition as a NRTL. This renewal covers TUVAM's existing NRTL scope of recognition. TUVAM submitted an acceptable application for renewal of its recognition as a NRTL on April 16, 2018. OSHA evaluated TUVAM's application for renewal and preliminarily determined that TUVAM can continue to meet the requirements prescribed by 29 CFR 1910.7 for recognition. Accordingly, OSHA is making a determination that it does not need to conduct an additional on-site review of TUVAM's facilities based on its evaluations of TUVAM's application and all other available information. This information includes OSHA's audits of TUVAM recognized NRTL sites during this recognition period, and the satisfactory resolution of non-conformances with the requirements of 29 CFR 1910.7. This preliminary finding does not constitute an interim or temporary approval of the request.

OSHA welcomes public comment as to whether TUVAM meets the requirements of 29 CFR 1910.7 for renewal of their recognition as a NRTL. Comments should consist of pertinent written documents and exhibits. Commenters needing more time to comment must submit a request in writing, stating the reasons for the request. OSHA must receive the written request for an extension by the due date for comments. OSHA will limit any extension to 30 days unless the requester justifies a longer period. OSHA may deny a request for an extension if it is not adequately justified. To obtain or review copies of the publicly available information in TUVAM's application and other pertinent documents (including exhibits), as well as all submitted comments, contact the Docket Office, Room N-3653, Occupational Safety and Health Administration, U.S. Department of Labor, at the above address; these materials also are available online at <http://www.regulations.gov> under Docket No. OSHA-2007-0043.

OSHA staff will review all comments to the docket submitted in a timely manner and, after addressing the issues raised by these comments, will make a recommendation to the Assistant Secretary on whether to grant TUVAM's application for renewal. The Assistant

Secretary will make the final decision on granting the application and, in making this decision, may undertake other proceedings prescribed in Appendix A to 29 CFR 1910.7.

OSHA will publish a public notice of this final decision in the **Federal Register**.

III. Authority and Signature

Loren Sweatt, Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, Washington, DC 20210, authorized the preparation of this notice. Accordingly, the agency is issuing this notice pursuant to Section 8(g)(2) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 657(g)(2)), Secretary of Labor's Order No. 1-2012 (77 FR 3912, Jan. 25, 2012), and 29 CFR 1910.7.

Signed at Washington, DC, on July 7, 2020.

Loren Sweatt,

Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2020-15070 Filed 7-10-20; 8:45 am]

BILLING CODE 4510-26-P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA-2007-0042]

TUV Rheinland of North America, Inc.: Request for Renewal of Recognition

AGENCY: Occupational Safety and Health Administration (OSHA), Labor

ACTION: Notice

SUMMARY: In this notice, OSHA announces the TUV Rheinland of North America, Inc. (TUVRNA), application containing a request for renewal of recognition as a Nationally Recognized Testing Laboratory (NRTL).

DATES: Submit comments, information, and documents in response to this notice, or requests for an extension of time to make a submission, on or before July 28, 2020.

ADDRESSES: Submit comments by any of the following methods:

Electronically: You may submit comments and attachments electronically at: <https://www.regulations.gov>, which is the Federal eRulemaking Portal. Follow the instructions online for submitting comments.

Facsimile: If your comments, including attachments, are not longer than 10 pages, you may fax them to the OSHA Docket Office at (202) 693-1648.

Mail, hand delivery, express mail, messenger, or courier service: When

using this method, you must submit a copy of your comments and attachments to the OSHA Docket Office, Docket No. OSHA–2007–0042, Occupational Safety and Health Administration, U.S. Department of Labor, Room N–3653, 200 Constitution Avenue NW, Washington, DC 20210. Deliveries (hand, express mail, messenger, and courier service) are accepted during the Docket Office’s normal business hours, 10:00 a.m. to 3:00 p.m., ET.

Instructions: All submissions must include the agency name and OSHA docket number (OSHA–2007–0042). All comments, including any personal information you provide, are placed in the public docket without change, and may be made available online at <https://www.regulations.gov>. Therefore, the agency cautions commenters about submitting statements they do not want made available to the public, or submitting comments that contain personal information (either about themselves or others) such as Social Security numbers, birth dates, and medical data.

Docket: To read or download comments or other material in the docket, go to <https://www.regulations.gov> or the OSHA Docket Office at the above address. All documents in the docket (including this **Federal Register** notice) are listed in the <https://www.regulations.gov> index; however, some information (e.g., copyrighted material) is not publicly available to read or download through the website. All submissions, including copyrighted material, are available for inspection at the OSHA Docket Office. Contact the OSHA Docket Office for assistance in locating docket submissions.

Extension of comment period: Submit requests for an extension of the comment period on or before July 28, 2020 to the Office of Technical Programs and Coordination Activities, Directorate of Technical Support and Emergency Management, Occupational Safety and Health Administration, U.S. Department of Labor, 200 Constitution Avenue NW, Room N–3653, Washington, DC 20210, or by fax to (202) 693–1644.

FOR FURTHER INFORMATION CONTACT: Information regarding this notice is available from the following sources:

Press inquiries: Contact Mr. Frank Meilinger, Director, OSHA Office of Communications, U.S. Department of Labor, telephone: (202) 693–1999; email: meilinger.francis@dol.gov.

General and technical information: Contact Mr. Kevin Robinson, Director, Office of Technical Programs and

Coordination Activities, Directorate of Technical Support and Emergency Management, Occupational Safety and Health Administration, U.S. Department of Labor, phone: (202) 693–2110 or email: robinson.kevin@dol.gov.

SUPPLEMENTARY INFORMATION:

I. Background

OSHA recognition of a NRTL signifies that the organization meets the requirements in Section 1910.7 of Title 29, Code of Federal Regulations (29 CFR 1910.7). Recognition is an acknowledgment that the organization can perform independent safety testing and certification of the specific products covered within its scope of recognition and is not a delegation or grant of government authority. As a result of recognition, employers may use products properly approved by the NRTL to meet OSHA standards that require testing and certification. OSHA maintains an informational website for each NRTL that details its scope of recognition available at <http://www.osha.gov/dts/otpca/nrtl/index.html>.

The agency processes applications by a NRTL for renewal of recognition following requirements in Appendix A to 29 CFR 1910.7. OSHA conducts renewals in accordance with the procedures in 29 CFR 1910.7, Appendix A, paragraph II.C. In accordance with these procedures, NRTLs submit a renewal request to OSHA, not less than nine months, or no more than one year, before the expiration date of its current recognition. The submission includes a request for renewal and any additional information the NRTL wishes to submit to demonstrate its continued compliance with the terms of its recognition and 29 CFR 1910.7. If OSHA has not conducted an on-site assessment of the NRTL’s headquarters and key sites within the past 18 to 24 months, it will schedule the necessary on-site assessments prior to the expiration date of the NRTL’s recognition. Upon review of the submitted material and, as necessary, the successful completion of the on-site assessment, OSHA announces its preliminary decision to grant or deny renewal in the **Federal Register** and solicit comments from the public. OSHA then publishes a final **Federal Register** notice responding to any comments and renewing the NRTL’s recognition for a period of five years, or denying the renewal of recognition.

TUVRNA initially received OSHA recognition as a NRTL on August 16, 1995 (60 FR 42594). TUVRNA’s most recent renewal was on July 30, 2014, for a five-year period, expiring on July 30, 2019. TUVRNA submitted a timely

request for renewal, dated August 16, 2018 (OSHA–2007–0042–0035), and retains its recognition pending OSHA’s final decision in this renewal process. The current addresses of TUVRNA facilities recognized by OSHA and included as part of the renewal request are:

1. TUVRNA Newtown, 12 Commerce Road, Newtown, Connecticut 06470;
2. TUVRNA Pleasanton, 1279 Quarry Lane, Suite A, Pleasanton, California 94566;
3. TUV Rheinland LGA Products GmbH (Germany), Am Grauen Stein 29, Koln, NRW 51105 Germany;
4. TUV Rheinland Japan Ltd., Global Technology Assessment Center, 4–25–2 Kita-Yamata, Tsuzuki-ku, Yokohama, Kanagawa, 224–0021 Japan;
5. TUV Rheinland (Shenzhen) Co., Ltd., 1F East & 2–4F, Cybio Technology Building No. 1, No. 16, Keibei 2nd Road High-Tech Industrial Park North, Nashan District, 518057 Shenzhen, China;
6. TUV Rheinland (Shanghai) Co. Ltd, TUV Rheinland Building No. 177, Lane 777, West Guangzhong Road Zhabei District, Shanghai 200072, P.R. China;
7. TUV Rheinland Taiwan Ltd., 11F, No. 758, Sec.4, Bade Road, Songshan District, Taipei City 105, Taiwan; and
8. TUV Rheinland Taiwan Ltd., Taichung Branch Office, No. 9, Lane 36, Minsheng Rod. Sec. 3, Daya District, Taichung City 428, Taiwan.

II. Notice of Preliminary Findings

OSHA is providing notice that TUVRNA is applying for renewal of its current recognition as a NRTL. This renewal covers TUVRNA’s existing NRTL scope of recognition. OSHA evaluated TUVRNA’s application for renewal and preliminarily determined that TUVRNA can continue to meet the requirements prescribed by 29 CFR 1910.7 for recognition. Accordingly, OSHA is making a determination that it does not need to conduct an on-site review of TUVRNA’s facilities based on its evaluations of TUVRNA’s application and all other available information. This information includes OSHA’s audit of TUVRNA’s recognized NRTL sites during this recognition period, and the satisfactory resolution of non-conformances with the requirements of 29 CFR 1910.7. This preliminary finding does not constitute an interim or temporary approval of the application for renewal.

OSHA welcomes public comment as to whether TUVRNA meets the requirements of 29 CFR 1910.7 for renewal of their recognition as a NRTL. Comments should consist of pertinent written documents and exhibits.

Commenters needing more time to comment must submit a request in writing, stating the reasons for the request. OSHA must receive the written request for an extension by the due date for comments. OSHA will limit any extension to 30 days unless the requester justifies a longer period. OSHA may deny a request for an extension if it is not adequately justified. To obtain or review copies of the publicly available information in TUVRNA's application and other pertinent documents (including exhibits), as well as all submitted comments, contact the Docket Office, Room N-3653, Occupational Safety and Health Administration, U.S. Department of Labor, at the above address; these materials also are available online at <http://www.regulations.gov> under Docket No. OSHA-2007-0042.

OSHA staff will review all comments to the docket submitted in a timely manner and, after addressing the issues raised by these comments, will make a recommendation to the Assistant Secretary as to whether to grant TUVRNA's application for renewal. The Assistant Secretary will make the final decision on granting the application and, in making this decision, may undertake other proceedings prescribed in Appendix A to 29 CFR 1910.7.

OSHA will publish a public notice of this final decision in the **Federal Register**.

III. Authority and Signature

Loren Sweatt, Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, Washington, DC 20210, authorized the preparation of this notice. Accordingly, the agency is issuing this notice pursuant to 29 U.S.C. 657(g)(2), Secretary of Labor's Order No. 1-2012 (77 FR 3912, Jan. 25, 2012), and 29 CFR 1910.7.

Signed at Washington, DC, on July 7, 2020.

Loren Sweatt,

Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2020-15069 Filed 7-10-20; 8:45 am]

BILLING CODE 4510-26-P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA-2013-0030]

IAPMO Ventures, LLC dba IAPMO EGS: Request for Renewal of Recognition

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice.

SUMMARY: In this notice, OSHA announces the application of IAPMO Ventures, LLC dba IAPMO EGS (IAPMO) requesting renewal of recognition as a Nationally Recognized Testing Laboratory (NRTL).

DATES: Submit comments, information, and documents in response to this notice, or requests for an extension of time to make a submission, on or before July 28, 2020.

ADDRESSES: Submit comments by any of the following methods:

Electronically: You may submit comments and attachments electronically at: <https://www.regulations.gov>, which is the Federal eRulemaking Portal. Follow the instructions online for submitting comments.

Facsimile: If your comments, including attachments, are not longer than 10 pages, you may fax them to the OSHA Docket Office at (202) 693-1648.

Mail, hand delivery, express mail, messenger, or courier service: When using this method, you must submit a copy of your comments and attachments to the OSHA Docket Office, Docket No. OSHA-2013-0030, Occupational Safety and Health Administration, U.S. Department of Labor, Room N-3653, 200 Constitution Avenue NW, Washington, DC 20210. Deliveries (hand, express mail, messenger, and courier service) are accepted during the Docket Office's normal business hours, 10:00 a.m. to 3:00 p.m., ET.

Instructions: All submissions must include the agency name and the OSHA docket number (OSHA-2013-0030). OSHA places comments and other materials, including any personal information, in the public docket without revision, and these materials will be available online at <http://www.regulations.gov>. Therefore, the agency cautions commenters about submitting statements they do not want made available to the public, or submitting comments that contain personal information (either about themselves or others) such as Social Security Numbers, birth dates, and medical data.

Docket: To read or download comments or other material in the docket, go to <https://www.regulations.gov> or the OSHA Docket Office at the above address. All documents in the docket (including this **Federal Register** notice) are listed in the <https://www.regulations.gov> index; however, some information (e.g., copyrighted material) is not publicly available to read or download through the website. All submissions, including

copyrighted material, are available for inspection at the OSHA Docket Office. Contact the OSHA Docket Office for assistance in locating docket submissions.

Extension of comment period: Submit requests for an extension of the comment period on or before July 28, 2020 to the Office of Technical Programs and Coordination Activities, Directorate of Technical Support and Emergency Management, Occupational Safety and Health Administration, U.S. Department of Labor, 200 Constitution Avenue NW, Room N-3653, Washington, DC 20210, or by fax to (202) 693-1644.

FOR FURTHER INFORMATION CONTACT: Information regarding this notice is available from the following sources:

Press inquiries: Contact Mr. Frank Meilinger, Director, OSHA Office of Communications, U.S. Department of Labor, telephone: (202) 693-1999; email: meilinger.francis2@dol.gov.

General and technical information: Contact Mr. Kevin Robinson, Director, Office of Technical Programs and Coordination Activities, Directorate of Technical Support and Emergency Management, Occupational Safety and Health Administration, U.S. Department of Labor, phone: (202) 693-2110 or email: robinson.kevin@dol.gov.

SUPPLEMENTARY INFORMATION:

I. Background

OSHA recognition of a NRTL signifies that the organization meets the requirements in § 1910.7 of title 29, Code of Federal Regulations (29 CFR 1910.7). Recognition is an acknowledgment that the organization can perform independent safety testing and certification of the specific products covered within its scope of recognition and is not a delegation or grant of government authority. As a result of recognition, employers may use products properly approved by the NRTL to meet OSHA standards that require testing and certification. OSHA maintains an informational web page for each NRTL that details its scope of recognition available at <http://www.osha.gov/dts/otpca/nrtl/index.html>.

The agency processes applications by a NRTL for renewal of recognition following requirements in appendix A to 29 CFR 1910.7. OSHA conducts renewals in accordance with the procedures in 29 CFR 1910.7, appendix A, paragraph II.C. In accordance with these procedures, NRTLs submit a renewal request to OSHA, not less than nine months or no more than one year, before the expiration date of its current

recognition. The submission includes a request for renewal and any additional information the NRTL wishes to submit to demonstrate its continued compliance with the terms of its recognition and 29 CFR 1910.7. If OSHA has not conducted an on-site assessment of the NRTL's headquarters and key sites within the past 18 to 24 months, it will schedule the necessary on-site assessments prior to the expiration date of the NRTL's recognition. Upon review of the submitted material and, as necessary, the successful completion of the on-site assessment, OSHA announces its preliminary decision to grant or deny renewal in the **Federal Register** and solicit comments from the public. OSHA then publishes a final **Federal Register** notice responding to any comments and renewing the NRTL's recognition for a period of five years, or denying the renewal of recognition.

IAPMO initially received OSHA recognition as a NRTL on December 22, 2014, for a five-year period expiring on December 22, 2019. IAPMO submitted a timely request for renewal, dated March 11, 2019 (OSHA-2013-0030-0012), and retains its recognition pending OSHA's final decision in this renewal process. The current address of the IAPMO facility recognized by OSHA and included as part of the renewal request is:

1. IAPMO, 5001 East Philadelphia Street, Ontario, California 91761.

II. Notice of Preliminary Findings

OSHA is providing notice that IAPMO is applying for renewal of its recognition as a NRTL. This renewal covers IAPMO's existing NRTL scope of recognition. OSHA evaluated IAPMO's application for renewal and preliminarily determined that IAPMO can continue to meet the requirements prescribed by 29 CFR 1910.7 for recognition. Accordingly, OSHA is making a determination that it does not need to conduct an additional on-site review of IAPMO's facility based on its evaluations of IAPMO's application and all other available information. This information includes OSHA's audits of IAPMO's recognized NRTL site during this recognition period, and the satisfactory resolution of non-conformances with the requirements of 29 CFR 1910.7. This preliminary finding does not constitute an interim or temporary approval of the request.

OSHA welcomes public comment as to whether IAPMO meets the requirements of 29 CFR 1910.7 for renewal of their recognition as a NRTL. Comments should consist of pertinent written documents and exhibits. Commenters needing more time to

comment must submit a request in writing, stating the reasons for the request. OSHA must receive the written request for an extension by the due date for comments. OSHA will limit any extension to 30 days unless the requester justifies a longer period. OSHA may deny a request for an extension if it is not adequately justified. To obtain or review copies of the publicly available information in IAPMO's application and other pertinent documents (including exhibits), as well as all submitted comments, contact the Docket Office, Room N-3653, Occupational Safety and Health Administration, U.S. Department of Labor, at the above address; these materials also are available online at <http://www.regulations.gov> under Docket No. OSHA-2013-0030.

OSHA staff will review all comments to the docket submitted in a timely manner and, after addressing the issues raised by these comments, will make a recommendation to the Assistant Secretary on whether to grant IAPMO's application for renewal. The Assistant Secretary will make the final decision on granting the application and, in making this decision, may undertake other proceedings prescribed in appendix A to 29 CFR 1910.7.

OSHA will publish a public notice of this final decision in the **Federal Register**.

III. Authority and Signature

Loren Sweatt, Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, Washington, DC 20210, authorized the preparation of this notice. Accordingly, the agency is issuing this notice pursuant to 29 U.S.C. 657(g)(2), Secretary of Labor's Order No. 1-2012 (77 FR 3912, Jan. 25, 2012), and 29 CFR 1910.7.

Signed at Washington, DC, on July 7, 2020.

Loren Sweatt,

Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2020-15066 Filed 7-10-20; 8:45 am]

BILLING CODE 4510-26-P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA-2007-0039]

Intertek Testing Services NA, Inc.: Request for Renewal of Recognition

AGENCY: Occupational Safety and Health Administration (OSHA), Labor

ACTION: Notice

SUMMARY: In this notice, OSHA announces the Intertek Testing Services NA, Inc. (ITSNA), application containing a request for renewal of recognition as a Nationally Recognized Testing Laboratory (NRTL).

DATES: Submit comments, information, and documents in response to this notice, or requests for an extension of time to make a submission, on or before July 28, 2020.

ADDRESSES: Submit comments by any of the following methods:

Electronically: You may submit comments and attachments electronically at: <https://www.regulations.gov>, which is the Federal eRulemaking Portal. Follow the instructions online for submitting comments.

Facsimile: If your comments, including attachments, are not longer than 10 pages, you may fax them to the OSHA Docket Office at (202) 693-1648.

Mail, hand delivery, express mail, messenger, or courier service: When using this method, you must submit a copy of your comments and attachments to the OSHA Docket Office, Docket No. OSHA-2007-0039, Occupational Safety and Health Administration, U.S. Department of Labor, Room N-3653, 200 Constitution Avenue NW, Washington, DC 20210. Deliveries (hand, express mail, messenger, and courier service) are accepted during the Docket Office's normal business hours, 10:00 a.m. to 3:00 p.m., ET.

Instructions: All submissions must include the agency name and the OSHA docket number (OSHA-2007-0039). OSHA places comments and other materials, including any personal information, in the public docket without revision, and these materials will be available online at <http://www.regulations.gov>. Therefore, the agency cautions commenters about submitting statements they do not want made available to the public, or submitting comments that contain personal information (either about themselves or others) such as Social Security Numbers, birth dates, and medical data.

Docket: To read or download comments or other material in the docket, go to <https://www.regulations.gov> or the OSHA Docket Office at the above address. All documents in the docket (including this **Federal Register** notice) are listed in the <https://www.regulations.gov> index; however, some information (e.g., copyrighted material) is not publicly available to read or download through the website. All submissions, including copyrighted material, are available for

inspection at the OSHA Docket Office. Contact the OSHA Docket Office for assistance in locating docket submissions.

Extension of comment period: Submit requests for an extension of the comment period on or before July 28, 2020 to the Office of Technical Programs and Coordination Activities, Directorate of Technical Support and Emergency Management, Occupational Safety and Health Administration, U.S. Department of Labor, 200 Constitution Avenue NW, Room N-3653, Washington, DC 20210, or by fax to (202) 693-1644.

FOR FURTHER INFORMATION CONTACT: Information regarding this notice is available from the following sources:

Press inquiries: Contact Mr. Frank Meilinger, Director, OSHA Office of Communications, U.S. Department of Labor, telephone: (202) 693-1999; email: meilinger.francis2@dol.gov.

General and technical information: Contact Mr. Kevin Robinson, Director, Office of Technical Programs and Coordination Activities, Directorate of Technical Support and Emergency Management, Occupational Safety and Health Administration, U.S. Department of Labor, phone: (202) 693-2110 or email: robinson.kevin@dol.gov.

SUPPLEMENTARY INFORMATION:

I. Background

OSHA recognition of a NRTL signifies that the organization meets the requirements in Section 1910.7 of Title 29, Code of Federal Regulations (29 CFR 1910.7). Recognition is an acknowledgment that the organization can perform independent safety testing and certification of the specific products covered within its scope of recognition and is not a delegation or grant of government authority. As a result of recognition, employers may use products properly approved by the NRTL to meet OSHA standards that require testing and certification. OSHA maintains an informational web page for each NRTL that details its scope of recognition available at <http://www.osha.gov/dts/otpca/nrtl/index.html>.

The agency processes applications by a NRTL for renewal of recognition following requirements in Appendix A to 29 CFR 1910.7. OSHA conducts renewals in accordance with the procedures in 29 CFR 1910.7, Appendix A, paragraph II.C. In accordance with these procedures, NRTLs submit a renewal request to OSHA, not less than nine months or no more than one year, before the expiration date of its current recognition. The submission includes a

request for renewal and any additional information the NRTL wishes to submit to demonstrate its continued compliance with the terms of its recognition and 29 CFR 1910.7. If OSHA has not conducted an on-site assessment of the NRTL's headquarters and key sites within the past 18 to 24 months, it will schedule the necessary on-site assessments prior to the expiration date of the NRTL's recognition. Upon review of the submitted material and, as necessary, the successful completion of the on-site assessment, OSHA announces its preliminary decision to grant or deny renewal in the **Federal Register** and solicit comments from the public. OSHA then publishes a final **Federal Register** notice responding to any comments and renewing the NRTL's recognition for a period of five years, or denying the renewal of recognition.

ITSNA initially received OSHA recognition as a NRTL on September 13, 1989 (54 FR 37845). ITSNA's most recent renewal was granted on July 14, 2014, for a five-year period, expiring on July 14, 2019. ITSNA submitted a timely request for renewal, dated September 13, 2018 (OSHA-2007-0039-0032), and retains its recognition pending OSHA's final decision in this renewal process. The current addresses of ITSNA facilities recognized by OSHA and included as part of the renewal request are:

1. ITSNA Cortland, 3933 U.S. Route 11, Cortland, New York 13045;
2. ITSNA Atlanta, 1950 Evergreen Boulevard, Duluth, Georgia 30096;
3. ITSNA Boxborough, 70 Codman Hill Road, Boxborough, Massachusetts 01719;
4. ITSNA San Francisco, 1365 Adams Court, Menlo Park, California 94025;
5. ITSNA Los Angeles, 25791 Commercentre Drive, Lake Forest, California 92630;
6. ITSNA Minneapolis, 7250 Hudson Boulevard, Suite 100, Oakdale, Minnesota 55128;
7. ITSNA Madison, 8431 Murphy Drive, Middleton, Wisconsin 53562;
8. ITSNA SEMKO, Box 1103, S-164 #22, Kista, Stockholm, Sweden;
9. ITSNA Chicago, 545 East Algonquin Road, Suite F, Arlington Heights, Illinois 60005;
10. ITSNA Hong Kong, 2/F., Garment Centre, 576 Castle Peak Road, Kowloon, Hong Kong;
11. ITSNA Vancouver, 1500 Brigantine Drive, Coquitlam, British Columbia, Canada V3K 7C1;
12. ITSNA Fairfield, 41 Plymouth Street, Fairfield, New Jersey 07004; and
13. ITSNA Dallas, 1809 10th Street, Suite 400, Plano, Texas 75074.

II. Notice of Preliminary Findings

OSHA is providing notice that ITSNA is applying for renewal of its recognition as a NRTL. This renewal covers ITSNA's existing NRTL scope of recognition. OSHA evaluated ITSNA's application for renewal and preliminarily determined that ITSNA can continue to meet the requirements prescribed by 29 CFR 1910.7 for recognition. Accordingly, OSHA is making a determination that it does not need to conduct an additional on-site review of ITSNA's facilities based on its evaluations of ITSNA's application and all other available information. This information includes OSHA's audits of ITSNA's recognized NRTL sites during this recognition period, and the satisfactory resolution of non-conformances with the requirements of 29 CFR 1910.7. This preliminary finding does not constitute an interim or temporary approval of the request.

OSHA welcomes public comment as to whether ITSNA meets the requirements of 29 CFR 1910.7 for renewal of their recognition as a NRTL. Comments should consist of pertinent written documents and exhibits. Commenters needing more time to comment must submit a request in writing, stating the reasons for the request. OSHA must receive the written request for an extension by the due date for comments. OSHA will limit any extension to 30 days unless the requester justifies a longer period. OSHA may deny a request for an extension if it is not adequately justified. To obtain or review copies of the publicly available information in ITSNA's application and other pertinent documents (including exhibits), as well as all submitted comments, contact the Docket Office, Room N-3653, Occupational Safety and Health Administration, U.S. Department of Labor, at the above address; these materials also are available online at <http://www.regulations.gov> under Docket No. OSHA-2007-0039.

OSHA staff will review all comments to the docket submitted in a timely manner and, after addressing the issues raised by these comments, will make a recommendation to the Assistant Secretary as to whether to grant ITSNA's application for renewal. The Assistant Secretary will make the final decision on granting the application and, in making this decision, may undertake other proceedings prescribed in Appendix A to 29 CFR 1910.7.

OSHA will publish a public notice of this final decision in the **Federal Register**.

III. Authority and Signature

Loren Sweatt, Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health, US Department of Labor, Washington, DC 20210, authorized the preparation of this notice. Accordingly, the agency is issuing this notice pursuant to 29 U.S.C. 657(g)(2), Secretary of Labor's Order No. 1-2012 (77 FR 3912, Jan. 25, 2012), and 29 CFR 1910.7.

Signed at Washington, DC, on July 7, 2020.

Loren Sweatt,

Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2020-15067 Filed 7-10-20; 8:45 am]

BILLING CODE 4510-26-P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA-2009-0026]

Bureau Veritas Consumer Products Services, Inc.: Request for Renewal of Recognition

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice.

SUMMARY: In this notice, OSHA announces the application of Bureau Veritas Consumer Products Services, Inc. requesting renewal of recognition as a Nationally Recognized Testing Laboratory (NRTL).

DATES: Submit comments, information, and documents in response to this notice, or requests for an extension of time to make a submission, on or before July 28, 2020.

ADDRESSES: Submit comments by any of the following methods:

Electronically: You may submit comments and attachments electronically at: <https://www.regulations.gov>, which is the Federal eRulemaking Portal. Follow the instructions online for submitting comments.

Facsimile: If your comments, including attachments, are not longer than 10 pages, you may fax them to the OSHA Docket Office at (202) 693-1648.

Mail, hand delivery, express mail, messenger, or courier service: When using this method, you must submit a copy of your comments and attachments to the OSHA Docket Office, Docket No. OSHA-2009-0026, Occupational Safety and Health Administration, U.S. Department of Labor, Room N-3653, 200 Constitution Avenue NW, Washington, DC 20210. Deliveries (hand, express mail, messenger, and

courier service) are accepted during the Docket Office's normal business hours, 10:00 a.m. to 3:00 p.m., ET.

Instructions: All submissions must include the agency name and the OSHA docket number (OSHA-2009-0026). OSHA places comments and other materials, including any personal information, in the public docket without revision, and these materials will be available online at <http://www.regulations.gov>. Therefore, the agency cautions commenters about submitting statements they do not want made available to the public, or submitting comments that contain personal information (either about themselves or others) such as Social Security numbers, birth dates, and medical data.

Docket: To read or download comments or other material in the docket, go to <https://www.regulations.gov> or the OSHA Docket Office at the above address. All documents in the docket (including this **Federal Register** notice) are listed in the <https://www.regulations.gov> index; however, some information (e.g., copyrighted material) is not publicly available to read or download through the website. All submissions, including copyrighted material, are available for inspection at the OSHA Docket Office. Contact the OSHA Docket Office for assistance in locating docket submissions.

Extension of comment period: Submit requests for an extension of the comment period on or before July 28, 2020 to the Office of Technical Programs and Coordination Activities, Directorate of Technical Support and Emergency Management, Occupational Safety and Health Administration, U.S. Department of Labor, 200 Constitution Avenue NW, Room N-3653, Washington, DC 20210, or by fax to (202) 693-1644.

FOR FURTHER INFORMATION CONTACT: Information regarding this notice is available from the following sources:

Press inquiries: Contact Mr. Frank Meilinger, Director, OSHA Office of Communications, U.S. Department of Labor, telephone: (202) 693-1999; email: meilinger.francis2@dol.gov.

General and technical information: Contact Mr. Kevin Robinson, Director, Office of Technical Programs and Coordination Activities, Directorate of Technical Support and Emergency Management, Occupational Safety and Health Administration, U.S. Department of Labor, phone: (202) 693-2110 or email: robinson.kevin@dol.gov.

SUPPLEMENTARY INFORMATION:

I. Background

OSHA recognition of a NRTL signifies that the organization meets the requirements in § 1910.7 of title 29, Code of Federal Regulations (29 CFR 1910.7). Recognition is an acknowledgment that the organization can perform independent safety testing and certification of the specific products covered within its scope of recognition and is not a delegation or grant of government authority. As a result of recognition, employers may use products properly approved by the NRTL to meet OSHA standards that require testing and certification. OSHA maintains an informational web page for each NRTL that details its scope of recognition available at <http://www.osha.gov/dts/otpca/nrtl/index.html>.

The agency processes applications by a NRTL for renewal of recognition following requirements in appendix A to 29 CFR 1910.7. OSHA conducts renewals in accordance with the procedures in 29 CFR 1910.7, appendix A, paragraph II.C. In accordance with these procedures, NRTLs would submit a renewal request to OSHA, not less than nine months or no more than one year, before the expiration date of its current recognition. A request would include a request for renewal and any additional information the NRTL wishes to submit to demonstrate its continued compliance with the terms of its recognition and 29 CFR 1910.7. If OSHA has not conducted an on-site assessment of the NRTL's headquarters and any key sites within the past 18-24 months, it will schedule the necessary on-site assessments prior to the expiration date of the NRTL's recognition. Upon review of the submitted material and, as necessary, the successful completion of the on-site assessment, OSHA announces its preliminary decision to grant or deny renewal in the **Federal Register** and solicit comments from the public. OSHA then publishes a final **Federal Register** notice responding to any comments and renewing the NRTL's recognition for a period of five years, or denying the renewal of recognition.

Bureau Veritas Consumer Products Services, Inc. (BVCPS) initially received OSHA recognition as a NRTL on May 8, 2000 (65 FR 26637), for a five-year period ending on January 25, 2007. Renewal of this recognition was granted on April 22, 2014, for a five year period ending on April 22, 2019. BVCPS submitted a timely request for renewal, dated May 25, 2018 (OSHA-2009-0026-0082), and retains its recognition pending OSHA's final decision in this renewal process. The current address of

the BVCPS facility recognized by OSHA and included as part of the renewal request is:

1. Bureau Veritas Consumer Products Services, Inc. (BVCPS), Littleton Distribution Center, One Distribution Center Circle, Suite #1, Littleton, Massachusetts 01460.

II. Notice of Preliminary Finding

OSHA is providing notice that BVCPS is applying for renewal of its recognition as a NRTL. This renewal covers BVCPS's existing NRTL scope of recognition. OSHA evaluated BVCPS's application for renewal and preliminarily determined that BVCPS can continue to meet the requirements prescribed by 29 CFR 1910.7 for recognition. Accordingly, OSHA is making a determination that it does not need to conduct an additional on-site review of BVCPS's facilities based on its evaluations of BVCPS's application and all other available information. This information includes OSHA audits of BVCPS recognized NRTL site during this recognition period, and the satisfactory resolution of non-conformances with the requirements of 29 CFR 1910.7. This preliminary finding does not constitute an interim or temporary approval of the request.

OSHA welcomes public comment as to whether BVCPS meets the requirements of 29 CFR 1910.7 for renewal of their recognition as a NRTL. Comments should consist of pertinent written documents and exhibits. Commenters needing more time to comment must submit a request in writing, stating the reasons for the request. OSHA must receive the written request for an extension by the due date for comments. OSHA will limit any extension to 30 days unless the requester justifies a longer period. OSHA may deny a request for an extension if it is not adequately justified. To obtain or review copies of the publicly available information in BVCPS's application and other pertinent documents (including exhibits), as well as all submitted comments, contact the Docket Office at the address listed above. These materials also are available online at <http://www.regulations.gov> under Docket No. OSHA-2009-0026.

The NRTL program staff will review all comments to the docket submitted in a timely manner and, after addressing the issues raised by these comments, will make a recommendation to the Assistant Secretary on whether to grant BVCPS's application for renewal. The Assistant Secretary will make the final decision on granting the application and, in making this decision, may

undertake other proceedings prescribed in appendix A to 29 CFR 1910.7.

OSHA will publish a public notice of this final decision in the **Federal Register**.

III. Authority and Signature

Loren Sweatt, Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, Washington, DC 20210, authorized the preparation of this notice. Accordingly, the agency is issuing this notice pursuant to Section 8(g)(2) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 657(g)(2)), Secretary of Labor's Order No. 1-2012 (77 FR 3912, Jan. 25, 2012), and 29 CFR 1910.7.

Signed at Washington, DC, on July 7, 2020.

Loren Sweatt,

Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2020-15064 Filed 7-10-20; 8:45 am]

BILLING CODE 4510-26-P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA-2005-0022]

TÜV SÜD Product Services GmbH: Request for Renewal of Recognition

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice.

SUMMARY: In this notice, OSHA announces the application of TÜV SÜD Product Services GmbH requesting renewal of recognition as a Nationally Recognized Testing Laboratory (NRTL). **DATES:** Submit comments, information, and documents in response to this notice, or requests for an extension of time to make a submission, on or before July 28, 2020.

ADDRESSES: Submit comments by any of the following methods: *Electronically:* You may submit comments and attachments electronically at: <https://www.regulations.gov>, which is the Federal eRulemaking Portal. Follow the instructions online for submitting comments.

Facsimile: If your comments, including attachments, are not longer than 10 pages, you may fax them to the OSHA Docket Office at (202) 693-1648.

Mail, hand delivery, express mail, messenger, or courier service: When using this method, you must submit a copy of your comments and attachments to the OSHA Docket Office, Docket No. OSHA-2005-0022, Occupational Safety

and Health Administration, U.S. Department of Labor, Room N-3653, 200 Constitution Avenue NW, Washington, DC 20210. Deliveries (hand, express mail, messenger, and courier service) are accepted during the Docket Office's normal business hours, 10:00 a.m. to 3:00 p.m., ET.

Instructions: All submissions must include the agency name and the OSHA docket number (OSHA-2005-0022). OSHA places comments and other materials, including any personal information, in the public docket without revision, and these materials will be available online at <http://www.regulations.gov>. Therefore, the agency cautions commenters about submitting statements they do not want made available to the public, or submitting comments that contain personal information (either about themselves or others) such as Social Security Numbers, birth dates, and medical data.

Docket: To read or download comments or other material in the docket, go to <https://www.regulations.gov> or the OSHA Docket Office at the above address. All documents in the docket (including this **Federal Register** notice) are listed in the <https://www.regulations.gov> index; however, some information (e.g., copyrighted material) is not publicly available to read or download through the website. All submissions, including copyrighted material, are available for inspection at the OSHA Docket Office. Contact the OSHA Docket Office for assistance in locating docket submissions.

Extension of comment period: Submit requests for an extension of the comment period on or before July 28, 2020 to the Office of Technical Programs and Coordination Activities, Directorate of Technical Support and Emergency Management, Occupational Safety and Health Administration, U.S. Department of Labor, 200 Constitution Avenue NW, Room N-3653, Washington, DC 20210, or by fax to (202) 693-1644.

FOR FURTHER INFORMATION CONTACT: Information regarding this notice is available from the following sources:

Press inquiries: Contact Mr. Frank Meilinger, Director, OSHA Office of Communications, U.S. Department of Labor, telephone: (202) 693-1999; email: meilinger.francis2@dol.gov.

General and technical information: Contact Mr. Kevin Robinson, Director, Office of Technical Programs and Coordination Activities, Directorate of Technical Support and Emergency Management, Occupational Safety and

Health Administration, U.S. Department of Labor, phone: (202) 693-2110 or email: robinson.kevin@dol.gov.

SUPPLEMENTARY INFORMATION:

I. Background

OSHA recognition of a NRTL signifies that the organization meets the requirements in Section 1910.7 of Title 29, Code of Federal Regulations (29 CFR 1910.7). Recognition is an acknowledgment that the organization can perform independent safety testing and certification of the specific products covered within its scope of recognition and is not a delegation or grant of government authority. As a result of recognition, employers may use products properly approved by the NRTL to meet OSHA standards that require testing and certification. OSHA maintains an informational web page for each NRTL that details its scope of recognition available at <http://www.osha.gov/dts/otpca/nrtl/index.html>.

The agency processes applications by a NRTL for renewal of recognition following requirements in Appendix A to 29 CFR 1910.7. OSHA conducts renewals in accordance with the procedures in 29 CFR 1910.7, Appendix A, Section II.C. In accordance with these procedures, NRTLs would submit a renewal request to OSHA, not less than nine months or no more than one year, before the expiration date of its current recognition. A request would include a request for renewal and any additional information the NRTL wishes to submit to demonstrate its continued compliance with the terms of its recognition and 29 CFR 1910.7. If OSHA has not conducted an on-site assessment of the NRTL headquarters and any key sites within the past 18 months, it will schedule the necessary on-site assessments prior to the expiration date of the NRTL's recognition. Upon review of the submitted material and, as necessary, the successful completion of the on-site assessment, OSHA announces its preliminary decision to grant or deny renewal in the **Federal Register** and solicit comments from the public. OSHA then publishes a final **Federal Register** notice responding to any comments and renewing the NRTL's recognition for a period of five years, or denying the renewal of recognition.

TÜV SÜD Product Services GmbH (TUVPSG) initially received OSHA recognition as a NRTL on July 20, 2001 (66 FR 38032). TUVPSG's most recent renewal was granted on January 30, 2014, for a five year period ending on January 30, 2019. TUVPSG submitted a timely request for renewal, dated April 16, 2018 (OSHA-2005-0022-0012), and

retains its recognition pending OSHA's final decision in this renewal process. The current addresses of TUVPSG facilities recognized by OSHA and included as part of the renewal request are:

1. TÜV SÜD Product Services GmbH Munich, Ridlerstrasse 65 D-80339 Munich, Germany; and
2. TÜV SÜD Product Services GmbH, Daimlerstrasse 11 D-85748 Garching, Germany.

II. Notice of Preliminary Findings

OSHA is providing notice that TUVPSG is applying for renewal of its recognition as a NRTL. This renewal covers TUVPSG's existing NRTL scope of recognition. TUVPSG submitted an acceptable application for renewal of its recognition as a NRTL on April 16, 2018. OSHA evaluated TUVPSG's application for renewal and preliminarily determined that TUVPSG can continue to meet the requirements prescribed by 29 CFR 1910.7 for recognition. Accordingly, OSHA is making a determination that it does not need to conduct an additional on-site review of TUVPSG's facilities based on its evaluations of TUVPSG's application and all other available information. This information includes OSHA's audits of TUVPSG's recognized NRTL sites during this recognition period, and the satisfactory resolution of non-conformances with the requirements of 29 CFR 1910.7. This preliminary finding does not constitute an interim or temporary approval of the request.

OSHA welcomes public comment as to whether TUVPSG meets the requirements of 29 CFR 1910.7 for renewal of their recognition as a NRTL. Comments should consist of pertinent written documents and exhibits. Commenters needing more time to comment must submit a request in writing, stating the reasons for the request. OSHA must receive the written request for an extension by the due date for comments. OSHA will limit any extension to 30 days unless the requester justifies a longer period. OSHA may deny a request for an extension if it is not adequately justified. To obtain or review copies of the publicly available information in TUVPSG's application and other pertinent documents (including exhibits), as well as all submitted comments, contact the Docket Office, Room N-3653, Occupational Safety and Health Administration, U.S. Department of Labor, at the above address; these materials also are available online at <http://www.regulations.gov> under Docket No. OSHA-2005-0022.

OSHA staff will review all comments to the docket submitted in a timely manner and, after addressing the issues raised by these comments, will make a recommendation to the Assistant Secretary on whether to grant TUVPSG's application for renewal. The Assistant Secretary will make the final decision on granting the application and, in making this decision, may undertake other proceedings prescribed in Appendix A to 29 CFR 1910.7.

OSHA will publish a public notice of this final decision in the **Federal Register**.

III. Authority and Signature

Loren Sweatt, Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, Washington, DC 20210, authorized the preparation of this notice. Accordingly, the agency is issuing this notice pursuant to Section 8(g)(2) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 657(g)(2)), Secretary of Labor's Order No. 1-2012 (77 FR 3912, Jan. 25, 2012), and 29 CFR 1910.7.

Signed at Washington, DC, on July 7, 2020.

Loren Sweatt,

Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2020-15071 Filed 7-10-20; 8:45 am]

BILLING CODE 4510-26-P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA-2010-0025]

The Hydrostatic Testing Provision of the Standard on Portable Fire Extinguishers; Extension of the Office of Management and Budget's (OMB) Approval of Information Collection (Paperwork) Requirements

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Request for public comments.

SUMMARY: OSHA solicits public comments concerning the proposal to extend the Office of Management and Budget's (OMB) approval of the information collection requirements specified in the Hydrostatic Testing Provision of the Standard on Portable Fire Extinguishers.

DATES: Comments must be submitted (postmarked, sent, or received) by September 11, 2020.

ADDRESSES:

Electronically: You may submit comments and attachments

electronically at <http://www.regulations.gov>, which is the Federal e-Rulemaking Portal. Follow the instructions online for submitting comments.

Facsimile: If your comments, including attachments, are not longer than 10 pages you may fax them to the OSHA Docket Office at (202) 693-1648.

Mail, hand delivery, express mail, messenger, or courier service: When using this method, you must submit your comments and attachments to the OSHA Docket Office, Docket No. OSHA-2010-0025, Occupational Safety and Health Administration, U.S. Department of Labor, Room N-3653, 200 Constitution Avenue NW, Washington, DC 20210. Deliveries (hand, express mail, messenger, and courier service) are accepted during the Docket Office's normal business hours, 10:00 a.m. to 3:00 p.m., ET.

Instructions: All submissions must include the agency name and the OSHA docket number (OSHA-2010-0025) for the Information Collection Request (ICR). All comments, including any personal information you provide, such as social security number and date of birth, are placed in the public docket without change, and may be made available online at <http://www.regulations.gov>. For further information on submitting comments see the "Public Participation" heading in the section of this notice titled **SUPPLEMENTARY INFORMATION**.

Docket: To read or download comments or other material in the docket, go to <http://www.regulations.gov> or the OSHA Docket Office at the above address. All documents in the docket (including this **Federal Register** notice) are listed in the <http://www.regulations.gov> index; however, some information (e.g., copyrighted material) is not publicly available to read or download from the website. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. You also may contact Theda Kenney at the below phone number to obtain a copy of the ICR.

FOR FURTHER INFORMATION CONTACT: Theda Kenney or Seleda Perryman, Directorate of Standards and Guidance, OSHA, U.S. Department of Labor; telephone (202) 693-2222.

SUPPLEMENTARY INFORMATION:

I. Background

The Department of Labor, as part of the continuing effort to reduce paperwork and respondent (*i.e.*, employer) burden, conducts a preclearance consultation program to

provide the public with an opportunity to comment on proposed and continuing information collection requirements in accordance with the Paperwork Reduction Act (PRA) (44 U.S.C. 3506(c)(2)(A)). This program ensures that information is in the desired format, reporting burden (time and costs) is minimal, collection instruments are clearly understood, and OSHA's estimate of the information collection burden is accurate. The Occupational Safety and Health Act of 1970 (the OSH Act) (29 U.S.C. 651 *et seq.*) authorizes information collection by employers as necessary or appropriate for enforcement of the OSH Act or for developing information regarding the causes and prevention of occupational injuries, illnesses, and accidents (29 U.S.C. 657). The OSH Act also requires that OSHA obtain such information with minimum burden upon employers, especially those operating small businesses, and to reduce to the maximum extent feasible unnecessary duplication of efforts in obtaining information (29 U.S.C. 657).

The collection of information contained in the Hydrostatic Testing Provision of the Portable Fire Extinguishers Standard are necessary to reduce workers' risk of death or serious injury by ensuring that portable fire extinguishers are in safe operating condition. The following paragraphs describe who uses the information in the testing certification record, as well as how they use it.

Test Records (§ 1910.157(f)(16))

Paragraph (f)(16) requires employers to develop and maintain a certification record of hydrostatic testing of portable fire extinguishers. The certification record must include the date of inspection, the signature of the person who performed the test, and the serial number (or other identifier) of the fire extinguisher that was tested.

Disclosure of Test Certification Records

The certification record must be made available to the Assistant Secretary or his/her representative upon request. The certification record provides assurance to employers, workers, and OSHA compliance officers that the fire extinguishers have been hydrostatically tested in accordance with and at the intervals specified in § 1910.157(f)(16), thereby ensuring that they will operate properly in the event workers need to use them. Additionally, these records provide the most efficient means for the compliance officers to determine that an employer is complying with the hydrostatic testing provision.

II. Special Issues for Comment

OSHA has a particular interest in comments on the following issues:

- Whether the proposed information collection requirements are necessary for the proper performance of the agency's functions, including whether the information is useful;
- The accuracy of OSHA's estimate of the burden (time and costs) of the information collection requirements, including the validity of the methodology and assumptions used;
- The quality, utility, and clarity of the information collected; and
- Ways to minimize the burden on employers who must comply; for example, by using automated or other technological information collection and transmission techniques.

III. Proposed Actions

OSHA is requesting that OMB extend the approval of the collection of information (paperwork) requirements contained in the Hydrostatic Testing Provision of the Standard on Portable Fire Extinguishers. There is an adjustment decrease in burden hours for this ICR. The burden hours have decreased a total of 14,784 hours (from 519,161 to 504,377 hours).

Type of Review: Extension of a currently approved collection.

Title: Hydrostatic Testing Provision of the Standard on Portable Fire Extinguishers. (29 CFR 1910.157(f)(16)).

OMB Number: 1218-0218.

Affected Public: Business or other for-profit; farms.

Number of Respondents: 5,869,911.

Frequency of Response: On occasion.

Total Responses: 5,217,699.

Average Time per Response: Ranges from one minute (1/60 hour) to maintain the certification records to 33 minutes (33/60 hour) to test an extinguisher, and generate and maintain the certification record.

Estimated Total Burden Hours: 504,377.

Estimated Cost (Operation and Maintenance): \$76,637,563.

IV. Public Participation—Submission of Comments on This Notice and internet Access to Comments and Submissions

You may submit comments in response to this document as follows: (1) Electronically at <http://www.regulations.gov>, which is the Federal e-Rulemaking Portal; (2) by facsimile; or (3) by hard copy. All comments, attachments, and other material must identify the agency name and the OSHA docket number for this ICR (Docket No. OSHA-2010-0025). You may supplement electronic

submissions by uploading document files electronically. If you wish to mail additional materials in reference to an electronic or facsimile submission, you must submit them to the OSHA Docket Office (see the section of this notice titled **ADDRESSES**). The additional materials must clearly identify your electronic comments by your name, date, and the docket number so the agency can attach them to your comments.

Because of security procedures, the use of regular mail may cause a significant delay in the receipt of comments. For information about security procedures concerning the delivery of materials by hand, express delivery, messenger, or courier service, please contact the OSHA Docket Office at (202) 693-2350, (TTY) (877) 889-5627).

Comments and submissions are posted without change at <http://www.regulations.gov>. Therefore, OSHA cautions commenters about submitting personal information such as your social security number and date of birth. Although all submissions are listed in the <http://www.regulations.gov> index, some information (e.g., copyrighted material) is not publicly available to read or download from this website. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. Information on using the <http://www.regulations.gov> website to submit comments and access the docket is available at the website's "User Tips" link. Contact the OSHA Docket Office for information about materials not available from the website, and for assistance in using the internet to locate docket submissions.

V. Authority and Signature

Loren Sweatt, Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health, directed the preparation of this notice. The authority for this notice is the Paperwork Reduction Act of 1995 (44 U.S.C. 3506 *et seq.*) and Secretary of Labor's Order No. 1-2012 (77 FR 3912).

Signed at Washington, DC, on July 7, 2020.

Loren Sweatt,

Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2020-15000 Filed 7-10-20; 8:45 am]

BILLING CODE 4510-26-P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA-2006-0042]

CSA Group Testing & Certification Inc.: Request for Renewal of Recognition

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice.

SUMMARY: In this notice, OSHA announces the application of CSA Group Testing & Certification Inc. (CSA) requesting renewal of recognition as a Nationally Recognized Testing Laboratory (NRTL).

DATES: Submit comments, information, and documents in response to this notice, or requests for an extension of time to make a submission, on or before July 28, 2020.

ADDRESSES: Submit comments by any of the following methods:

Electronically: You may submit comments and attachments electronically at <https://www.regulations.gov>, which is the Federal eRulemaking Portal. Follow the instructions online for submitting comments.

Facsimile: If your comments, including attachments, are not longer than 10 pages, you may fax them to the OSHA Docket Office at (202) 693-1648.

Mail, hand delivery, express mail, messenger, or courier service: When using this method, you must submit a copy of your comments and attachments to the OSHA Docket Office, Docket No. OSHA-2006-0042, Occupational Safety and Health Administration, U.S. Department of Labor, Room N-3653, 200 Constitution Avenue NW, Washington, DC 20210. Deliveries (hand, express mail, messenger, and courier service) are accepted during the Docket Office's normal business hours, 10:00 a.m. to 3:00 p.m., ET.

Instructions: All submissions must include the agency name and the OSHA docket number (OSHA-2006-0042). OSHA places comments and other materials, including any personal information, in the public docket without revision, and these materials will be available online at <http://www.regulations.gov>. Therefore, the agency cautions commenters about submitting statements they do not want made available to the public, or submitting comments that contain personal information (either about themselves or others) such as Social Security Numbers, birth dates, and medical data.

Docket: To read or download comments or other material in the docket, go to <https://www.regulations.gov> or the OSHA Docket Office at the above address. All documents in the docket (including this **Federal Register** notice) are listed in the <https://www.regulations.gov> index; however, some information (e.g., copyrighted material) is not publicly available to read or download through the website. All submissions, including copyrighted material, are available for inspection at the OSHA Docket Office. Contact the OSHA Docket Office for assistance in locating docket submissions.

Extension of comment period: Submit requests for an extension of the comment period on or before July 28, 2020 to the Office of Technical Programs and Coordination Activities, Directorate of Technical Support and Emergency Management, Occupational Safety and Health Administration, U.S. Department of Labor, 200 Constitution Avenue NW, Room N-3653, Washington, DC 20210, or by fax to (202) 693-1644.

FOR FURTHER INFORMATION CONTACT: Information regarding this notice is available from the following sources:

Press inquiries: Contact Mr. Frank Meilinger, Director, OSHA Office of Communications, U.S. Department of Labor, telephone: (202) 693-1999; email: meilinger.francis2@dol.gov.

General and technical information: Contact Mr. Kevin Robinson, Director, Office of Technical Programs and Coordination Activities, Directorate of Technical Support and Emergency Management, Occupational Safety and Health Administration, U.S. Department of Labor, phone: (202) 693-2110 or email: robinson.kevin@dol.gov.

SUPPLEMENTARY INFORMATION:

I. Background

OSHA recognition of a NRTL signifies that the organization meets the requirements in § 1910.7 of title 29, Code of Federal Regulations (29 CFR 1910.7). Recognition is an acknowledgment that the organization can perform independent safety testing and certification of the specific products covered within its scope of recognition and is not a delegation or grant of government authority. As a result of recognition, employers may use products properly approved by the NRTL to meet OSHA standards that require testing and certification. OSHA maintains an informational web page for each NRTL that details its scope of recognition available at <http://www.osha.gov/dts/otpcanrntl/index.html>.

The agency processes applications by a NRTL for renewal of recognition following requirements in appendix A to 29 CFR 1910.7. OSHA conducts renewals in accordance with the procedures in 29 CFR 1910.7, appendix A, paragraph II.C. In accordance with these procedures, NRTLs submit a renewal request to OSHA, not less than nine months or no more than one year, before the expiration date of its current recognition. The submission includes a request for renewal and any additional information the NRTL wishes to submit to demonstrate its continued compliance with the terms of its recognition and 29 CFR 1910.7. If OSHA has not conducted an on-site assessment of the NRTL's headquarters and key sites within the past 18 to 24 months, it will schedule the necessary on-site assessments prior to the expiration date of the NRTL's recognition. Upon review of the submitted material and, as necessary, the successful completion of the on-site assessment, OSHA announces its preliminary decision to grant or deny renewal in the **Federal Register** and solicit comments from the public. OSHA then publishes a final **Federal Register** notice responding to any comments and renewing the NRTL's recognition for a period of five years, or denying the renewal of recognition.

CSA initially received OSHA recognition as a NRTL on December 24, 1992 (57 FR 61452). CSA's most recent renewal was granted on August 7, 2014, for a five-year period ending on August 7, 2019. CSA submitted a timely request for renewal, dated August 20, 2018 (OSHA-2006-0042-0016), and retains its recognition pending OSHA's final decision in this renewal process. The current addresses of CSA facilities recognized by OSHA and included as part of the renewal request are:

1. CSA Group Toronto, 178 Rexdale Boulevard, Etobicoke, Ontario, Canada M9W 1R3;
2. CSA Group Montreal, 865 Ellingham Street, Pointe-Claire, Quebec, Canada H9R 5E8;
3. CSA Group Irvine, 2805 Barranca Parkway, Irvine, California 92606;
4. CSA Group Edmonton, 1707-94th Street, Edmonton, Alberta, Canada T6N 1E6;
5. CSA Group Vancouver, 13799 Commerce Parkway, Richmond, British Columbia, Canada V6V 2N9; and
6. CSA Group Cleveland, 8501 East Pleasant Valley Road, Cleveland, Ohio, 44131.

II. Notice of Preliminary Findings

OSHA is providing notice that CSA is applying for renewal of its recognition

as a NRTL. This renewal covers CSA's existing NRTL scope of recognition. OSHA evaluated CSA's application for renewal and preliminarily determined that CSA can continue to meet the requirements prescribed by 29 CFR 1910.7 for recognition. Accordingly, OSHA is making a determination that it does not need to conduct an additional on-site review of CSA's facilities based on its evaluations of CSA's application and all other available information. This information includes OSHA's audits of CSA's recognized NRTL sites during this recognition period, and the resolution of non-conformances with the requirements of 29 CFR 1910.7 that were addressed sufficiently to meet the applicable NRTL requirements. This preliminary finding does not constitute an interim or temporary approval of the request.

OSHA welcomes public comment as to whether CSA meets the requirements of 29 CFR 1910.7 for renewal of their recognition as a NRTL. Comments should consist of pertinent written documents and exhibits. Commenters needing more time to comment must submit a request in writing, stating the reasons for the request. OSHA must receive the written request for an extension by the due date for comments. OSHA will limit any extension to 30 days unless the requester justifies a longer period. OSHA may deny a request for an extension if it is not adequately justified. To obtain or review copies of the publicly available information in CSA's application and other pertinent documents (including exhibits), as well as all submitted comments, contact the Docket Office, Room N-3653, Occupational Safety and Health Administration, U.S. Department of Labor, at the above address; these materials also are available online at <http://www.regulations.gov> under Docket No. OSHA-2006-0042.

OSHA staff will review all comments to the docket submitted in a timely manner and, after addressing the issues raised by these comments, will make a recommendation to the Assistant Secretary on whether to grant CSA's application for renewal. The Assistant Secretary will make the final decision on granting the application and, in making this decision, may undertake other proceedings prescribed in appendix A to 29 CFR 1910.7.

OSHA will publish a public notice of this final decision in the **Federal Register**.

III. Authority and Signature

Loren Sweatt, Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health, U.S.

Department of Labor, Washington, DC 20210, authorized the preparation of this notice. Accordingly, the agency is issuing this notice pursuant to 29 U.S.C. 657(g)(2), Secretary of Labor's Order No. 1-2012 (77 FR 3912, Jan. 25, 2012), and 29 CFR 1910.7.

Signed at Washington, DC, on July 7, 2020.

Loren Sweatt,

Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2020-15063 Filed 7-10-20; 8:45 am]

BILLING CODE 4510-26-P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA-2007-0041]

FM Approvals LLC: Request for Renewal of Recognition

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice.

SUMMARY: In this notice, OSHA announces the application of FM Approvals, LLC (FM) requesting renewal of recognition as a Nationally Recognized Testing Laboratory (NRTL).

DATES: Submit comments, information, and documents in response to this notice, or requests for an extension of time to make a submission, on or before July 28, 2020.

ADDRESSES: Submit comments by any of the following methods:

Electronically: You may submit comments and attachments electronically at: <https://www.regulations.gov>, which is the Federal eRulemaking Portal. Follow the instructions online for submitting comments.

Facsimile: If your comments, including attachments, are not longer than 10 pages, you may fax them to the OSHA Docket Office at (202) 693-1648.

Mail, hand delivery, express mail, messenger, or courier service: When using this method, you must submit a copy of your comments and attachments to the OSHA Docket Office, Docket No. OSHA-2007-0041, Occupational Safety and Health Administration, U.S. Department of Labor, Room N-3653, 200 Constitution Avenue NW, Washington, DC 20210. Deliveries (hand, express mail, messenger, and courier service) are accepted during the Docket Office's normal business hours, 10:00 a.m. to 3:00 p.m., ET.

Instructions: All submissions must include the agency name and the OSHA docket number (OSHA-2007-0041).

OSHA places comments and other materials, including any personal information, in the public docket without revision, and these materials will be available online at <http://www.regulations.gov>. Therefore, the agency cautions commenters about submitting statements they do not want made available to the public, or submitting comments that contain personal information (either about themselves or others) such as Social Security Numbers, birth dates, and medical data.

Docket: To read or download comments or other material in the docket, go to <https://www.regulations.gov> or the OSHA Docket Office at the above address. All documents in the docket (including this **Federal Register** notice) are listed in the <https://www.regulations.gov> index; however, some information (e.g., copyrighted material) is not publicly available to read or download through the website. All submissions, including copyrighted material, are available for inspection at the OSHA Docket Office. Contact the OSHA Docket Office for assistance in locating docket submissions.

Extension of comment period: Submit requests for an extension of the comment period on or before July 28, 2020 to the Office of Technical Programs and Coordination Activities, Directorate of Technical Support and Emergency Management, Occupational Safety and Health Administration, U.S. Department of Labor, 200 Constitution Avenue NW, Room N-3653, Washington, DC 20210, or by fax to (202) 693-1644.

FOR FURTHER INFORMATION CONTACT: Information regarding this notice is available from the following sources:

Press inquiries: Contact Mr. Frank Meilinger, Director, OSHA Office of Communications, U.S. Department of Labor, telephone: (202) 693-1999; email: meilinger.francis@dol.gov.

General and technical information: Contact Mr. Kevin Robinson, Director, Office of Technical Programs and Coordination Activities, Directorate of Technical Support and Emergency Management, Occupational Safety and Health Administration, U.S. Department of Labor, phone: (202) 693-2110 or email: robinson.kevin@dol.gov.

SUPPLEMENTARY INFORMATION:

I. Background

OSHA recognition of a NRTL signifies that the organization meets the requirements in § 1910.7 of title 29, Code of Federal Regulations (29 CFR 1910.7). Recognition is an

acknowledgment that the organization can perform independent safety testing and certification of the specific products covered within its scope of recognition and is not a delegation or grant of government authority. As a result of recognition, employers may use products properly approved by the NRTL to meet OSHA standards that require testing and certification. OSHA maintains an informational web page for each NRTL that details its scope of recognition available at <http://www.osha.gov/dts/otpca/nrtl/index.html>.

The agency processes applications by a NRTL for renewal of recognition following requirements in appendix A to 29 CFR 1910.7. OSHA conducts renewals in accordance with the procedures in 29 CFR 1910.7, appendix A, paragraph II.C. In accordance with these procedures, NRTLs submit a renewal request to OSHA, not less than nine months or no more than one year, before the expiration date of its current recognition. A request includes a request for renewal and any additional information the NRTL wishes to submit to demonstrate its continued compliance with the terms of its recognition and 29 CFR 1910.7. If OSHA has not conducted an on-site assessment of the NRTL's headquarters and key sites within the past 18 to 24 months, it will schedule the necessary on-site assessments prior to the expiration date of the NRTL's recognition. Upon review of the submitted material and, as necessary, the successful completion of the on-site assessment, OSHA announces its preliminary decision to grant or deny renewal in the **Federal Register** and solicit comments from the public. OSHA then publishes a final **Federal Register** notice responding to any comments and renewing the NRTL's recognition for a period of five years, or denying the renewal of recognition.

FM initially received OSHA recognition as a NRTL on June 13, 1988, and referenced in a **Federal Register** notice dated March 29, 1995 (60 FR 16167). FM's most recent renewal was granted on July 14, 2014, for a five-year period expiring on July 14, 2019. FM submitted a timely request for renewal, dated August 3, 2018 (OSHA-2007-0041-0012), and retains its recognition pending OSHA's final decision in this renewal process. The current addresses of FM facilities recognized by OSHA and included as part of the renewal request are:

1. FM Norwood, 1151 Boston-Providence Turnpike, Norwood, Massachusetts 02062; and

2. FM West Gloucester, 743 Reynolds Road, West Gloucester, Rhode Island 02814.

II. Notice of Preliminary Findings

OSHA is providing notice that FM is applying for renewal of its recognition as a NRTL. This renewal covers FM's existing NRTL scope of recognition. OSHA evaluated FM's application for renewal and preliminarily determined that FM can continue to meet the requirements prescribed by 29 CFR 1910.7 for recognition. Accordingly, OSHA is making a determination that it does not need to conduct an additional on-site review of FM's facilities based on its evaluations of FM's application and all other available information. This information includes OSHA's audits of FM's recognized NRTL sites during this recognition period, and the satisfactory resolution of non-conformances with the requirements of 29 CFR 1910.7. This preliminary finding does not constitute an interim or temporary approval of the request.

OSHA welcomes public comment as to whether FM meets the requirements of 29 CFR 1910.7 for renewal of their recognition as a NRTL. Comments should consist of pertinent written documents and exhibits. Commenters needing more time to comment must submit a request in writing, stating the reasons for the request. OSHA must receive the written request for an extension by the due date for comments. OSHA will limit any extension to 30 days unless the requester justifies a longer period. OSHA may deny a request for an extension if it is not adequately justified. To obtain or review copies of the publicly available information in FM's application and other pertinent documents (including exhibits), as well as all submitted comments, contact the Docket Office, Room N-3653, Occupational Safety and Health Administration, U.S. Department of Labor, at the above address; these materials also are available online at <http://www.regulations.gov> under Docket No. OSHA-2007-0041.

OSHA staff will review all comments to the docket submitted in a timely manner and, after addressing the issues raised by these comments, will make a recommendation to the Assistant Secretary on whether to grant FM's application for renewal. The Assistant Secretary will make the final decision on granting the application and, in making this decision, may undertake other proceedings prescribed in appendix A to 29 CFR 1910.7.

OSHA will publish a public notice of this final decision in the **Federal Register**.

III. Authority and Signature

Loren Sweatt, Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, Washington, DC 20210, authorized the preparation of this notice. Accordingly, the agency is issuing this notice pursuant to 29 U.S.C. 657(g)(2), Secretary of Labor's Order No. 1-2012 (77 FR 3912, Jan. 25, 2012), and 29 CFR 1910.7.

Signed at Washington, DC, on July 7, 2020.

Loren Sweatt,

Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2020-15065 Filed 7-10-20; 8:45 am]

BILLING CODE 4510-26-P

NUCLEAR REGULATORY COMMISSION

[NRC-2020-0001]

Sunshine Act Meetings

TIME AND DATE: Weeks of July 13, 20, 27, August 3, 10, 17, 2020.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public.

Week of July 13, 2020

There are no meetings scheduled for the week of July 13, 2020.

Week of July 20, 2020—Tentative

There are no meetings scheduled for the week of July 20, 2020.

Week of July 27, 2020—Tentative

There are no meetings scheduled for the week of July 27, 2020.

Week of August 3, 2020—Tentative

There are no meetings scheduled for the week of August 3, 2020.

Week of August 10, 2020—Tentative

There are no meetings scheduled for the week of August 10, 2020.

Week of August 17, 2020—Tentative

There are no meetings scheduled for the week of August 17, 2020.

CONTACT PERSON FOR MORE INFORMATION:

For more information or to verify the status of meetings, contact Denise McGovern at 301-415-0681 or via email at Denise.McGovern@nrc.gov. The schedule for Commission meetings is subject to change on short notice.

The NRC Commission Meeting Schedule can be found on the internet at: <https://www.nrc.gov/public-involve/public-meetings/schedule.html>.

The NRC provides reasonable accommodation to individuals with

disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings or need this meeting notice or the transcript or other information from the public meetings in another format (e.g., braille, large print), please notify Anne Silk, NRC Disability Program Specialist, at 301-287-0745, by videophone at 240-428-3217, or by email at Anne.Silk@nrc.gov. Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

Members of the public may request to receive this information electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555 (301-415-1969), or by email at Wendy.Moore@nrc.gov or Tyesha.Bush@nrc.gov.

The NRC is holding the meetings under the authority of the Government in the Sunshine Act, 5 U.S.C. 552b.

Dated: July 9, 2020.

For the Nuclear Regulatory Commission.

Denise L. McGovern,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2020-15191 Filed 7-9-20; 4:15 pm]

BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50-237, 50-249, 50-373, 50-374, 50-352, 50-353, 50-410, 50-277, 50-278, 50-254, and 50-265; NRC-2020-0151]

Exelon Generation Company, LLC; Dresden Nuclear Power Station, Units 2 and 3; LaSalle County Station, Units 1 and 2; Limerick Generating Station, Units 1 and 2; Nine Mile Point Nuclear Station, Unit 2; Peach Bottom Atomic Power Station, Units 2 and 3; and Quad Cities Nuclear Power Station, Units 1 and 2

Correction

In notice document 2020-14405, appearing on pages 40323 through 40327 in the issue of Monday, July 6, 2020 make the following correction.

On page 40323, in the third column, on the second line, "August 5, 2020" should read "September 4, 2020".

[FR Doc. C1-2020-14405 Filed 7-10-20; 8:45 am]

BILLING CODE 1300-01-D

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50-219; 72-27; 72-17; 50-213, 72-39; and 50-29, 72-31; NRC-2020-0110]

Issuance of Multiple Exemptions in Response to COVID-19 Public Health Emergency

AGENCY: Nuclear Regulatory Commission.

ACTION: Exemptions; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) issued multiple exemptions in response to requests from Holtec Decommissioning International, LLC.; Pacific Gas and Electric Company; Portland General Electric Company; Connecticut Yankee Atomic Power Company; and Yankee Atomic Electric Company. The exemptions allow the licensees to extend certain training and requalification frequency requirements of NRC's general criteria for security personnel in response to the COVID-19 public health emergency (PHE). The NRC is issuing a single notice to announce the issuance of these exemptions.

DATES: The exemptions were issued between May 20, 2020 and June 23, 2020.

ADDRESSES: Please refer to Docket ID NRC-2020-0110 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-2020-0110. Address questions about NRC docket IDs in *Regulations.gov* to Jennifer Borges; telephone: 301-287-9127; email: Jennifer.Borges@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.

FOR FURTHER INFORMATION CONTACT: John McKirgan, Office of Nuclear Material Safety and Safeguards, telephone: 301-415-5722, email: John.McKirgan@nrc.gov or Bruce Watson, Office of Nuclear Material Safety and Safeguards, telephone: 301-415-6221, email: Bruce.Watson@nrc.gov. Both are staff of U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

SUPPLEMENTARY INFORMATION:

I. Introduction

The NRC issued multiple exemptions in response to requests dated between May 7, 2020, and May 20, 2020, from Holtec Decommissioning International, LLC.; Pacific Gas and Electric Company; Portland General Electric Company; Connecticut Yankee Atomic Power

Company; and Yankee Atomic Electric Company. The exemptions allow the licensees to extend training and requalification frequency requirements in specific regulations (cited below) of title 10 of the *Code of Federal Regulations* (10 CFR) part 73, “Physical Protection of Plants And Materials.”

The exemptions from certain sections of 10 CFR part 73 ensure that the extension of training and requalification frequency facilitates the implementation of security measures regarding physical and medical requalification in a manner that does not conflict with practices recommended to limit the spread of COVID-19.

The NRC is periodically providing this compiled listing of related exemptions using a single **Federal Register** notice for COVID-19 related

exemptions, instead of issuing individual **Federal Register** notices. Additionally, the NRC publishes a list of approved licensing actions related to the COVID-19 PHE on its public website at <https://www.nrc.gov/about-nrc/covid-19/materials/storage.html> and <https://www.nrc.gov/about-nrc/covid-19/materials/decommissioning.html>.

II. Availability of Documents

The table below provides the licensee name, the plant name, docket number, and ADAMS Accession Numbers for information on each exemption issued, including the exemption request submitted by the respective licensee. For additional directions on accessing information in ADAMS, see the **ADDRESSES** section of this document.

HOLTEC DECOMMISSIONING INTERNATIONAL, LLC. OYSTER CREEK NUCLEAR GENERATING STATION DOCKET NO. 50-219

Document Title	ADAMS Accession No.
Oyster Creek Nuclear Generating Station—Exemption Request from Certain Requirements of 10 CFR Part 73, Appendix B, “General Criteria for Security Personnel,” Section VI.	ML20140A130.

PACIFIC GAS AND ELECTRIC COMPANY HUMBOLDT BAY INDEPENDENT SPENT FUEL STORAGE INSTALLATION DOCKET NO. 72-27

Document title	ADAMS Accession No.
Request for Temporary Exemption from 10 CFR Part 73, Appendix B for the Humboldt Bay Independent Spent Fuel Storage Installation.	ML20134J007.
Issuance of Temporary Exemption from 10 CFR Part 73, Appendix B I.E, II.E, AND IV. for Humboldt Bay Independent Spent Fuel Storage Installation.	ML20162A061.

PORTLAND GENERAL ELECTRIC COMPANY TROJAN INDEPENDENT SPENT FUEL STORAGE INSTALLATION DOCKET NO. 72-17

Document title	ADAMS Accession No.
Request for Temporary Exemption from 10 CFR Part 73, Appendix B, General Criteria for Security Personnel	ML20147A606.
Issuance of Temporary Exemption from 10 CFR Part 73, Appendix B, Section I.E. for Trojan Independent Spent Fuel Storage Installation.	ML20149K418.

CONNECTICUT YANKEE ATOMIC POWER COMPANY HADDAM NECK PLANT INDEPENDENT SPENT FUEL STORAGE INSTALLATION DOCKET NOS. 50-213 AND 72-39

Document title	ADAMS Accession No.
Request for a Temporary Exemption from 10 CFR 73, Appendix B, Section LE and 10 CFR 73.55(r) Annual Physical Requalification Requirement.	ML20143A061.
Issuance of Temporary Exemption from 10 CFR Part 73, Appendix B, Section I.E for Haddam Neck Independent Spent Fuel Storage Installation.	ML20150A335.

YANKEE ATOMIC ELECTRIC COMPANY YANKEE ROWE INDEPENDENT SPENT FUEL STORAGE INSTALLATION DOCKET NOS. 50-029 & 72-31

Document title	ADAMS Accession No.
Request for a Temporary Exemption from 10 CFR 73, Appendix B, Section I.E and Revision 19 of the Yankee Rowe Independent Spent Fuel Storage Installation Physical Security Plan, Annual Physical Qualification Requirement.	ML20160A040.
Response to Request for Additional Information: Yankee Atomic Electric Company Temporary Exemption for Annual Physicals Requirement.	ML20161A191.

YANKEE ATOMIC ELECTRIC COMPANY YANKEE ROWE INDEPENDENT SPENT FUEL STORAGE INSTALLATION DOCKET NOS. 50-029 & 72-31—Continued

Document title	ADAMS Accession No.
Issuance of Temporary Exemptions from 10 CFR Part 73, Appendix B, Section I.E. for Yankee Rowe Independent Spent Fuel Storage Installation.	ML20162A128.

The NRC may post additional materials to the Federal rulemaking website at <https://www.regulations.gov>, under Docket ID NRC-2020-0110. The Federal rulemaking website allows you to receive alerts when changes or additions occur in a docket folder. To subscribe: (1) Navigate to the docket folder (NRC-2020-0110); (2) click the "Sign up for Email Alerts" link; and (3) enter your email address and select how frequently you would like to receive emails (daily, weekly, or monthly).

Dated: July 8, 2020.

For the Nuclear Regulatory Commission.

John B. McKirgan,

Chief, Storage and Transportation Licensing Branch, Division of Fuel Management, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2020-15046 Filed 7-10-20; 8:45 am]

BILLING CODE 7590-01-P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2020-196 and CP2020-221]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning negotiated service agreements. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* July 15, 2020.

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.

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).

II. Docketed Proceeding(s)

1. *Docket No(s):* MC2020-196 and CP2020-221; *Filing Title:* USPS Request to Add Priority Mail Contract 637 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* July 7, 2020; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Kenneth R. Moeller; *Comments Due:* July 15, 2020.

This Notice will be published in the **Federal Register**.

Erica A. Barker,

Secretary.

[FR Doc. 2020-15049 Filed 7-10-20; 8:45 am]

BILLING CODE 7710-FW-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-89235; File No. SR-CboeBYX-2020-020]

Self-Regulatory Organizations; Cboe BYX Exchange, Inc.; Notice of Filing and Order Granting Accelerated Approval of a Proposed Rule Change Relating to Add the Consolidated Audit Trail Industry Member Compliance Rules to the List of Minor Rule Violations in Rule 8.15

July 7, 2020.

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 July 2, 2020, Cboe BYX Exchange, Inc. (the "Exchange" or "BYX") 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 Commission is publishing this notice to solicit comments on the proposed rule change from interested persons and approving the proposal on an accelerated basis.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe BYX Exchange, Inc. (the "Exchange" or "BYX") proposes to add

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

the Consolidated Audit Trail (“CAT”) industry member compliance rules (“CAT Compliance Rules”) to the list of minor rule violations in Rule 8.15. 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/byx/), 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

In order to implement the National Market System Plan Governing the Consolidated Audit Trail (the “CAT NMS Plan” or “Plan”) the Exchange codified the CAT Compliance Rules in Rules 4.5 through 4.16.³ The CAT NMS Plan was filed by the Plan Participants to comply with Rule 613 of Regulation NMS under the Exchange Act,⁴ and each Plan Participant accordingly has adopted the same compliance rules as the Exchange’s Rules 4.5 through 4.16. The common compliance rules adopted by each Plan Participant are designed to require industry members to comply with the provisions of the CAT NMS Plan, which broadly calls for industry members to record and report timely and accurate customer, order, and trade information relating to activity in NMS Securities and OTC Equity Securities.

Rule 8.15 provides for disposition of certain violations through assessment of fines in lieu of conducting a formal disciplinary proceeding. Rule 8.15.01, specifically, sets forth the list of specific

BYX Rules under which a any Member, associated person of a Member, or registered or non-registered employee of a Member may be subject to a fine for violations of such Rules. The Exchange proposes to amend Rule 8.15.01 to add the CAT Compliance Rules in Rules 4.5 through 4.16 to the list of rules in Rule 8.15.01 eligible for disposition pursuant to a minor fine; specifically, under proposed Rule 8.15.01(h).⁵ Proposed Rule 8.15.01(h) provides that for failures to comply with the Consolidated Audit Trail Compliance Rule requirements of Rules 4.5 through 4.16, the Exchange may impose a minor rule violation fine of up to \$2,500. The Exchange may seek other disciplinary action for more serious violations.

The Exchange is coordinating with the Financial Industry Regulatory Authority, Inc. (“FINRA”) and other Plan Participants to promote harmonized and consistent enforcement of all the Plan Participants’ CAT Compliance Rules. The Commission recently approved a Rule 17d–2 Plan under which the regulation of CAT Compliance Rules will be allocated among Plan Participants to reduce regulatory duplication for industry members that are members of more than one Participant (“common members”).⁶ Under the Rule 17d–2 Plan, the regulation of CAT Compliance Rules with respect to common members that are members of FINRA is allocated to FINRA. Similarly, under the Rule 17d–2 Plan, responsibility for common members of multiple other Plan Participants and not a member of FINRA will be allocated among those other Plan Participants, including to the Exchange. For those non-common members who are allocated to BYX pursuant to the Rule 17d–2 Plan, the Exchange and FINRA have entered into a Regulatory Services Agreement (“RSA”) pursuant to which FINRA will assist the Exchange with conducting surveillance, investigation, examination, and

³ FINRA’s maximum fine for minor rule violations under FINRA Rule 9216(b) is \$2,500. The Exchange will apply an identical maximum fine amount for eligible violations of Rules 4.5 through 4.16 to achieve consistency with FINRA and also amend its minor rule violation plan (“MRVP”) to include such fines. Like FINRA, the Exchange would be able to pursue a fine greater than \$2,500 for violations of Rules 4.5 through 4.16 in a regular disciplinary proceeding or a letter of consent under Chapter 8 as appropriate. Any fine imposed in excess of \$2,500 or not otherwise covered by Rule 19d–1(c)(2) of the Act would be subject to prompt notice to the Commission pursuant to Rule 19d–1 under the Act. As noted below, in assessing the appropriateness of a minor rule fine with respect to CAT Compliance Rules, the Exchange will be guided by the same factors that FINRA utilizes. See text accompanying notes 7–8 [sic], *infra*.

⁶ See Securities Exchange Act Release No. 88366 (March 12, 2020), 85 FR 15238 (March 17, 2020).

enforcement activity in connection with the CAT Compliance Rules on the Exchange’s behalf. The Exchange expects that the other exchanges will be entering into similar RSAs.

The Exchange notes that this proposal is based upon the FINRA filing to amend FINRA Rule 9217 in order to add FINRA’s corresponding CAT Compliance Rules to FINRA’s list of rules that are eligible for minor rule violation plan treatment.⁷ The Exchange also notes that the New York Stock Exchange LLC (“NYSE”) submitted a filing to amend its Minor Rule Violation Plan (“MRVP”) to add its CAT Compliance Rules in a manner consistent with FINRA’s proposal,⁸ and other Plan Participants intend to submit the same. Thus, in order to achieve consistency with FINRA and the other Plan Participants, the Exchange proposes to adopt fines up to \$2,500 in connection with minor rule fines for violations of the CAT Compliance Rules (Rules 4.5 through 4.16) in proposed Rule 8.15.01(h) under the Exchange’s MRVP. In connection with FINRA’s proposed amendment to FINRA Rule 9217 to make FINRA’s CAT Compliance Rules MRVP eligible, FINRA has stated that it will apply the minor fines for CAT Compliance Rules in the same manner that FINRA has for its similar existing audit trail-related rules.⁹ Accordingly, in order to promote regulatory consistency, the Exchange plans to do the same. Specifically, application of a minor fine with respect to CAT Compliance Rule violations will be guided by the same factors that FINRA references in its filing. However, more formal disciplinary proceedings may be warranted instead of minor rule dispositions in certain circumstances such as where violations prevent regulatory users of the CAT from performing their regulatory functions. Where minor rule dispositions are appropriate, the following factors help guide the determination of fine amounts:

- Total number of reports that are not submitted or submitted late;
- The timeframe over which the violations occur;
- Whether violations are batched;
- Whether the violations are the result of the actions of one individual or

⁷ See Securities Exchange Act Release No. 88870 (May 14, 2020), 85 FR 30768 (May 20, 2020) (SR–FINRA–2020–013).

⁸ See SR–NYSE–2020–51 (filed June 12, 2020).

⁹ See *supra* note 7; see also FINRA Notice to Members 04–19 (March 2004) available at <https://www.finra.org/rules-guidance/notices/04-19> (providing specific factors used to inform dispositions for violations of OATS reporting rules).

³ See Securities Exchange Act Release Nos. 79944 (February 2, 2017), 82 FR 9846 (February 8, 2017) (SR–BatsBYX–2017–02); and 80256 (March 15, 2017), 82 FR 14526 (March 21, 2017) (Order Approving Proposed Rule Changes To Adopt Consolidated Audit Trail Compliance Rules).

⁴ 17 CFR 242.613.

the result of faulty systems or procedures;

- Whether the firm has taken remedial measures to correct the violations;
- Prior minor rule violations within the past 24 months;
- Collateral effects that the failure has on customers; and
- Collateral effects that the failure has on the Exchange's ability to perform its regulatory function.¹⁰

Upon effectiveness of this rule change, the Exchange will publish a regulatory bulletin notifying its Members of the rule change and the specific factors that will be considered in connection with assessing minor rule fines described above.

For the foregoing reasons, the Exchange believes that the proposed rule change will result in a coordinated, harmonized approach to CAT Compliance Rule enforcement across Plan Participants that will be consistent with the approach FINRA has taken with the CAT rules.

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.¹¹ Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)¹² 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)¹³ requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

Minor rule fines provide a meaningful sanction for minor or technical violations of rules when the conduct at issue does not warrant stronger, immediately reportable disciplinary sanctions. The inclusion of a rule in the

Exchange's MRVP does not minimize the importance of compliance with the rule, nor does it preclude the Exchange from choosing to pursue violations of eligible rules through a letter of consent if the nature of the violations or prior disciplinary history warrants more significant sanctions. Rather, the Exchange believes that the proposed rule change will strengthen the Exchange's ability to carry out its oversight and enforcement responsibilities in cases where full disciplinary proceedings are unwarranted in view of the minor nature of the particular violation. The Exchange believes the option to impose a minor rule sanction gives the Exchange additional flexibility to administer its enforcement program in the most effective and efficient manner while still fully meeting the Exchange's remedial objectives in addressing violative conduct.¹⁴ Specifically, the proposed rule change is designed to prevent fraudulent and manipulative acts and practices because it will provide the Exchange the ability to issue a minor rule fine for violations of the CAT Compliance Rules in Rules 4.5 through 4.16 where a more formal disciplinary action may not be warranted or appropriate consistent with the approach of other Plan Participants for the same conduct.

In connection with the fine level specified in the proposed rule change, adding proposed Rule 8.15.01(h) to specifically provide that for violations of the CAT Compliance Rules in Rules 4.5 through 4.16 the Exchange may impose a fine not to exceed \$2,500 would further the goal of transparency within the Exchange's rules. Adopting the same cap as FINRA for minor rule fines in connection with the CAT Compliance Rules would also promote regulatory consistency across self-regulatory organizations.

The Exchange further believes that the proposed amendment to Rule 8.15.01 is consistent with Section 6(b)(6) of the Act,¹⁵ which provides that members and persons associated with members shall be appropriately disciplined for violation of the provisions of the rules of the exchange, by expulsion, suspension, limitation of activities, functions, and operations, fine, censure, being suspended or barred from being

associated with a member, or any other fitting sanction. As noted, the proposed rule change would provide the Exchange the ability to sanction minor or technical violations of Rules 4.5 through 4.16 pursuant to the Exchange's rules.

Finally, the Exchange also believes that the proposed change is designed to provide a fair procedure for the disciplining of members and persons associated with members, consistent with Sections 6(b)(7) and 6(d) of the Act.¹⁶ Rule 8.15 does not preclude a Member, associated person of a Member, or registered or non-registered employee of a Member from contesting an alleged violation and receiving a hearing on the matter with the same procedural rights through a litigated disciplinary proceeding.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not intended to address competitive issues but rather is concerned solely with making the CAT Compliance Rules in Rules 4.5 through 4.16 eligible for a minor rule fine disposition, thereby strengthening the Exchange's ability to carry out its oversight and enforcement functions and deter potential violative conduct. Also, as stated above, the proposed rule change is consistent with similar proposals recently filed by FINRA and NYSE, and other Plan Participants intend to submit the same.

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. 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

¹⁶ 15 U.S.C. 78f(b)(7) and 78f(d).

¹⁰ See *id.*

¹¹ 15 U.S.C. 78f(b).

¹² 15 U.S.C. 78f(b)(5).

¹³ *Id.*

¹⁴ Pursuant to Rule 8.15(a) and (e), the Exchange has the discretion to impose a fine in lieu of commencing a disciplinary proceeding for a violation that is minor in nature. Rule 8.15(e) states specifically that nothing in Rule 8.15 requires the Exchange to impose a fine pursuant to Rule 8.15 with respect to the violation of any Rule included in any such listing.

¹⁵ 15 U.S.C. 78f(b)(6).

• Send an email to rule-comments@sec.gov. Please include File Number SR-CboeBYX-2020-020 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-CboeBYX-2020-020. 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 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-CboeBYX-2020-020 and should be submitted on or before August 3, 2020.

IV. Commission's Findings and Order Granting Accelerated Approval of Proposed Rule Change

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.¹⁷ In particular, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,¹⁸ which requires that

¹⁷ In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

¹⁸ 15 U.S.C. 78f(b)(5).

the rules of an exchange be designed to promote just and equitable principles of trade, to remove impediments and to perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. The Commission also believes that the proposal is consistent with Sections 6(b)(1) and 6(b)(6) of the Act¹⁹ which require that the rules of an exchange enforce compliance with, and provide appropriate discipline for, violations of Commission and Exchange rules. Finally, the Commission finds that the proposal is consistent with the public interest, the protection of investors, or otherwise in furtherance of the purposes of the Act, as required by Rule 19d-1(c)(2) under the Act,²⁰ which governs minor rule violation plans.

As stated above, the Exchange proposes to add the CAT Compliance Rules to the list of minor rule violations in Rule 8.15 to be consistent with the approach FINRA has taken for minor violations of its corresponding CAT Compliance Rules.²¹ The Commission has already approved FINRA's treatment of CAT Compliance Rules violations when it approved the addition of CAT Compliance Rules to FINRA's MRVP.²² As noted in that order, and similarly herein, the Commission believes that Exchange's treatment of CAT Compliance Rules violations as part of its MRVP provides a reasonable means of addressing violations that do not rise to the level of requiring formal disciplinary proceedings, while providing greater flexibility in handling certain violations. However, the Commission expects that, as with FINRA, the Exchange will continue to conduct surveillance with due diligence and make determinations based on its findings, on a case-by-case basis, regarding whether a sanction under the rule is appropriate, or whether a violation requires formal disciplinary action. Accordingly, the Commission believes the proposal raises no novel or significant issues.

¹⁹ 15 U.S.C. 78f(b)(1) and 78f(b)(6).

²⁰ 17 CFR 240.19d-1(c)(2).

²¹ As discussed above, the Exchange has entered into a Rule 17d-2 Plan and an RSA with FINRA with respect to the CAT Compliance Rules. The Commission notes that, unless relieved by the Commission of its responsibility, as may be the case under the Rule 17d-2 Plan, the Exchange continues to bear the responsibility for self-regulatory conduct and liability for self-regulatory failures, not the self-regulatory organization retained to perform regulatory functions on the Exchange's behalf pursuant to an RSA. See Securities Exchange Release No. 61419 (January 26, 2010), 75 FR 5157 (February 1, 2010) (SR-BATS-2009-031), note 93 and accompanying text.

²² See *supra* note 7.

For the same reasons discussed above, the Commission finds good cause, pursuant to Section 19(b)(2) of the Act,²³ for approving the proposed rule change prior to the thirtieth day after the date of publication of the notice of the filing thereof in the **Federal Register**. The proposal merely adds the CAT Compliance Rules to the Exchange's MRVP and harmonizes its application with FINRA's application of CAT Compliance Rules under its own MRVP. Accordingly, the Commission believes that a full notice-and-comment period is not necessary before approving the proposal.

V. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act²⁴ and Rule 19d-1(c)(2) thereunder,²⁵ that the proposed rule change (SR-CboeBYX-2020-020) be, and hereby is, approved on an accelerated basis.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁶

J. Matthew DeLesDernier,
Assistant Secretary.

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BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-89241; File No. SR-NYSEAMER-2020-47]

Self-Regulatory Organizations; NYSE American LLC; Notice of Filing and Immediate Effectiveness of a Proposed Change To Modify the NYSE American Options Fee Schedule

July 7, 2020.

Pursuant to Section 19(b)(1)¹ of the Securities Exchange Act of 1934 (the "Act")² and Rule 19b-4 thereunder,³ notice is hereby given that, on June 25, 2020, NYSE American LLC ("NYSE American" or the "Exchange") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

²³ 15 U.S.C. 78s(b)(2).

²⁴ 15 U.S.C. 78s(b)(2).

²⁵ 17 CFR 240.19d-1(c)(2).

²⁶ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b-4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to modify the NYSE American Options Fee Schedule ("Fee Schedule") to waive certain Floor-based fixed fees for July 2020. The Exchange proposes to implement the fee change effective July 1, 2020. The proposed change is available on the Exchange's website at www.nyse.com, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this filing is to modify the Fee Schedule to waive certain Floor-based fixed fees for July 2020 for market participants that have been unable to resume their Floor operations to a certain capacity level, as discussed below. The Exchange proposes to implement the fee change effective July 1, 2020.

On March 18, 2020, the Exchange announced that it would temporarily close the Trading Floor, effective Monday, March 23, 2020, as a precautionary measure to prevent the potential spread of COVID-19. Following the temporary closure of the Trading Floor, the Exchange temporarily modified certain fees for April, May and June 2020.⁴ Although the Trading Floor partially reopened on May 26, 2020 and

⁴ See Securities Exchange Act Release Nos. 88595 (April 8, 2020), 85 FR 20737 (April 14, 2020) (SR-NYSEAMER-2020-25) (waiving Floor-based fixed fees); 88840 (May 8, 2020), 85 FR 28992 (May 14, 2020) (SR-NYSEAMER-2020-37) (extending April 2020 fee changes through May 2020); and 89049 (June 11, 2020), 85 FR 36649 (June 17, 2020) (SR-NYSEAMER-2020-44) (extending April and May fee changes through 2020). See also Fee Schedule, Section III.B, Monthly Trading Permit, Rights, Floor Access and Premium Product Fees, and IV. Monthly Floor Communication, Connectivity, Equipment and Booth or Podia Fees.

Floor-based open outcry activity is supported, certain participants have been unable to resume pre-Floor closure levels of operations. Thus, the Exchange proposes to extend the fee waiver through July 2020, but only for Floor Broker firms that are unable to operate at more than 50% of their March 2020 on-Floor staffing levels and for Market Maker firms that have vacant or "unmanned" Podia for the entire month due to COVID-19 related considerations (the "Qualifying Firms").⁵

Specifically, the proposed fee waiver covers the following fixed fees for Qualifying Firms, which relate directly to Floor operations, are charged only to Floor participants and do not apply to participants that conduct business off-Floor:

- Floor Access Fee;
- Floor Broker Handheld;
- Transport Charges;
- Floor Market Maker Podia;
- Booth Premises; and
- Wire Services.⁶

Like the previous fee waiver, the proposed fee change is designed to reduce monthly costs for Qualifying Firms whose operations continue to be disrupted, despite the fact that the Trading Floor has partially reopened. In reducing this monthly financial burden, the proposed change would allow Qualifying Firms to reallocate funds to assist with the cost of shifting and maintaining their prior fully-staffed on-Floor operations to off-Floor and recoup losses as a result of the partial reopening of the Floor. Absent this change, such participants may experience an unexpected increase in the cost of doing business on the Exchange.⁷ The Exchange believes that all Qualifying Firms would benefit from this proposed fee change.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,⁸ in general, and furthers the objectives of Sections 6(b)(4) and (5) of the Act,⁹ in particular, because it provides for the equitable

⁵ See proposed Fee Schedule, Section III.B, Monthly Trading Permit, Rights, Floor Access and Premium Product Fees, and IV. Monthly Floor Communication, Connectivity, Equipment and Booth or Podia Fees.

⁶ See *id.*

⁷ The Exchange will refund participants of the Floor Broker Prepayment Program for any prepaid July 2020 fees that are waived. See proposed Fee Schedule, Section III.E (providing that "the Exchange will refund certain of the prepaid Eligible Fixed costs that were waived for July 2020 for Qualifying Firms, as defined, and set forth in, Sections III.B and IV").

⁸ 15 U.S.C. 78f(b).

⁹ 15 U.S.C. 78f(b)(4) and (5).

allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Exchange operates in a highly competitive market. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. 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."¹⁰

There are currently 16 registered options exchanges competing for order flow. Based on publicly-available information, and excluding index-based options, no single exchange has more than 16% of the market share of executed volume of multiply-listed equity and ETF options trades.¹¹ Therefore, currently no exchange possesses significant pricing power in the execution of multiply-listed equity & ETF options order flow. More specifically, in January 2020, the Exchange had less than 10% market share of executed volume of multiply-listed equity & ETF options trades.¹²

This proposed fee change is reasonable, equitable, and not unfairly discriminatory because it would reduce monthly costs for Qualifying Firms whose operations have been disrupted despite the fact that the Trading Floor has partially reopened because of the social distancing requirements and/or other health concerns related to resuming operation on the Floor. In reducing this monthly financial burden, the proposed change would allow Qualifying Firms to reallocate funds to assist with the cost of shifting and maintaining their prior fully-staffed on-Floor operations to off-Floor and recoup losses as a result of the partial reopening. Absent this change, such participants may experience an unexpected increase in the cost of doing business on the Exchange.

¹⁰ See Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (S7-10-04) ("Reg NMS Adopting Release").

¹¹ The OCC publishes options and futures volume in a variety of formats, including daily and monthly volume by exchange, available here: <https://www.theocc.com/market-data/volume/default.jsp>.

¹² Based on OCC data, see *id.*, the Exchange's market share in equity-based options declined from 9.82% for the month of January 2019 to 8.08% for the month of January 2020.

The Exchange believes the proposed rule change is an equitable allocation of its fees and credits as it merely continues the previous fee waiver, which affects fees charged only to Floor participants and do not apply to participants that conduct business off-Floor. The Exchange believes it is an equitable allocation of fees and credits to extend this fee waiver to Qualifying Firms because such firms have either less than half of their Floor staff (March 2020) levels or have vacant podia—and this reduction in physical capacity on the Floor impacts the speed, volume and efficiency with which these firms can operate, which is to their detriment.

The Exchange believes that the proposal is not unfairly discriminatory because the proposed continuation of the fee waiver would affect all similarly-situated market participants on an equal and non-discriminatory basis.

Finally, the Exchange believes that it is subject to significant competitive forces, as described below in the Exchange's statement regarding the burden on competition.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act, the Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that the proposed changes would encourage the continued participation of Qualifying Firms, thereby promoting market depth, price discovery and transparency and enhancing order execution opportunities for all market participants. As a result, the Exchange believes that the proposed change furthers the Commission's goal in adopting Regulation NMS of fostering integrated competition among orders, which promotes "more efficient pricing of individual stocks for all types of orders, large and small."¹³

Intramarket Competition. The proposed change, which continues the fee waiver in place when the Floor was temporarily closed but only for Qualifying Firms, is designed to reduce monthly costs for Floor participants whose operations continue to be impacted, despite the fact that the Trading Floor has partially reopened. In reducing this monthly financial burden, the proposed change would allow Qualifying Firms to reallocate funds to assist with the cost of shifting and maintaining their previously on-Floor

operations to off-Floor. Absent this change, such Qualifying Firms may experience an unintended increase in the cost of doing business on the Exchange, given that the Floor has only reopened in a limited capacity. The Exchange believes that the proposed waiver of fees for Qualifying Firms would not impose a disparate burden on competition among market participants on the Exchange because off-Floor market participants are not subject to these Floor-based fixed fees, and Floor-based firms that are not subject to the extent of staffing shortfalls as the Qualifying Firms—*i.e.*, have at least 50% of their March 2020 staffing levels on the Floor and/or have no vacant Podia during June 2020, do not face the same operational disruption and potential financial impact during the partial reopening of the Floor.

Intermarket Competition. The Exchange operates in a highly competitive market in which market participants can readily favor one of the 16 competing option exchanges if they deem fee levels at a particular venue to be excessive. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges and to attract order flow to the Exchange. Based on publicly-available information, and excluding index-based options, no single exchange currently has more than 16% of the market share of executed volume of multiply-listed equity and ETF options trades.¹⁴ Therefore, currently no exchange possesses significant pricing power in the execution of multiply-listed equity & ETF options order flow. More specifically, in January 2020, the Exchange had less than 10% market share of executed volume of multiply-listed equity & ETF options trades.¹⁵

The Exchange believes that the proposed rule change reflects this competitive environment because it waives fees for Qualifying Firms and is designed to reduce monthly costs for Floor participants whose operations continue to be disrupted despite the fact that the Trading Floor has partially reopened. In reducing this monthly financial burden, the proposed change would allow affected participants to reallocate funds to assist with the cost of shifting and maintaining their prior fully-staffed on-Floor operations to off-Floor. Absent this change, Qualifying Firms may experience an unintended increase in the cost of doing business on

the Exchange, which would make the Exchange a less competitive venue on which to trade as compared to other options 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

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A)¹⁶ of the Act and subparagraph (f)(2) of Rule 19b-4¹⁷ 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)¹⁸ of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-NYSEAMER-2020-47 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to File Number SR-NYSEAMER-2020-47. This file number should be included on the

¹⁴ See *supra* note 11.

¹⁵ Based on OCC data, *supra* note 12, the Exchange's market share in equity-based options was 9.82% for the month of January 2019 and 8.08% for the month of January 2020.

¹⁶ 15 U.S.C. 78s(b)(3)(A).

¹⁷ 17 CFR 240.19b-4(f)(2).

¹⁸ 15 U.S.C. 78s(b)(2)(B).

¹³ See Reg NMS Adopting Release, *supra* note 10, at 37499.

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-NYSEAMER-2020-47, and should be submitted on or before August 3, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁹

J. Matthew DeLesDernier,
Assistant Secretary.

[FR Doc. 2020-14966 Filed 7-10-20; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-89242; File No. SR-NYSEArca-2020-60]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Modify the NYSE Arca Options Fee Schedule

July 7, 2020.

Pursuant to Section 19(b)(1)¹ of the Securities Exchange Act of 1934 (the "Act")² and Rule 19b-4 thereunder,³ notice is hereby given that, on June 25, 2020, NYSE Arca, Inc. ("NYSE Arca" or

the "Exchange") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to modify the NYSE Arca Options Fee Schedule ("Fee Schedule") to extend the waiver of certain Floor-based fixed fees through July 2020. The Exchange proposes to implement the fee change effective July 1, 2020. The proposed rule change is available on the Exchange's website at www.nyse.com, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this filing is to modify the Fee Schedule to extend the waiver of certain Floor-based fixed fees through July 2020 for market participants that have been unable to resume their Floor operations to a certain capacity level, as discussed below. The Exchange proposes to implement the fee change effective July 1, 2020.

On March 18, 2020, the Exchange announced that it would temporarily close the Trading Floor, effective Monday, March 23, 2020, as a precautionary measure to prevent the potential spread of COVID-19. Following the temporary closure of the Trading Floor, the Exchange waived certain Floor-based fixed fees for April

and May 2020 (the "fee waiver").⁴ Although the Trading Floor partially reopened on May 4, 2020 and Floor-based open outcry activity is supported, certain participants have been unable to resume pre-Floor closure levels of operations. As a result, the Exchange extended the fee waiver through June 2020, but only for Floor Broker firms that are unable to operate at more than 50% of their March 2020 on-Floor staffing levels and for Market Maker firms that have vacant or "unmanned" Podia for the entire month due to COVID-19 related considerations (the "Qualifying Firms").⁵ Because the Trading Floor will continue to operate with reduced capacity, the Exchange proposes to extend the fee waiver for Qualifying Firms through July 2020.

Specifically, the proposed fee waiver covers the following fixed fees for Qualifying Firms, which relate directly to Floor operations, are charged only to Floor participants and do not apply to participants that conduct business off-Floor:

- Floor Booths;
- Market Maker Podia;
- Options Floor Access;
- Wire Services; and
- ISP Connection.⁶

Like the previous June 2020 fee waiver, the proposed fee change is designed to reduce monthly costs for Qualifying Firms whose operations continue to be disrupted despite the fact that the Trading Floor has partially reopened. In reducing this monthly financial burden, the proposed change would allow Qualifying Firms to reallocate funds to assist with the cost of shifting and maintaining their prior fully-staffed on-Floor operations to off-Floor and recoup losses as a result of the partial reopening. Absent this change, such participants may experience an unexpected increase in the cost of doing business on the Exchange.⁷

⁴ See Securities Exchange Act Release Nos. 88596 (April 8, 2020), 85 FR 20796 (April 14, 2020) (SR-NYSEArca-2020-29); 88812 (May 5, 2020), 85 FR 27787 (May 11, 2020) (SR-NYSEArca-2020-38). See also Fee Schedule, NYSE Arca OPTIONS: FLOOR and EQUIPMENT and CO-LOCATION FEES.

⁵ See proposed Fee Schedule, NYSE Arca OPTIONS: FLOOR and EQUIPMENT and CO-LOCATION FEES (adding "and July" between "June" and "2020" as applicable to effectuate this change).

⁶ See *id.*

⁷ The Exchange will refund participants of the Floor Broker Prepayment Program for any prepaid July 2020 fees that are waived. See proposed Fee Schedule, FLOOR BROKER FIXED COST PREPAYMENT INCENTIVE PROGRAM (the "FB Prepay Program") (providing that "the Exchange will refund certain of the prepaid Eligible Fixed costs that were waived for July 2020 for Qualifying Firms as defined, and set forth in, NYSE Arca

¹⁹ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b-4.

The Exchange believes that all Qualifying Firms would benefit from this proposed fee change.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,⁸ in general, and furthers the objectives of Sections 6(b)(4) and (5) of the Act,⁹ in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Exchange operates in a highly competitive market. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. 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.”¹⁰

There are currently 16 registered options exchanges competing for order flow. Based on publicly-available information, and excluding index-based options, no single exchange has more than 16% of the market share of executed volume of multiply-listed equity and ETF options trades.¹¹ Therefore, currently no exchange possesses significant pricing power in the execution of multiply-listed equity & ETF options order flow. More specifically, in January 2020, the Exchange had less than 10% market share of executed volume of multiply-listed equity & ETF options trades.¹²

This proposed fee change is reasonable, equitable, and not unfairly discriminatory because it would reduce monthly costs for Qualifying Firms whose operations have been disrupted despite the fact that the Trading Floor has partially reopened because of the

social distancing requirements and/or other health concerns related to resuming operation on the Floor. In reducing this monthly financial burden, the proposed change would allow Qualifying Firms to reallocate funds to assist with the cost of shifting and maintaining their prior fully-staffed on-Floor operations to off-Floor and recoup losses as a result of the partial reopening of the Floor. Absent this change, such participants may experience an unexpected increase in the cost of doing business on the Exchange. The Exchange believes that all Qualifying Firms would benefit from this proposed fee change.

The Exchange believes the proposed rule change is an equitable allocation of its fees and credits as it merely continues the previous June 2020 fee waiver, which affects fees charged only to Floor participants and do not apply to participants that conduct business off-Floor. The Exchange believes it is an equitable allocation of fees and credits to extend the June 2020 fee waiver for Qualifying Firms because such firms have either less than half of their Floor staff (March 2020) levels or have vacant podia—and this reduction in physical capacity on the Floor impacts the speed, volume and efficiency with which these firms can operate, which is to their detriment.

The Exchange believes that the proposal is not unfairly discriminatory because the proposed continuation of the fee waiver would affect all similarly-situated market participants on an equal and non-discriminatory basis.

Finally, the Exchange believes that it is subject to significant competitive forces, as described below in the Exchange’s statement regarding the burden on competition.

B. Self-Regulatory Organization’s Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act, the Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that the proposed changes would encourage the continued participation of Qualifying Firms, thereby promoting market depth, price discovery and transparency and enhancing order execution opportunities for all market participants. As a result, the Exchange believes that the proposed change furthers the Commission’s goal in adopting Regulation NMS of fostering integrated competition among orders, which promotes “more efficient pricing

of individual stocks for all types of orders, large and small.”¹³

Intramarket Competition. The proposed change, which continues the June 2020 fee for Qualifying Firms, is designed to reduce monthly costs for those Floor participants whose operations continue to be impacted despite the fact that the Trading Floor has partially reopened. In reducing this monthly financial burden, the proposed change would allow Qualifying Firms to reallocate funds to assist with the cost of shifting and maintaining their previously on-Floor operations to off-Floor. Absent this change, such Qualifying Firms may experience an unintended increase in the cost of doing business on the Exchange, given that the Floor has only reopened in a limited capacity. The Exchange believes that the proposed waiver of fees for Qualifying Firms would not impose a disparate burden on competition among market participants on the Exchange because off-Floor market participants are not subject to these Floor-based fixed fees and Floor-based firms that are not subject to the extent of staffing shortfalls as the Qualifying Firms—*i.e.*, have at least 50% of their March 2020 staffing levels on the Floor and/or have no vacant Podia during June 2020, do not face the same operational disruption and potential financial impact during the partial reopening of the Floor.

Intermarket Competition. The Exchange operates in a highly competitive market in which market participants can readily favor one of the 16 competing option exchanges if they deem fee levels at a particular venue to be excessive. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges and to attract order flow to the Exchange. Based on publicly-available information, and excluding index-based options, no single exchange currently has more than 16% of the market share of executed volume of multiply-listed equity and ETF options trades.¹⁴ Therefore, currently no exchange possesses significant pricing power in the execution of multiply-listed equity & ETF options order flow. More specifically, in January 2020, the Exchange had less than 10% market share of executed volume of multiply-listed equity & ETF options trades.¹⁵

The Exchange believes that the proposed rule change reflects this

OPTIONS: FLOOR and EQUIPMENT and CO-LOCATION FEES”).

⁸ 15 U.S.C. 78f(b).

⁹ 15 U.S.C. 78f(b)(4) and (5).

¹⁰ See Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (S7-10-04) (“Reg NMS Adopting Release”).

¹¹ The OCC publishes options and futures volume in a variety of formats, including daily and monthly volume by exchange, available here: <https://www.theocc.com/market-data/volume/default.jsp>.

¹² Based on OCC data, *see id.*, in 2019, the Exchange’s market share in equity-based options was 9.57% for the month of January 2019 and 9.59% for the month of January 2020.

¹³ See Reg NMS Adopting Release, *supra* note 10, at 37499.

¹⁴ See *supra* note 11.

¹⁵ Based on OCC data, *supra* note 12, the Exchange’s market share in equity-based options was 9.57% for the month of January 2019 and 9.59% for the month of January, 2020.

competitive environment because it waives fees for Qualifying Firms and is designed to reduce monthly costs for Floor participants whose operations continue to be disrupted despite the fact that the Trading Floor has partially reopened. In reducing this monthly financial burden, the proposed change would allow affected participants to reallocate funds to assist with the cost of shifting and maintaining their prior fully-staffed on-Floor operations to off-Floor. Absent this change, Qualifying Firms may experience an unintended increase in the cost of doing business on the Exchange, which would make the Exchange a less competitive venue on which to trade as compared to other options 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

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A)¹⁶ of the Act and subparagraph (f)(2) of Rule 19b-4¹⁷ 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)¹⁸ of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-NYSEArca-2020-60 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-2020-60. 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-2020-60, and should be submitted on or before August 3, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁹

J. Matthew DeLesDernier,
Assistant Secretary.

[FR Doc. 2020-14968 Filed 7-10-20; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[No. 34-89236; File No. SR-CboeEDGA-2020-020]

Self-Regulatory Organizations; Cboe EDGA Exchange, Inc.; Notice of Filing and Order Granting Accelerated Approval of a Proposed Rule Change To Add the Consolidated Audit Trail Industry Member Compliance Rules to the List of Minor Rule Violations in Rule 8.15

July 7, 2020.

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 July 2, 2020, Cboe EDGA Exchange, Inc. (the "Exchange" or "EDGA") 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 Commission is publishing this notice to solicit comments on the proposed rule change from interested persons and approving the proposal on an accelerated basis.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe EDGA Exchange, Inc. (the "Exchange" or "EDGA") proposes to add the Consolidated Audit Trail ("CAT") industry member compliance rules ("CAT Compliance Rules") to the list of minor rule violations in Rule 8.15. 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.

¹⁶ 15 U.S.C. 78s(b)(3)(A).

¹⁷ 17 CFR 240.19b-4(f)(2).

¹⁸ 15 U.S.C. 78s(b)(2)(B).

¹⁹ 17 CFR 200.30-3(a)(12).

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

In order to implement the National Market System Plan Governing the Consolidated Audit Trail (the "CAT NMS Plan" or "Plan") the Exchange codified the CAT Compliance Rules in Rules 4.5 through 4.16.³ The CAT NMS Plan was filed by the Plan Participants to comply with Rule 613 of Regulation NMS under the Exchange Act,⁴ and each Plan Participant accordingly has adopted the same compliance rules as in Exchange's Rules 4.5 through 4.16. The common compliance rules adopted by each Plan Participant are designed to require industry members to comply with the provisions of the CAT NMS Plan, which broadly calls for industry members to record and report timely and accurate customer, order, and trade information relating to activity in NMS Securities and OTC Equity Securities.

Rule 8.15 provides for disposition of certain violations through assessment of fines in lieu of conducting a formal disciplinary proceeding. Rule 8.15.01, specifically, sets forth the list of specific EDGA Rules under which a any Member, associated person of a Member, or registered or non-registered employee of a Member may be subject to a fine for violations of such Rules. The Exchange proposes to amend Rule 8.15.01 to add the CAT Compliance Rules in Rules 4.5 through 4.16 to the list of rules in Rule 8.15.01 eligible for disposition pursuant to a minor fine; specifically, under proposed Rule 8.15.01(h).⁵ Proposed Rule 8.15.01(h) provides that for failures to comply with the Consolidated Audit Trail Compliance Rule requirements of Rules

4.5 through 4.16, the Exchange may impose a minor rule violation fine of up to \$2,500. The Exchange may seek other disciplinary action for more serious violations.

The Exchange is coordinating with the Financial Industry Regulatory Authority, Inc. ("FINRA") and other Plan Participants to promote harmonized and consistent enforcement of all the Plan Participants' CAT Compliance Rules. The Commission recently approved a Rule 17d-2 Plan under which the regulation of CAT Compliance Rules will be allocated among Plan Participants to reduce regulatory duplication for industry members that are members of more than one Participant ("common members").⁶ Under the Rule 17d-2 Plan, the regulation of CAT Compliance Rules with respect to common members that are members of FINRA is allocated to FINRA. Similarly, under the Rule 17d-2 Plan, responsibility for common members of multiple other Plan Participants and not a member of FINRA will be allocated among those other Plan Participants, including to the Exchange. For those non-common members who are allocated to EDGA pursuant to the Rule 17d-2 Plan, the Exchange and FINRA have entered into a Regulatory Services Agreement ("RSA") pursuant to which FINRA will assist the Exchange with conducting surveillance, investigation, examination, and enforcement activity in connection with the CAT Compliance Rules on the Exchange's behalf. The Exchange expects that the other exchanges will be entering into similar RSAs.

The Exchange notes that this proposal is based upon the FINRA filing to amend FINRA Rule 9217 in order to add FINRA's corresponding CAT Compliance Rules to FINRA's list of rules that are eligible for minor rule violation plan treatment.⁷ The Exchange also notes that the New York Stock Exchange LLC ("NYSE") submitted a filing to amend its Minor Rule Violation Plan ("MRVP") to add its CAT Compliance Rules in a manner consistent with FINRA's proposal,⁸ and other Plan Participants intend to submit the same. Thus, in order to achieve consistency with FINRA and the other Plan Participants, the Exchange proposes to adopt fines up to \$2,500 in connection with minor rule fines for violations of the CAT Compliance Rules (Rules 4.5 through 4.16) in proposed

Rule 8.15.01(h) under the Exchange's MRVP. In connection with FINRA's proposed amendment to FINRA Rule 9217 to make FINRA's CAT Compliance Rules MRVP eligible, FINRA has stated that it will apply the minor fines for CAT Compliance Rules in the same manner that FINRA has for its similar existing audit trail-related rules.⁹ Accordingly, in order to promote regulatory consistency, the Exchange plans to do the same. Specifically, application of a minor fine with respect to CAT Compliance Rule violations will be guided by the same factors that FINRA references in its filing. However, more formal disciplinary proceedings may be warranted instead of minor rule dispositions in certain circumstances such as where violations prevent regulatory users of the CAT from performing their regulatory functions. Where minor rule dispositions are appropriate, the following factors help guide the determination of fine amounts:

- Total number of reports that are not submitted or submitted late;
- The timeframe over which the violations occur;
- Whether violations are batched;
- Whether the violations are the result of the actions of one individual or the result of faulty systems or procedures;
- Whether the firm has taken remedial measures to correct the violations;
- Prior minor rule violations within the past 24 months;
- Collateral effects that the failure has on customers; and
- Collateral effects that the failure has on the Exchange's ability to perform its regulatory function.¹⁰

Upon effectiveness of this rule change, the Exchange will publish a regulatory bulletin notifying its Members of the rule change and the specific factors that will be considered in connection with assessing minor rule fines described above.

For the foregoing reasons, the Exchange believes that the proposed rule change will result in a coordinated, harmonized approach to CAT Compliance Rule enforcement across Plan Participants that will be consistent with the approach FINRA has taken with the CAT rules.

³ See Securities Exchange Act Release Nos. 79962 (February 3, 2017), 82 FR 10047 (February 9, 2017) (SR-BatsEDGA-2017-03); and 80256 (March 15, 2017), 82 FR 14526 (March 21, 2017) (Order Approving Proposed Rule Changes To Adopt Consolidated Audit Trail Compliance Rules).

⁴ 17 CFR 242.613.

⁵ FINRA's maximum fine for minor rule violations under FINRA Rule 9216(b) is \$2,500. The Exchange will apply an identical maximum fine amount for eligible violations of Rules 4.5 through 4.16 to achieve consistency with FINRA and also amend its minor rule violation plan ("MRVP") to include such fines. Like FINRA, the Exchange would be able to pursue a fine greater than \$2,500 for violations of Rules 4.5 through 4.16 in a regular disciplinary proceeding or a letter of consent under Chapter 8 as appropriate. Any fine imposed in excess of \$2,500 or not otherwise covered by Rule 19d-1(c)(2) of the Act would be subject to prompt notice to the Commission pursuant to Rule 19d-1 under the Act. As noted below, in assessing the appropriateness of a minor rule fine with respect to CAT Compliance Rules, the Exchange will be guided by the same factors that FINRA utilizes. See text accompanying notes 7-8 [sic], *infra*.

⁶ See Securities Exchange Act Release No. 88366 (March 12, 2020), 85 FR 15238 (March 17, 2020).

⁷ See Securities Exchange Act Release No. 88870 (May 14, 2020), 85 FR 30768 (May 20, 2020) (SR-FINRA-2020-013).

⁸ See SR-NYSE-2020-51 (filed June 12, 2020).

⁹ See *supra* note 7; see also FINRA Notice to Members 04-19 (March 2004) available at <https://www.finra.org/rules-guidance/notices/04-19> (providing specific factors used to inform dispositions for violations of OATS reporting rules).

¹⁰ See *id*.

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.¹¹ Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)¹² 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)¹³ requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

Minor rule fines provide a meaningful sanction for minor or technical violations of rules when the conduct at issue does not warrant stronger, immediately reportable disciplinary sanctions. The inclusion of a rule in the Exchange's MRVP does not minimize the importance of compliance with the rule, nor does it preclude the Exchange from choosing to pursue violations of eligible rules through a letter of consent if the nature of the violations or prior disciplinary history warrants more significant sanctions. Rather, the Exchange believes that the proposed rule change will strengthen the Exchange's ability to carry out its oversight and enforcement responsibilities in cases where full disciplinary proceedings are unwarranted in view of the minor nature of the particular violation. The Exchange believes the option to impose a minor rule sanction gives the Exchange additional flexibility to administer its enforcement program in the most effective and efficient manner while still fully meeting the Exchange's remedial objectives in addressing violative conduct.¹⁴ Specifically, the

proposed rule change is designed to prevent fraudulent and manipulative acts and practices because it will provide the Exchange the ability to issue a minor rule fine for violations of the CAT Compliance Rules in Rules 4.5 through 4.16 where a more formal disciplinary action may not be warranted or appropriate consistent with the approach of other Plan Participants for the same conduct.

In connection with the fine level specified in the proposed rule change, adding proposed Rule 8.15.01(h) to specifically provide that for violations of the CAT Compliance Rules in Rules 4.5 through 4.16 the Exchange may impose a fine not to exceed \$2,500 would further the goal of transparency within the Exchange's rules. Adopting the same cap as FINRA for minor rule fines in connection with the CAT Compliance Rules would also promote regulatory consistency across self-regulatory organizations.

The Exchange further believes that the proposed amendment to Rule 8.15.01 is consistent with Section 6(b)(6) of the Act,¹⁵ which provides that members and persons associated with members shall be appropriately disciplined for violation of the provisions of the rules of the exchange, by expulsion, suspension, limitation of activities, functions, and operations, fine, censure, being suspended or barred from being associated with a member, or any other fitting sanction. As noted, the proposed rule change would provide the Exchange the ability to sanction minor or technical violations of Rules 4.5 through 4.16 pursuant to the Exchange's rules.

Finally, the Exchange also believes that the proposed change is designed to provide a fair procedure for the disciplining of members and persons associated with members, consistent with Sections 6(b)(7) and 6(d) of the Act.¹⁶ Rule 8.15 does not preclude a Member, associated person of a Member, or registered or non-registered employee of a Member from contesting an alleged violation and receiving a hearing on the matter with the same procedural rights through a litigated disciplinary proceeding.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not

necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not intended to address competitive issues but rather is concerned solely with making the CAT Compliance Rules in Rules 4.5 through 4.16 eligible for a minor rule fine disposition, thereby strengthening the Exchange's ability to carry out its oversight and enforcement functions and deter potential violative conduct. Also, as stated above, the proposed rule change is consistent with similar proposals recently filed by FINRA and NYSE, and other Plan Participants intend to submit the same.

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. 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-CboeEDGA-2020-020 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-2020-020. 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

¹¹ 15 U.S.C. 78f(b).

¹² 15 U.S.C. 78f(b)(5).

¹³ *Id.*

¹⁴ Pursuant to Rule 8.15(a) and (e), the Exchange has the discretion to impose a fine in lieu of commencing a disciplinary proceeding for a violation that is minor in nature. Rule 8.15(e) states specifically that nothing in Rule 8.15 requires the

Exchange to impose a fine pursuant to Rule 8.15 with respect to the violation of any Rule included in any such listing.

¹⁵ 15 U.S.C. 78f(b)(6).

¹⁶ 15 U.S.C. 78f(b)(7) and 78f(d).

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-CboeEDGA-2020-020 and should be submitted on or before August 3, 2020.

IV. Commission's Findings and Order Granting Accelerated Approval of Proposed Rule Change

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.¹⁷ In particular, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,¹⁸ which requires that the rules of an exchange be designed to promote just and equitable principles of trade, to remove impediments and to perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. The Commission also believes that the proposal is consistent with Sections 6(b)(1) and 6(b)(6) of the Act¹⁹ which require that the rules of an exchange enforce compliance with, and provide appropriate discipline for, violations of Commission and Exchange rules. Finally, the Commission finds that the proposal is consistent with the public interest, the protection of investors, or otherwise in furtherance of the purposes of the Act, as required by Rule 19d-1(c)(2) under the Act,²⁰ which governs minor rule violation plans.

As stated above, the Exchange proposes to add the CAT Compliance Rules to the list of minor rule violations in Rule 8.15 to be consistent with the approach FINRA has taken for minor violations of its corresponding CAT

Compliance Rules.²¹ The Commission has already approved FINRA's treatment of CAT Compliance Rules violations when it approved the addition of CAT Compliance Rules to FINRA's MRVP.²² As noted in that order, and similarly herein, the Commission believes that Exchange's treatment of CAT Compliance Rules violations as part of its MRVP provides a reasonable means of addressing violations that do not rise to the level of requiring formal disciplinary proceedings, while providing greater flexibility in handling certain violations. However, the Commission expects that, as with FINRA, the Exchange will continue to conduct surveillance with due diligence and make determinations based on its findings, on a case-by-case basis, regarding whether a sanction under the rule is appropriate, or whether a violation requires formal disciplinary action. Accordingly, the Commission believes the proposal raises no novel or significant issues.

For the same reasons discussed above, the Commission finds good cause, pursuant to Section 19(b)(2) of the Act,²³ for approving the proposed rule change prior to the thirtieth day after the date of publication of the notice of the filing thereof in the **Federal Register**. The proposal merely adds the CAT Compliance Rules to the Exchange's MRVP and harmonizes its application with FINRA's application of CAT Compliance Rules under its own MRVP. Accordingly, the Commission believes that a full notice-and-comment period is not necessary before approving the proposal.

V. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act²⁴ and Rule 19d-1(c)(2) thereunder,²⁵ that the proposed rule change (SR-CboeEDGA-2020-020) be, and hereby is, approved on an accelerated basis.

²¹ As discussed above, the Exchange has entered into a Rule 17d-2 Plan and an RSA with FINRA with respect to the CAT Compliance Rules. The Commission notes that, unless relieved by the Commission of its responsibility, as may be the case under the Rule 17d-2 Plan, the Exchange continues to bear the responsibility for self-regulatory conduct and liability for self-regulatory failures, not the self-regulatory organization retained to perform regulatory functions on the Exchange's behalf pursuant to an RSA. See Securities Exchange Release No. 61419 (January 26, 2010), 75 FR 5157 (February 1, 2010) (SR-BATS-2009-031), note 93 and accompanying text.

²² See *supra* note 7.

²³ 15 U.S.C. 78s(b)(2).

²⁴ 15 U.S.C. 78s(b)(2).

²⁵ 17 CFR 240.19d-1(c)(2).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁶

J. Matthew DeLesDernier,
Assistant Secretary.

[FR Doc. 2020-14967 Filed 7-10-20; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-89239; File No. SR-CBOE-2020-064]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Fees Schedule in Connection With Migration

July 7, 2020.

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 July 2, 2020, 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, II and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

Cboe Exchange, Inc. (the "Exchange" or "Cboe Options") proposes to amend its Fees Schedule in connection with migration. The text of the proposed rule change is provided in Exhibit 5.³

²⁶ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ The Exchange notes that subsequent to the Original Filing that proposed these changes on October 1 and 2, 2019 (SR-CBOE-2019-077 and SR-CBOE-2019-082) and subsequent to the Second Proposed Rule Change and Third Proposed Rule Change Filings that proposed these changes on November 29, 2019 (SR-CBOE-2019-111) and January 28, 2020 (SR-CBOE-2020-005), the Exchange submitted SR-CBOE-2020-021 which adopted Footnote 12. Footnote 12 governs pricing changes in the event the Exchange trading floor becomes inoperable and is appended to the Market-Maker Tier Appointment Fees and Floor Broker Trading Permit Sliding Scales tables. Additionally, subsequent to the Fourth Proposed Rule Change filed on March 27, 2020 (SR-CBOE-2020-028), the Exchange submitted SR-CBOE-2020-044, which appended Footnotes 41 to the Market maker Tier Appointment Fees table and the Floor Broker Trading Surcharge. Lastly, subsequent to the Exchange's Fifth Proposed Rule Change filed on May 22, 2020 (SR-CBOE-2020-48), the Exchange submitted (1) SR-CBOE-2020-058, which adopted new Footnote 24, appended Footnote 24 in the Market-Maker Tier Appointment Fees table and

¹⁷ In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

¹⁸ 15 U.S.C. 78f(b)(5).

¹⁹ 15 U.S.C. 78f(b)(1) and 78f(b)(6).

²⁰ 17 CFR 240.19d-1(c)(2).

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

In 2016, the Exchange's parent company, Cboe Global Markets, Inc. (formerly named CBOE Holdings, Inc.) ("Cboe Global"), which is also the parent company of Cboe C2 Exchange, Inc. ("C2"), acquired Cboe EDGA Exchange, Inc. ("EDGA"), Cboe EDGX Exchange, Inc. ("EDGX" or "EDGX Options"), Cboe BZX Exchange, Inc. ("BZX" or "BZX Options"), and Cboe BYX Exchange, Inc. ("BYX" and, together with Cboe Options, C2, EDGX, EDGA, and BZX, the "Affiliated Exchanges"). The Cboe Affiliated Exchanges recently aligned certain system functionality, including with respect to connectivity, retaining only intended differences between the Affiliated Exchanges, in the context of a technology migration. The Exchange migrated its trading platform to the same system used by the Affiliated Exchanges, which the Exchange completed on October 7, 2019 (the "migration"). As a result of this migration, the Exchange's pre-migration connectivity architecture was rendered obsolete, and as such, the Exchange now offers new functionality, including new logical connectivity, and therefore

Floor Trading Permit Sliding Scales Table, as well as added language to the Floor Broker ADV Discount Table and (2) SR-CBOE-2020-061 which added further language in Footnote 24. The additions proposed by filings SR-CBOE-2020-021, SR-CBOE-2020-044, SR-CBOE-2020-058 and SR-CBOE-2020-061 are double underlined in Exhibit 5A.

proposes to adopt corresponding fees.⁴ In determining the proposed fee changes, the Exchange assessed the impact on market participants to ensure that the proposed fees would not create an undue financial burden on any market participants, including smaller market participants. While the Exchange has no way of predicting with certainty the impact of the proposed changes, the Exchange had anticipated its post-migration connectivity revenue⁵ to be approximately 1.75% lower than connectivity revenue pre-migration.⁶ In addition to providing a consistent technology offering across the Cboe Affiliated Exchanges, the migration also provided market participants a latency equalized infrastructure, improved

⁴ As of October 7, 2019, market participants no longer have the ability to connect to the old Exchange architecture.

⁵ Connectivity revenue post-migration includes revenue from physical port fees (other than for disaster recovery), Cboe Data Services Port Fee, logical port fees, Trading Permit Fees, Market-Maker EAP Appointment Unit fees, Tier Appointment Surcharges and Floor Broker Trading Surcharges, less the Floor Broker ADV discounts and discounts on BOE Bulk Ports via the Affiliate Volume Plan and the Market-Maker Access Credit program.

⁶ For February 2020, the Exchange's connectivity revenue was approximately 2.5% higher than connectivity revenue pre-migration. For purposes of a fair comparison of the Exchange's initial projection of post-migration connectivity revenue to realized post-migration revenue connectivity, the Exchange excluded from the February 2020 calculation revenue from a Trading Permit Holder who became a Market-Maker post October 7, 2019, a Trading Permit Holder that grew its footprint on the Exchange significantly, and revenue derived from incremental usage in light of the extreme volatility and volume experienced in February, as such circumstances were not otherwise anticipated or incorporated into the Exchange's original projection. As noted, the Exchange had no way of predicting with certainty the impact of the proposed changes, nor control over choices market participants ultimately decided to make. The Exchange notes connectivity revenue was higher than anticipated in part due to (1) a higher number of 10 Gb Physical Ports being maintained by TPHs than expected (although 34% of Trading Permit Holders maintained the same number of 10 Gb Physical Ports and 44% reduced the amount of 10 Gb Physical Ports maintained), (2) a higher quantity of BOE/FIX Logical Ports being purchased than predicted, and (3) a significantly higher quantity of the optional Drop, GRP, Multicast PITCH/Top Spin Server Ports and Purge Ports being purchased than predicted. For April 2020, the Exchange's connectivity revenue was approximately 21.97% less than connectivity revenue pre-migration using the same calculation. For May 2020, the Exchange's connectivity revenue was approximately 22.32% less than connectivity revenue pre-migration using the same calculation. The Exchange notes that due to the closure of its trading floor on March 16, 2020 through June 15, 2020, it adopted a number of corresponding temporary pricing changes, including waiving floor Trading Permit fees. See Cboe Options Fees Schedule. The Exchange also notes that it provided the dollar amounts of the Exchange's monthly connectivity revenue to the Securities and Exchange Commission (the "Commission") for the months of February–May 2020 with a confidential treatment request.

system performance, and increased sustained order and quote per second capacity, as discussed more fully below. Accordingly, in connection with the migration and in order to more closely align the Exchange's fee structure with that of its Affiliated Exchanges, the Exchange intends to update and simplify its fee structure with respect to access and connectivity and adopt new access and connectivity fees.

The Exchange initially filed the proposed fee changes on October 1, 2019 (SR-CBOE-2019-077) (the "Original Filing").⁷ The Commission received only one comment letter on the Original Filing, six days after the comment period deadline ended.⁸ On November 29, 2019, the Exchange withdrew the Original Filing and submitted SR-CBOE-2019-111 ("Second Proposed Rule Change").⁹ Among other things, the Second Proposed Rule Change was filed in response to, and addressed, the Commission's request for inclusion of the following information: Clarity as to what revenue streams are included in the Exchange's calculation of "connectivity" revenue; an update on post-migration connectivity revenue;¹⁰ further information regarding the Exchange's new latency equalized infrastructure including additional detail regarding the benefits of such structure; clarity on how the Cboe Data Services Port fee is applied; data regarding the number of market participants that connect directly versus indirectly and the volume attributed to each; enhanced discussion regarding products that compete with exclusively listed products; an update on whether any market participant terminated their direct connectivity or membership post-migration (and whether it was because of the fee changes); and generally provide an update on various projections made in the filing, including how many ports market participants purchased post-migration, how many Trading Permit Holders were paying higher or lower fees, and how many

⁷ On business date October 2, 2019, due to a technical error, the Exchange withdrew that filing and submitted SR-CBOE-2019-082. See Securities Exchange Act Release No. 87304 (October 15, 2019), 84 FR 56240, (October 21, 2019) ("Original Filing").

⁸ See Letter from Tyler Gellasch, Executive Director, The Healthy Markets Association ("Healthy Markets"), to Vanessa Countryman, Secretary, Commission, dated November 18, 2019.

⁹ See Securities Exchange Act Release No. 87727 (December 12, 2019), 84 FR 69428 (December 18, 2019).

¹⁰ Many market participants were still transitioning to the new connectivity structure at that time and as such, the Exchange noted it did not expect its connectivity revenue projections regarding port purchases to be realized prior to February 2020.

Trading Permit Holders achieved proposed incentive tiers. The Commission received no comment letters on the Second Proposed Rule Change.

On January 28, 2020, the Exchange withdrew the Second Proposed Rule Change filing and submitted SR-CBOE-2020-005 (“Third Proposed Rule Change”).¹¹ The Third Proposed Rule Change was filed in response to, and addressed, the Commission’s request for further discussion regarding how competitive forces constrained fees, further detail on potential substitute products for the Exchange’s exclusively listed products, updated data on the number of ports purchased post-migration and an update on the projected post-migration connectivity revenue.¹² The Exchange also provided updated data on how many Trading Permit Holders connected directly versus indirectly to the Exchange and the volume attributed to each. The Commission received no comment letters on the Third Proposed Rule Change.

On March 27, 2020, the Exchange submitted SR-CBOE-2020-028 (“Fourth Proposed Rule Change”).¹³ The Fourth Proposed Rule Change was filed in response to the Commission’s sole request to update the connectivity revenue collected in February 2020, as the transition of physical ports had been completed. The Commission received only one comment letter on the Fourth Proposed Rule Change.¹⁴

On May 21, 2020, the Exchange withdrew that filing and submitted SR-CBOE-2020-048 (“Fifth Proposed Rule Change”).¹⁵ The Fifth Proposed Rule

Change was filed in response to the Commission’s request for (1) updated connectivity revenue for April 2020, (2) examples of alternative products to VIX and (3) any further evidence the Exchange had to support its argument that competitive forces constrain pricing. The Commission received no comment letters on the Fifth Proposed Rule Change.

Today, the Exchange is withdrawing the Fifth Proposed Rule Change and submitting this filing (“Sixth Proposed Rule Change”) as part of its ongoing efforts to adopt the post-migration connectivity fees and to respond to the Commission’s request for another update on the Exchange’s post-migration connectivity revenue and to provide further data demonstrating competition in the marketplace. The Exchange notes the proposed fees have been effective, and thus have been paid by Trading Permit Holders, for approximately nine months. The Exchange has received no feedback from market participants claiming the proposed fees are unreasonable.

As discussed herein, the Exchange believes that the proposed changes are consistent with the Act because they are reasonable, equitably allocated, not unfairly discriminatory, and not an undue burden on competition, as they are supported by evidence (including data and analysis) and are constrained by significant competitive forces. The Exchange also believes the proposed fees are reasonable as they are in line with the amounts assessed by other exchanges for similar connectivity offerings. Additionally, the Exchange believes the proposed changes are consistent with the SEC Division of Trading and Markets (the “Division”) issued non-rulemaking fee filing guidance titled “Staff Guidance on SRO Rule Filings Relating to Fees” (“Fee Guidance”) issued on May 21, 2020.¹⁶

¹⁶ Where possible, the Exchange is including numerical examples and percentages, including with respect to revenue impact. In addition, the Exchange is providing data to the Commission in support of its arguments herein, which is consistent with the Fee Guidance. The non-rulemaking Fee Guidance covers all aspects of a fee filing, but as acknowledged by the Commission, has “no legal force or effect”, is “not a rule, regulation or statement of the Commission”, does not “alter or amend applicable law” and “creates no new or additional obligations for SROs and the Commission.” See Chairman Jay Clayton, Statement on Division of Trading and Markets Staff Fee Guidance, June 12, 2019. The Exchange nonetheless has extensively addressed the Fee Guidance

Accordingly, the Exchange believes that the Commission should find that the Proposed Fee Increases are consistent with the Act. The proposed rule change is immediately effective upon filing with the Commission pursuant to Section 19(b)(3)(A) of the Act.

Physical Connectivity

A physical port is utilized by a Trading Permit Holder (“TPH”) or non-TPH to connect to the Exchange at the data centers where the Exchange’s servers are located. The Exchange currently assesses fees for Network Access Ports for these physical connections to the Exchange. Specifically, TPHs and non-TPHs can elect to connect to Cboe Options’ trading system via either a 1 gigabit per second (“Gb”) Network Access Port or a 10 Gb Network Access Port. Pre-migration the Exchange assessed a monthly fee of \$1,500 per port for 1 Gb Network Access Ports and a monthly fee of \$5,000 per port for 10 Gb Network Access Ports for access to Cboe Options primary system. Through January 31, 2020, Cboe Options market participants will continue to have the ability to connect to Cboe Options’ trading system via the current Network Access Ports. As of October 7, 2019, in connection with the migration, TPHs and non-TPHs may alternatively elect to connect to Cboe Options via new latency equalized Physical Ports.¹⁷ The new Physical Ports similarly allow TPHs and non-TPHs the ability to connect to the Exchange at the data center where the Exchange’s servers are located and TPHs and non-TPHs have the option to connect via 1 Gb or 10 Gb Physical Ports. As noted above, both the new 1 Gb and 10 Gb Physical Ports provide latency equalization, meaning that each market participant will be afforded the same latency for 1 Gb or 10 Gb Physical Ports in the primary data center to the Exchange’s customer-facing switches regardless of location of the market participant’s cage¹⁸ in the primary data center relative to the Exchange’s servers.

throughout this filing and prior versions of this filing.

¹⁷ As previously noted, market participants will continue to have the option of connecting to Cboe Options via a 1 Gbps or 10 Gbps Network Access Port at the same rates as proposed, respectively.

¹⁸ A market participant’s “cage” is the cage within the data center that contains a market participant’s servers, switches and cabling.

¹¹ See Securities Exchange Act Release No. 88164 (February 11, 2020), 85 FR 8897, (February 18, 2020).

¹² Many market participants were still transitioning to the new connectivity structure at that time and as such, the Exchange again noted it did not expect its connectivity revenue projections regarding port purchases to be realized prior to February 2020.

¹³ See Securities Exchange Act Release No. 88586 (April 8, 2020), 85 FR 20773, (April 14, 2020).

¹⁴ See Letter from Tyler Gellasch, Executive Director, The Healthy Markets Association (“Healthy Markets”), to Vanessa Countryman, Secretary, Commission, dated May 5, 2020, which letter mischaracterized the Exchange’s proposed fees as linking market data costs to trading volume, among other factual inaccuracies.

¹⁵ The Exchange refiled the Fifth Proposed Rule Change on May 22, 2020 due to a technical error (SR-CBOE-2020-048). See Securities Exchange Act Release No. 88984 (June 1, 2020), 85 FR 34670, (June 6, 2020).

Conversely, the legacy Network Access Ports are not latency equalized, meaning the location of a market participant's cage within the data center may affect latency. For example, in the legacy system, a cage located further from the Exchange's servers may experience higher latency than those located closer to the Exchange's servers.¹⁹ As such, the proposed Physical Ports ensure all market participants connected to the Exchange via the new Physical Ports will receive the same respective latency for each port size and ensure that no market participant has a latency advantage over another market participant within the primary data center.²⁰ Additionally, the new infrastructure utilizes new and faster switches resulting in lower overall latency.

The Exchange proposes to assess the following fees for any physical port, regardless of whether the TPH or non-TPH connects via the current Network Access Ports or the new Physical Ports. Specifically, the Exchange proposes to continue to assess a monthly fee of \$1,500 per port for 1 Gb Network Access Ports and new Physical Ports and increase the monthly fee for 10 Gb Network Access Ports and new Physical Ports to \$7,000 per port. Physical port fees will be prorated based on the remaining trading days in the calendar month. The proposed fee for 10 Gb Physical Ports is in line with the amounts assessed by other exchanges for similar connections by its Affiliated Exchanges and other Exchanges that utilize the same connectivity infrastructure.²¹

¹⁹ The Exchange equalizes physical connectivity in the data center for its primary system by taking the farthest possible distance that a Cboe market participant cage may exist from the Exchange's customer-facing switches and using that distance as the cable length for any cross-connect.

²⁰ The Exchange notes that 10 Gb Physical Ports have an 11 microsecond latency advantage over 1 Gb Physical Ports. Other than this difference, there are no other means to receive a latency advantage as compared to another market participant in the new connectivity structure.

²¹ See Cboe EDGA U.S. Equities Exchange Fee Schedule, Physical Connectivity Fees; Cboe EDGX U.S. Equities Exchange Fee Schedule, Physical Connectivity Fees; Cboe BZX U.S. Equities Exchange Fee Schedule, Physical Connectivity Fees; Cboe BYX U.S. Equities Exchange Fee Schedule, Physical Connectivity Fees; Cboe EDGX Options Exchange Fee Schedule, Physical Connectivity Fees; and Cboe BZX Options Exchange Fee Schedule, Physical Connectivity Fees (collectively, "Affiliated Exchange Fee Schedules"). See e.g., Nasdaq PHLX and ISE Rules, General Equity and Options Rules, General 8. Phlx and ISE each charge a monthly fee of \$2,500 for each 1Gb connection, \$10,000 for each 10Gb connection and \$15,000 for each 10Gb Ultra connection. See also Nasdaq Price List—Trading Connectivity. Nasdaq charges a monthly fee of \$7,500 for each 10Gb direct connection to Nasdaq and \$2,500 for each direct connection that supports up to 1Gb. See also

In addition to the benefits resulting from the new Physical Ports providing latency equalization and new switches (*i.e.*, improved latency), TPHs and non-TPHs may be able to reduce their overall physical connectivity fees. Particularly, Network Access Port fees are assessed for unicast (orders, quotes) and multicast (market data) connectivity separately. More specifically, Network Access Ports may only receive one type of connectivity each (thus requiring a market participant to maintain two ports if that market participant desires both types of connectivity). The new Physical Ports however, allow access to both unicast and multicast connectivity with a single physical connection to the Exchange. Therefore, TPHs and non-TPHs that currently purchase two legacy Network Access Ports for the purpose of receiving each type of connectivity now have the option to purchase only one new Physical Port to accommodate their connectivity needs, which may result in reduced costs for physical connectivity.²²

Cboe Data Services—Port Fees

The Exchange proposes to amend the "Port Fee" under the Cboe Data Services ("CDS") Fees Schedule. Currently, the Port Fee is payable by any Customer²³ that receives data through two types of sources; a direct connection to CDS ("direct connection") or through a connection to CDS provided by an extranet service provider ("extranet connection"). The Port Fee applies to receipt of any Cboe Options data feed but is only assessed once per data port. The Exchange proposes to amend the

NYSE American Fee Schedule, Section V.B, and Arca Fees and Charges, Co-Location Fees. NYSE American and Arca each charge a monthly fee of \$5,000 for each 1Gb circuit, \$14,000 for each 10Gb circuit and \$22,000 for each 10Gb LX circuit.

²² The Exchange proposes to eliminate the current Cboe Command Connectivity Charges table in its entirety and create and relocate such fees in a new table in the Fees Schedule that addresses fees for physical connectivity, including fees for the current Network Access Ports, the new Physical Ports and Disaster Recovery ("DR") Ports. The Exchange notes that it is not proposing any changes with respect to DR Ports other than renaming the DR ports from "Network Access Ports" to "Physical Ports" to conform to the new Physical Port terminology. The Exchange also notes that subsequent to the initial filings that proposed these fee changes on October 1 and 2, 2019 (SR-CBOE-2019-077 and SR-CBOE-2019-082), the Exchange amended the proposed port fees to waive fees for ports used for PULSe in filing No. SR-CBOE-2019-105. The additions proposed by filing SR-CBOE-2019-105 are double underlined in Exhibit 5A and the deletions are doubled bracketed in Exhibit 5A.

²³ A Customer is any person, company or other entity that, pursuant to a market data agreement with CDS, is entitled to receive data, either directly from CDS or through an authorized redistributor (*i.e.*, a Customer or extranet service provider), whether that data is distributed externally or used internally.

monthly CDS Port Fee to provide that it is payable "per source" used to receive data, instead of "per data port". The Exchange also proposes to increase the fee from \$500 per data port/month to \$1,000 per data source/month.²⁴ The Exchange notes the proposed change in assessing the fee (*i.e.*, per source vs per port) and the proposed fee amount are the same as the corresponding fee on its affiliate C2.²⁵

In connection with the proposed change, the Exchange also proposes to rename the "Port Fee" to "Direct Data Access Fee". As the fee will be payable "per data source" used to receive data, instead of "per data port", the Exchange believes the proposed name is more appropriate and that eliminating the term "port" from the fee will eliminate confusion as to how the fee is assessed.

Logical Connectivity

Next, the Exchange proposes to amend its login fees. By way of background, Cboe Options market participants were able to access Cboe Command via either a CMI or a FIX Port, depending on how their systems are configured. Effective October 7, 2019, market participants are no longer able to use CMI and FIX Login IDs. Rather, the Exchange utilizes a variety of logical connectivity ports as further described below. Both a legacy CMI/FIX Login ID and logical port represent a technical port established by the Exchange within the Exchange's trading system for the delivery and/or receipt of trading messages—*i.e.*, orders, accepts, cancels, transactions, etc. Market participants that wish to connect directly to the Exchange can request a number of different types of ports, including ports that support order entry, customizable purge functionality, or the receipt of market data. Market participants can also choose to connect indirectly through a number of different third-party providers, such as another broker-dealer or service bureau that the Exchange permits through specialized

²⁴ For example, under the pre-migration "per port" methodology, if a TPH maintained 4 ports that receive market data, that TPH would be assessed \$2,000 per month (*i.e.*, \$500 × 4 ports), regardless of how many sources it used to receive data. Under the proposed "per source" methodology, if a TPH maintains 4 ports that receive market data, but receives data through only one source (*e.g.*, a direct connection) that TPH would be assessed \$1,000 per month (*i.e.*, \$1000 × 1 source). If that TPH maintains 4 ports but receives data from both a direct connection and an extranet connection, that TPH would be assessed \$2,000 per month (*i.e.*, \$1,000 × 2 sources). Similarly, if that TPH maintains 4 ports and receives data from two separate extranet providers, that TPH would be assessed \$2,000 per month (*i.e.*, \$1,000 × 2).

²⁵ See Cboe C2 Options Exchange Fee Schedule, Cboe Data Services, LLC Fees, Section IV, Systems Fees.

access to the Exchange’s trading system and that may provide additional services or operate at a lower mutualized cost by providing access to

multiple members. In light of the discontinuation of CMI and FIX Login IDs, the Exchange proposes to eliminate the fees associated with the CMI and

FIX login IDs and adopt the below pricing for logical connectivity in its place.

Service	Cost per month
Logical Ports (BOE, FIX) 1 to 5	\$750 per port.
Logical Ports (BOE, FIX) >5	\$800 per port.
Logical Ports (Drop)	\$750 per port.
BOE Bulk Ports 1 to 5	\$1,500 per port.
BOE Bulk Ports 6 to 30	\$2,500 per port.
BOE Bulk Ports >30	\$3,000 per port.
Purge ports	\$850 per port.
GRP Ports	\$750/primary (A or C Feed).
Multicast PITCH/Top Spin Server Ports	\$750/set of primary (A or C feed)

The Exchange proposes to provide for each of the logical connectivity fees that new requests will be prorated for the first month of service. Cancellation requests are billed in full month increments as firms are required to pay for the service for the remainder of the month, unless the session is terminated within the first month of service. The Exchange notes that the proration policy is the same on its Affiliated Exchanges.²⁶

Logical Ports (BOE, FIX, Drop): The new Logical Ports represent ports

established by the Exchange within the Exchange’s system for trading purposes. Each Logical Port established is specific to a TPH or non-TPH and grants that TPH or non-TPH the ability to operate a specific application, such as order/quote²⁷ entry (FIX and BOE Logical Ports) or drop copies (Drop Logical Ports). Similar to CMI and FIX Login IDs, each Logical Port will entitle a firm to submit message traffic of up to specified number of orders per second.²⁸ The Exchange proposes to assess \$750 per port per month for all

Drop Logical Ports and also assess \$750 per port per month (which is the same amount currently assessed per CMI/FIX Login ID per month), for the first 5 FIX/BOE Logical Ports and thereafter assess \$800 per port, per month for each additional FIX/BOE Logical Port. While the proposed ports will be assessed the same monthly fees as current CMI/FIX Login IDs (for the first five logical ports), the proposed logical ports provide for significantly more message traffic (and thus cost less per message sent) as shown below:

	CMI/FIX Login Ids		BOE/FIX Logical ports
	Quotes	Orders	Quotes/orders
Bandwidth Limit per login	5,000 quotes/3 sec ²⁹	30 orders/sec	15,000 quotes/orders/3 sec.
Cost	\$750 each	\$750 each	\$750/\$800 each.
Cost per Quote/Order Sent @ Limit.	\$0.15 per quote/3 sec	\$25.00 per order/sec	\$0.05/\$0.053 per quote/order/3 sec.

Logical Port fees will be limited to Logical Ports in the Exchange’s primary data center and no Logical Port fees will be assessed for redundant secondary data center ports. Each BOE or FIX Logical Port will incur the logical port fee indicated in the table above when used to enter up to 70,000 orders per trading day per logical port as measured on average in a single month. Each incremental usage of up to 70,000 per day per logical port will incur an additional logical port fee of \$800 per month. Incremental usage will be determined on a monthly basis based on the average orders per day entered in a single month across all of a market participant’s subscribed BOE and FIX

Logical Ports. The Exchange believes that the pricing implications of going beyond 70,000 orders per trading day per Logical Port encourage users to mitigate message traffic as necessary. The Exchange notes that the proposed fee of \$750 per port is the same amount assessed not only for current CMI and FIX Login Ids, but also similar ports available on an affiliate exchange.³⁰

The Exchange also proposes to provide that the fee for one FIX Logical Port connection to PULSe and one FIX Logical Port connection to Cboe Silexx will be waived per TPH. The Exchange notes that only one FIX Logical Port connection is required to support a

firm’s access through each of PULSe and Cboe Silexx FLEX.

BOE Bulk Logical Ports: The Exchange also offers BOE Bulk Logical Ports, which provide users with the ability to submit single and bulk order messages to enter, modify, or cancel orders designated as Post Only Orders with a Time-in-Force of Day or GTD with an expiration time on that trading day. While BOE Bulk Ports will be available to all market participants, the Exchange anticipates they will be used primarily by Market-Makers or firms that conduct similar business activity, as the primary purpose of the proposed bulk message functionality is to encourage market-maker quoting on exchanges. As

²⁶ See Affiliated Exchange Fee Schedules, Logical Port Fees.

²⁷ As of October 7, 2019, the definition of quote in Cboe Options Rule 1.1 means a firm bid or offer a Market-Maker (a) submits electronically as an order or bulk message (including to update any bid or offer submitted in a previous order or bulk message) or (b) represents in open outcry on the trading floor.

²⁸ Login Ids restrict the maximum number of orders and quotes per second in the same way logical ports do, and Users may similarly have multiple logical ports as they may have Trading Permits and/or bandwidth packets to accommodate their order and quote entry needs.

²⁹ Each Login ID has a bandwidth limit of 80,000 quotes per 3 seconds. However, in order to place such bandwidth onto a single Login ID, a TPH or

non-TPH would need to purchase a minimum of 15 Market-Maker Permits or Bandwidth Packets (each Market-Maker Permit and Bandwidth Packet provides 5,000 quotes/3 sec). For purposes of comparing “quote” bandwidth, the provided example assumes only 1 Market-Maker Permit or Bandwidth Packet has been purchased.

³⁰ See Cboe BZX Options Exchange Fee Schedule, Options Logical Port Fees.

indicated above, BOE Bulk Logical Ports are assessed \$1,500 per port, per month for the first 5 BOE Bulk Logical Ports, assessed \$2,500 per port, per month thereafter up to 30 ports and thereafter assessed \$3,000 per port, per month for

each additional BOE Bulk Logical Port. Like CMI and FIX Login IDs, and FIX/BOX Logical Ports, BOE Bulk Ports will also entitle a firm to submit message traffic of up to specified number of quotes/orders per second.³¹ The

proposed BOE Bulk ports also provide for significantly more message traffic (and thus cost less per message sent) as compared to current CMI/FIX Login IDs, as shown below:

	CMI/FIX Login Ids	BOE Bulk ports
	Quotes	Quotes ³²
Bandwidth Limit	5,000 quotes/3 sec ³³	225,000 quotes 3 sec.
Cost	\$750 each	\$1,500/\$2,500/\$3,000 each.
Cost per Quote/Order Sent @Limit	\$0.15 per quote/3 sec	\$0.006/\$0.011/\$0.013 per quote/3 sec.

Each BOE Bulk Logical Port will incur the logical port fee indicated in the table above when used to enter up to 30,000,000 orders per trading day per logical port as measured on average in a single month. Each incremental usage of up to 30,000,000 orders per day per BOE Bulk Logical Port will incur an additional logical port fee of \$3,000 per month. Incremental usage will be determined on a monthly basis based on the average orders per day entered in a single month across all of a market participant's subscribed BOE Bulk Logical Ports. The Exchange believes that the pricing implications of going beyond 30,000,000 orders per trading day per BOE Bulk Logical Port encourage users to mitigate message traffic as necessary. The Exchange notes that the proposed BOE Bulk Logical Port fees are similar to the fees assessed for these ports by BZX Options.³⁴

Purge Ports: As part of the migration, the Exchange introduced Purge Ports to provide TPHs additional risk management and open order control functionality. Purge ports were designed to assist TPHs, in the management of, and risk control over, their quotes, particularly if the TPH is dealing with a large number of options. Particularly, Purge Ports allow TPHs to submit a cancellation for all open orders, or a subset thereof, across multiple sessions under the same Executing Firm ID ("EFID"). This would allow TPHs to seamlessly avoid unintended executions, while continuing to evaluate

the direction of the market. While Purge Ports are available to all market participants, the Exchange anticipates they will be used primarily by Market-Makers or firms that conduct similar business activity and are therefore exposed to a large amount of risk across a number of securities. The Exchange notes that market participants are also able to cancel orders through FIX/BOE Logical Ports and as such a dedicated Purge Port is not required nor necessary. Rather, Purge Ports were specially developed as an optional service to further assist firms in effectively managing risk. As indicated in the table above, the Exchange proposes to assess a monthly charge of \$850 per Purge Port. The Exchange notes that the proposed fee is in line with the fee assessed by other exchanges, including its Affiliated Exchanges, for Purge Ports.³⁵

Multicast PITCH/Top Spin Server and GRP Ports: In connection with the migration, the Exchange also offers optional Multicast PITCH/Top Spin Server ("Spin") and GRP ports and proposes to assess \$750 per month, per port. Spin Ports and GRP Ports are used to request and receive a retransmission of data from the Exchange's Multicast PITCH/Top data feeds. The Exchange's Multicast PITCH/Top data feeds are available from two primary feeds, identified as the "A feed" and the "C feed", which contain the same information but differ only in the way such feeds are received. The Exchange

also offers two redundant feeds, identified as the "B feed" and the "D feed." All secondary feed Spin and GRP Ports will be provided for redundancy at no additional cost. The Exchange notes a dedicated Spin and GRP Port is not required nor necessary. Rather, Spin ports enable a market participant to receive a snapshot of the current book quickly in the middle of the trading session without worry of gap request limits and GRP Ports were specially developed to request and receive retransmission of data in the event of missed or dropped message. The Exchange notes that the proposed fee is in line with the fee assessed for the same ports on BZX Options.³⁶

Access Credits

The Exchange next proposes to amend its Affiliate Volume Plan ("AVP") to provide Market-Makers an opportunity to obtain credits on their monthly BOE Bulk Port Fees.³⁷ By way of background, under AVP, if a TPH Affiliate³⁸ or Appointed OFP³⁹ (collectively, an "affiliate") of a Market-Maker qualifies under the Volume Incentive Program ("VIP") (i.e., achieves VIP Tiers 2-5), that Market-Maker will also qualify for a discount on that Market-Maker's Liquidity Provider ("LP") Sliding Scale transaction fees and Trading Permit fees. The Exchange proposes to amend AVP to provide that qualifying Market-Makers will receive a discount on Bulk Port fees (instead of Trading Permits) where an affiliate achieves VIP Tiers 4

³¹ The Exchange notes that while technically there is no bandwidth limit per BOE Bulk Port, there may be possible performance degradation at 15,000 messages per second (which is the equivalent of 225,000 quotes/orders per 3 seconds). As such, the Exchange uses the number at which performance may be degraded for purposes of comparison.

³² See Cboe Options Rule 1.1.

³³ Each Login ID has a bandwidth limit of 80,000 quotes per 3 seconds. However, in order to place such bandwidth onto a single Login ID, a TPH or non-TPH would need to purchase a minimum of 15 Market-Maker Permits or Bandwidth Packets (each Market-Maker Permit and Bandwidth Packet

provides 5,000 quotes/3 sec). For purposes of comparing "quote" bandwidth, the provided example assumes only 1 Market-Maker Permit or Bandwidth Packet has been purchased.

³⁴ See Cboe BZX Options Exchange Fee Schedule, Options Logical Port Fees.

³⁵ See e.g., Nasdaq ISE Options Pricing Schedule, Section 7(C), Ports and Other Services. See also Cboe EDGX Options Exchange Fee Schedule, Options Logical Port Fees; Cboe C2 Options Exchange Fee Schedule, Options Logical Port Fees and Cboe BZX Options Exchange Fee Schedule, Options Logical Port Fees.

³⁶ See Cboe BZX Options Exchange Fee Schedule, Options Logical Port Fees.

³⁷ As noted above, while BOE Bulk Ports will be available to all market participants, the Exchange anticipates they will be used primarily by Market Makers or firms that conduct similar business activity.

³⁸ For purposes of AVP, "Affiliate" is defined as having at least 75% common ownership between the two entities as reflected on each entity's Form BD, Schedule A.

³⁹ See Cboe Options Fees Schedule Footnote 23. Particularly, a Market-Maker may designate an Order Flow Provider ("OFP") as its "Appointed OFP" and an OFP may designate a Market-Maker to be its "Appointed Market-Maker" for purposes of qualifying for credits under AVP.

or 5. As discussed more fully below, the Exchange is amending its Trading Permit structure, such that off-floor

Market-Makers no longer need to hold more than one Market-Maker Trading Permit. As such, in place of credits for

Trading Permits, the Exchange will provide credits for BOE Bulk Ports.⁴⁰ The proposed credits are as follows:

Market maker affiliate access credit	VIP Tier	Percent credit on monthly BOE bulk port fees
Credit Tier	1	0
	2	0
	3	0
	4	15
	5	25

The Exchange believes the proposed change to AVP continues to allow the Exchange to provide TPHs that have both Market-Maker and agency operations reduced Market-Maker costs via the credits, albeit credits on BOE Bulk Port fees instead of Trading Permit fees. AVP also continues to provide incremental incentives for TPHs to strive for the higher tier levels, which provide increasingly higher benefits for satisfying increasingly more stringent criteria.

In addition to the opportunity to receive credits via AVP, the Exchange proposes to provide an additional

opportunity for Market-Makers to obtain credits on their monthly BOE Bulk Port fees based on the previous month's make rate percentage. By way of background, the Liquidity Provider Sliding Scale Adjustment Table provides that Taker fees be applied to electronic "Taker" volume and a Maker rebate be applied to electronic "Maker" volume, in addition to the transaction fees assessed under the Liquidity Provider Sliding Scale.⁴¹ The amount of the Taker fee (or Maker rebate) is determined by the Liquidity Provider's percentage of volume from the previous month that was Maker ("Make Rate").⁴²

Market-Makers are given a Performance Tier based on their Make Rate percentage which currently provides adjustments to transaction fees. Thus, the program is designed to attract liquidity from traditional Market-Makers. The Exchange proposes to now also provide BOE Bulk Port fee credits if Market-Makers satisfy the thresholds of certain Performance Tiers. Particularly, the Performance Tier earned will also determine the percentage credit applied to a Market-Maker's monthly BOE Bulk Port fees, as shown below:

Market maker access credit	Liquidity provider sliding scale adjustment performance tier	Make rate (percent based on prior month)	Percent credit on monthly BOE bulk port fees
Credit Tier	1	0%–50%	0
	2	Above 50%–60%	0
	3	Above 60%–75%	0
	4	Above 75%–90%	40
	5	Above 90%	40

The Exchange believes the proposal mitigates costs incurred by traditional Market-Makers that focus on adding liquidity to the Exchange (as opposed to those that provide and take, or just take). The Exchange lastly notes that both the Market-Maker Affiliate Access Credit under AVP and the Market-Maker Access Credit tied to Performance Tiers can both be earned by a TPH, and these credits will each apply to the total monthly BOE Bulk Port Fees including any incremental BOE Bulk Port fees incurred, before any credits/adjustments

have been applied (*i.e.* an electronic MM can earn a credit from 15% to 65%).

Bandwidth Packets

As described above, post-migration, the Exchange utilizes a variety of logical ports. Part of this functionality is similar to bandwidth packets that were previously available on the Exchange. Bandwidth packets restricted the maximum number of orders and quotes per second. Post-migration, market participants may similarly have

multiple Logical Ports and/or BOE Bulk Ports as they may have had bandwidth packets to accommodate their order and quote entry needs. As such, the Exchange proposes to eliminate all of the current Bandwidth Packet fees.⁴³ The Exchange believes that the proposed pricing implications of going beyond specified bandwidth described above in the logical connectivity fees section will be able to otherwise mitigate message traffic as necessary.

⁴⁰ The Exchange notes that Trading Permits currently each include a set bandwidth allowance and 3 logins. Current logins and bandwidth are akin to the proposed logical ports, including BOE Bulk Ports which will primarily be used by Market-Makers.

⁴¹ See Cboe Options Exchange Fees Schedule, Liquidity Provider Sliding Scale Adjustment Table.

⁴² More specifically, the Make Rate is derived from a Liquidity Provider's electronic volume the previous month in all symbols excluding Underlying Symbol List A using the following formula: (i) The Liquidity Provider's total electronic

automatic execution ("auto-ex") volume (*i.e.*, volume resulting from that Liquidity Provider's resting quotes or single sided quotes/orders that were executed by an incoming order or quote), divided by (ii) the Liquidity Provider's total auto-ex volume (*i.e.*, volume that resulted from the Liquidity Provider's resting quotes/orders and volume that resulted from that LP's quotes/orders that removed liquidity). For example, a TPH's electronic Make volume in September 2019 is 2,500,000 contracts and its total electronic auto-ex volume is 3,000,000 contracts, resulting in a Make Rate of 83% (Performance Tier 4). As such, the TPH would receive a 40% credit on its monthly Bulk

Port fees for the month of October 2019. For the month of October 2019, the Exchange will be billing certain incentive programs separately, including the Liquidity Provider Sliding Scale Adjustment Table, for the periods of October 1–October 4 and October 7–October 31 in light of the migration of its billing system. As such, a Market-Maker's Performance Tier for November 2019 will be determined by the Market-Maker's percentage of volume that was Maker from the period of October 7–October 31, 2019.

⁴³ See Cboe Options Fees Schedule, Bandwidth Packet Fees.

CAS Servers

By way of background, in order to connect to the legacy Cboe Command, which allowed a TPH to trade on the Cboe Options System, a TPH had to connect via either a CMI or FIX interface (depending on the configuration of the TPH's own systems). For TPHs that connected via a CMI interface, they had to use CMI CAS Servers. In order to ensure that a CAS Server was not overburdened by quoting activity for Market-Makers, the Exchange allotted each Market-Maker a certain number of CASs (in addition to the shared backups) based on the amount of quoting bandwidth that they had. The Exchange no longer uses CAS Servers, post-migration. In light of the elimination of CAS Servers, the Exchange proposes to eliminate the CAS Server allotment table and extra CAS Server fee.

Trading Permit Fees

By way of background, the Exchange may issue different types of Trading Permits and determine the fees for those Trading Permits.⁴⁴ Pre-migration, the Exchange issued the following three types of Trading Permits: (1) Market-Maker Trading Permits, which were assessed a monthly fee of \$5,000 per permit; (2) Floor Broker Trading Permits, which were assessed a monthly fee of \$9,000 per permit; and (3) Electronic Access Permits ("EAPs"), which were assessed a monthly fee of \$1,600 per permit. The Exchange also offered separate Market-Maker and Electronic Access Permits for the Global Trading Hours ("GTH") session, which were assessed a monthly fee of \$1,000 per permit and \$500 per permit respectively.⁴⁵ For further color, a Market-Maker Trading Permit entitled the holder to act as a Market-Maker, including a Market-Maker trading remotely, DPM, eDPM, or LMM, and also provided an appointment credit of 1.0, a quoting and order entry bandwidth allowance, up to three logins, trading floor access and TPH status.⁴⁶ A Floor Broker Trading Permit entitled the holder to act as a Floor Broker, provided an order entry bandwidth allowance, up to 3 logins, trading floor access and TPH status.⁴⁷ Lastly, an EAP entitled the holder to electronic access to the Exchange. Holders of EAPs must have been broker-dealers registered with the Exchange in

one or more of the following capacities: (a) Clearing TPH, (b) TPH organization approved to transact business with the public, (c) Proprietary TPHs and (d) order service firms. The permit did not provide access to the trading floor. An EAP also provided an order entry bandwidth allowance, up to 3 logins and TPH status.⁴⁸ The Exchange also provided an opportunity for TPHs to pay reduced rates for Trading Permits via the Market Maker and Floor Broker Trading Permit Sliding Scale Programs ("TP Sliding Scales"). Particularly, the TP Sliding Scales allowed Market-Makers and Floor Brokers to pay reduced rates for their Trading Permits if they committed in advance to a specific tier that includes a minimum number of eligible Market-Maker and Floor Broker Trading Permits, respectively, for each calendar year.⁴⁹

As noted above, Trading Permits were tied to bandwidth allocation, logins and appointment costs, and as such, TPH organizations may hold multiple Trading Permits of the same type in order to meet their connectivity and appointment cost needs. Post-Migration, bandwidth allocation, logins and appointment costs are no longer tied to a Trading Permit, and as such, the Exchange proposes to modify its Trading Permit structure. Particularly, in connection with the migration, the Exchange adopted separate on-floor and off-floor Trading Permits for Market-Makers and Floor Brokers, adopted a new Clearing TPH Permit, and proposes to modify the corresponding fees and discounts. As was the case pre-migration, the proposed access fees discussed below will continue to be non-refundable and will be assessed through the integrated billing system during the first week of the following month. If a Trading Permit is issued during a calendar month after the first trading day of the month, the access fee for the Trading Permit for that calendar month is prorated based on the remaining trading days in the calendar month. Trading Permits will be renewed automatically for the next month unless the Trading Permit Holder submits written notification to the Membership Services Department by 4 p.m. CT on the second-to-last business day of the prior month to cancel the Trading Permit effective at or prior to the end of the applicable month. Trading Permit

Holders will only be assessed a single monthly fee for each type of electronic Trading Permit it holds.

First, TPHs no longer need to hold multiple permits for each type of electronic Trading Permit (*i.e.*, electronic Market-Maker Trading Permits and/or and Electronic Access Permits). Rather, for electronic access to the Exchange, a TPH need only purchase one of the following permit types for each trading function the TPH intends to perform: Market-Maker Electronic Access Permit ("MM EAP") in order to act as an off-floor Market-Maker and which will continue to be assessed a monthly fee of \$5,000, Electronic Access Permit ("EAP") in order to submit orders electronically to the Exchange⁵⁰ and which will be assessed a monthly fee of \$3,000, and a Clearing TPH Permit, for TPHs acting solely as a Clearing TPH, which will be assessed a monthly fee of \$2,000 (and is more fully described below). For example, a TPH organization that wishes to act as a Market-Maker and also submit orders electronically in a non-Market Maker capacity would have to purchase one MM EAP and one EAP. TPHs will be assessed the monthly fee for each type of Permit once per electronic access capacity.

Next, the Exchange proposes to adopt a new Trading Permit, exclusively for Clearing TPHs that are approved to act solely as a Clearing TPH (as opposed to those that are also approved in a capacity that allows them to submit orders electronically). Currently any TPH that is registered to act as a Clearing TPH must purchase an EAP, whether or not that Clearing TPH acts solely as a Clearing TPH or acts as a Clearing TPH and submits orders electronically. The Exchange proposes to adopt a new Trading Permit, for any TPH that is registered to act solely as Clearing TPH at a discounted rate of \$2,000 per month.⁵¹

Additionally, the Exchange proposes to eliminate its fees for Global Trading Hours Trading Permits. Particularly, the Exchange proposes to provide that any Market-Maker EAP, EAP and Clearing TPH Permit provides access (at no

⁵⁰ EAPs may be purchased by TPHs that both clear transactions for other TPHs (*i.e.*, a "Clearing TPH") and submit orders electronically.

⁵¹ Cboe Option Rules provides the Exchange authority to issue different types of Trading Permits which allows holders, among other things, to act in one or more trading functions authorized by the Rules. See Cboe Options Rule 3.1(a)(iv). The Exchange notes that currently 17 out of 38 Clearing TPHs are acting solely as a Clearing TPH on the Exchange.

⁴⁴ See Cboe Options Rules 3.1(a)(iv)-(v).

⁴⁵ The fees were waived through September 2019 for the first Market-Maker and Electronic Access GTH Trading Permits.

⁴⁶ See Cboe Options Fees Schedule.

⁴⁷ *Id.*

⁴⁸ *Id.*

⁴⁹ Due to the October 7 migration, the Exchange had amended the TP Sliding Scale Programs to provide that any commitment to Trading Permits under the TP Sliding Scales shall be in place through September 2019, instead of the calendar year. See Cboe Options Fees Schedule, Footnotes 24 and 25.

additional cost) to the GTH session.⁵² Additionally, the Exchange proposes to amend Footnote 37 of the Fees Schedule regarding GTH in connection with the migration. Currently Footnote 37 provides that separate access permits and connectivity is needed for the GTH session. The Exchange proposes to eliminate this language as that is no longer the case post-migration (*i.e.*, an electronic Trading Permits will grant access to both sessions and physical and logical ports may be used in both sessions, eliminating the need to purchase separate connectivity). The Exchange also notes that in connection with migration, the Book used during Regular Trading Hours (“RTH”) will be the same Book used during GTH (as compared to pre-migration where the Exchange maintained separate Books for each session). The Exchange therefore also proposes to eliminate language in Footnote 37 stating that GTH is a segregated trading session and that there is no market interaction between the two sessions.

The Exchange next proposes to adopt MM EAP Appointment fees. By way of background, a registered Market-Maker may currently create a Virtual Trading Crowd (“VTC”) Appointment, which

confers the right to quote electronically in an appropriate number of classes selected from “tiers” that have been structured according to trading volume statistics, except for the AA tier.⁵³ Each Trading Permit historically held by a Market-Maker had an appointment credit of 1.0. A Market-Maker could select for each Trading Permit the Market-Maker held any combination of classes whose aggregate appointment cost did not exceed 1.0. A Market-Maker could not hold a combination of appointments whose aggregate appointment cost was greater than the number of Trading Permits that Market-Maker held.⁵⁴

As discussed, post-migration, bandwidth allocation, logins and appointment costs are no longer tied to a single Trading Permit and therefore TPHs no longer need to have multiple permits for each type of electronic Trading Permit. Market-Makers must still select class appointments in the classes they seek to make markets electronically.⁵⁵ Particularly, a Market-Maker firm will only be required to have one permit and will thereafter be charged for one or more “Appointment Units” (which will scale from 1 “unit” to more than 5 “units”), depending on

which classes they elect appointments in. Appointment Units will replace the standard 1.0 appointment cost, but function in the same manner. Appointment weights (formerly known as “appointment costs”) for each appointed class will be set forth in Cboe Options Rule 5.50(g) and will be summed for each Market-Maker in order to determine the total appointment units, to which fees will be assessed. This was the manner in which the tier costs per class appointment were summed to meet the 1.0 appointment cost, the only difference being that if a Market-Maker exceeds this “unit”, then their fees will be assessed under the “unit” that corresponds to the total of their appointment weights, as opposed to holding another Trading Permit because it exceeded the 1.0 “unit”. Particularly, the Exchange proposes to adopt a new MM EAP Appointment Sliding Scale. Appointment Units for each assigned class will be aggregated for each Market-Maker and Market-Maker affiliate. If the sum of appointments is a fractional amount, the total will be rounded up to the next highest whole Appointment Unit. The following lists the progressive monthly fees for Appointment Units:⁵⁶

Market-Maker EAP appointments	Quantity	Monthly fees (per unit)
Appointment Units	1	\$0
	2	6,000
	3 to 5	4,000
	>5	3,100

As noted above, upon migration the Exchange required separate Trading Permits for on-floor and off-floor activity. As such, the Exchange proposes to maintain a Floor Broker Trading Permit and adopt a new Market-Maker Floor Permit for on-floor Market-Makers. In addition, RUT, SPX, and VIX Tier Appointment fees will be charged

separately for Permit, as discussed more fully below.

As briefly described above, the Exchange currently maintains TP Sliding Scales, which allow Market-Makers and Floor Brokers to pay reduced rates for their Trading Permits if they commit in advance to a specific tier that includes a minimum number of

eligible Market-Maker and Floor Broker Trading Permits, respectively, for each calendar year. The Exchange proposes to eliminate the current TP Sliding Scales, including the requirement to commit to a specific tier, and replace it with new TP Sliding Scales as follows:⁵⁷

Floor TPH permits	Current permit qty	Current monthly fee (per permit)	Proposed permit qty	Proposed monthly fee (per permit)
Market-Maker Floor Permit	1–10	\$5,000	1	\$6,000
	11–20	3,700	2 to 5	4,500
	21 or more	1,800	6 to 10	3,500
			>10	2,000

⁵²The Exchange notes that Clearing TPHs must be properly authorized by the Options Clearing Corporation (“OCC”) to operate during the Global Trading Hours session and all TPHs must have a Letter of Guarantee to participate in the GTH session (as is the case today).

⁵³ See Cboe Options Rule 5.50 (Appointment of Market-Makers).

⁵⁴ For example, if a Market-Maker selected a combination of appointments that has an aggregate

appointment cost of 2.5, that Market-Maker must hold at least 3 Market-Maker Trading Permits.

⁵⁵ See Cboe Options Rule 5.50(a).

⁵⁶ For example, if a Market-Maker’s total appointment costs amount to 3.5 unites, the Market-Maker will be assessed a total monthly fee of \$14,000 (1 appointment unit at \$0, 1 appointment unit at \$6,000 and 2 appointment units at \$4,000) as and for appointment fees and \$5,000 for a Market-Maker Trading Permit, for a total monthly

sum of \$19,000, where a Market-Maker currently (*i.e.*, prior to migration) with a total appointment cost of 3.5 would need to hold 4 Trading Permits and would therefore be assessed a monthly fee of \$20,000.

⁵⁷ In light of the proposed change to eliminate the TP Sliding Scale, the Exchange proposes to eliminate Footnote 24 in its entirety.

Floor TPH permits	Current permit qty	Current monthly fee (per permit)	Proposed permit qty	Proposed monthly fee (per permit)
Floor Broker Permit	1	9,000	1	7,500
	2-5	5,000	2 to 3	5,700
	6 or more	3,000	4 to 5	4,500
			>5	3,200

Floor Broker ADV Discount

Footnote 25, which governs rebates on Floor Broker Trading Permits, currently provides that any Floor Broker that executes a certain average of customer or professional customer/voluntary customer (collectively “customer”) open-outcry contracts per day over the course of a calendar month in all underlying symbols excluding Underlying Symbol List A (except RLG, RLV, RUI, and UKXM), DJX, XSP, and subcabinet trades (“Qualifying Symbols”), will receive a rebate on that TPH’s Floor Broker Trading Permit Fees.

Specifically, any Floor Broker Trading Permit Holder that executes an average of 15,000 customer (“C” origin code) and/or professional customer and voluntary customer (“W” origin code) open-outcry contracts per day over the course of a calendar month in Qualifying Symbols will receive a rebate of \$9,000 on that TPH’s Floor Broker Trading Permit fees. Additionally, any Floor Broker that executes an average of 25,000 customer open-outcry contracts per day over the course of a calendar month in Qualifying Symbols will receive a rebate of \$14,000 on that

TPH’s Floor Broker Trading Permit fees. The Exchange proposes to maintain, but modify, its discount for Floor Broker Trading Permit fees. First, the measurement criteria to qualify for a rebate will be modified to only include customer (“C” origin code) open-outcry contracts executed per day over the course of a calendar month in all underlying symbols, while the rebate amount will be modified to be a percentage of the TPH’s Floor Broker Permit total costs, instead of a straight rebate.⁵⁸ The criteria and corresponding percentage rebates are noted below.⁵⁹

Floor broker ADV discount tier	ADV	Floor broker permit rebate (percent)
1	0 to 99,999	0
2	100,000 to 174,999	15
3	>174,999	25

Next, the Exchange proposes to modify its SPX, VIX and RUT Tier Appointment Fees. Currently, these fees are assessed to any Market-Maker TPH that either (i) has the respective SPX, VIX or RUT appointment at any time during a calendar month and trades a specified number of contracts or (ii) trades a specified number of contracts in open outcry during a calendar month. More specifically, the Fees Schedule provides that the \$3,000 per month SPX Tier Appointment is assessed to any Market-Maker Trading Permit Holder that either (i) has an SPX Tier Appointment at any time during a calendar month and trades at least 100 SPX contracts while that appointment is active or (ii) conducts any open outcry transaction in SPX or SPX Weeklys at any time during the month. The \$2,000 per month VIX Tier Appointment is assessed to any Market-Maker Trading Permit Holder that either (i) has an SPX Tier Appointment at any time during a calendar month and trades at least 100

VIX contracts while that appointment is active or (ii) conducts at least 1000 open outcry transaction in VIX at any time during the month. Lastly, the \$1,000 RUT Tier Appointment is assessed to any Market-Maker Trading Permit Holder that either (i) has an RUT Tier Appointment at any time during a calendar month and trades at least 100 RUT contracts while that appointment is active or (ii) conducts at least 1000 open outcry transaction in RUT at any time during the month. Because the Exchange is separating Market-Maker Trading Permits for electronic and open-outcry market-making, the Exchange will be assessing separate Tier Appointment Fees for each type of Market-Maker Trading Permit. The Exchange proposes that a MM EAP will be assessed the Tier Appointment Fee whenever the Market-Maker executes the corresponding specified number of contracts, if any. The Exchange also proposes to modify the threshold number of contracts a Market-

Maker must execute in a month to trigger the fee for SPX, VIX and RUT. Particularly, for SPX, the Exchange proposes to eliminate the 100 contract threshold for electronic SPX executions.⁶⁰ The Exchange notes that historically, all TPHs that trade SPX electronically executed more than 100 contracts electronically each month (*i.e.*, no TPH electronically traded between 1 and 100 contracts of SPX). As no TPH would currently be negatively impacted by this change, the Exchange proposes to eliminate the threshold for SPX and align the electronic SPX Tier Appointment Fee with that of the floor SPX Tier Appointment Fee, which is not subject to any executed volume threshold. For the VIX and RUT Tier appointments, the Exchange proposes to increase the threshold from 100 contracts a month to 1,000 contracts a month. The Exchange notes the Tier Appointment Fee amounts are not

⁵⁸ As is the case today, the Floor Broker ADV Discount will be available for all Floor Broker Trading Permits held by affiliated Trading Permit Holders and TPH organizations.

⁵⁹ In light of the proposal to eliminate the TP Sliding Scales and the Floor Broker rebates currently set forth under Footnote 25, the Exchange proposes to eliminate Footnote 25 in its entirety.

⁶⁰ The Exchange notes that subsequent to the Original Filing that proposed these changes on October 1 and 2, 2019 (SR-CBOE-2019-077 and SR-CBOE-2019-082), and subsequent to the Second Proposed Rule Change filing that proposed these changes on November 29, 2019 (SR-CBOE-2019-111), the Exchange amended the proposed Market-Maker Tier Appointment fees to provide that the SPX Tier Appointment Fee will be assessed

to any Market-Maker EAP that executes at least 1,000 contracts in SPX (including SPXW) excluding contracts executed during the opening rotation on the final settlement date of VIX options and futures with the expiration used in the VIX settlement calculation in filing No. SR-CBOE-2019-124. The additions proposed by filing SR-CBOE-2019-124 are double underlined in Exhibit 5A and the deletions are doubled bracketed in Exhibit 5A.

changing.⁶¹ In connection with the proposed changes, the Exchange proposes to relocate the Tier Appointment Fees to a new table and eliminate the language in the current respective notes sections of each Tier Appointment Fee as it is no longer necessary.

Trading Permit Holder Regulatory Fee

The Fees Schedule provides for a Trading Permit Holder Regulatory Fee of \$90 per month, per RTH Trading Permit, applicable to all TPHs, which fee helps more closely cover the costs of regulating all TPHs and performing regulatory responsibilities. In light of the changes to the Exchange's Trading Permit structure, the Exchange proposes to eliminate the TPH Regulatory Fee. The Exchange notes that there is no regulatory requirement to maintain this fee.

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.⁶² Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)⁶³ 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 Section 6(b)(4) of the Act,⁶⁴ which requires that Exchange rules provide for the equitable allocation of reasonable dues, fees, and other charges among its Trading Permit Holders and other persons using its facilities. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)⁶⁵ requirement that the rules of

an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange first stresses that the proposed changes were not designed with the objective to generate an overall increase in access fee revenue, as demonstrated by the anticipated loss of revenue discussed above. Rather, the proposed changes were prompted by the Exchange's technology migration and the adoption of a new (and improved) connectivity infrastructure, rendering the pre-migration structure obsolete. Such changes accordingly necessitated an overhaul of the Exchange's previous access fee structure and corresponding fees. Moreover, the proposed changes more closely align the Exchange's access fees to those of its Affiliated Exchanges, and reasonably so, as the Affiliated Exchanges offer substantially similar connectivity and functionality and are on the same platform that the Exchange has now migrated to.

The Exchange also notes that it operates in a highly competitive environment. The SEC Division of Trading and Markets' Fee Guidance provides that in determining whether a proposed fee is constrained by significant competitive forces, the Commission will consider whether there are reasonable substitutes for the product or service that is the subject of a proposed fee. As described in further detail below, the Exchange believes substitutable products and services are in fact available to market participants, including, among other things, other options exchanges a market participant may connect to in lieu of the Exchange, indirect connectivity to the Exchange via a third-party reseller of connectivity and/or trading of any options product, including proprietary products, in the Over-the-Counter (OTC) markets. Indeed, there are currently 16 registered options exchanges that trade options, some of which have similar or lower connectivity fees.⁶⁶ Based on publicly available information, no single options exchange has more than 17% of the market share.⁶⁷ Further, low barriers to entry mean that new exchanges may rapidly and inexpensively enter the market and offer additional substitute platforms to further compete with the Exchange. For example, there have been 4 exchanges that have been added in the U.S. options markets in the last 5 years

(i.e., Cboe EDGX Inc., Nasdaq MRX, LLC, MIAX Pearl, LLC and MIAX Emerald LLC).

There is also no regulatory requirement that any market participant connect to any one options exchange, that any market participant connect at a particular connection speed or act in a particular capacity on the Exchange, or trade any particular product offered on an exchange. Moreover, membership is not a requirement to participate on the Exchange. A market participant may submit orders to the Exchange via a TPH broker.⁶⁸ Indeed, the Exchange is unaware of any one options exchange whose membership includes every registered broker-dealer. In fact, the Exchange believes that as of June 2020, only 9 broker-dealers out of approximately 250 broker-dealers that are members of at least one exchange that lists options for trading were members of all 16 options exchanges.⁶⁹ Additionally, several broker-dealers are members of only a single exchange that lists options for trading.⁷⁰ The Exchange has also identified numerous broker-dealers that are members of other options exchanges, but not the Exchange. For example, the Exchange has identified approximately 20 broker-dealers that are members of Nasdaq ISE, LLC (an exchange that lists only options), but not Cboe Exchange, Inc (which also lists only options). Similarly, the Exchange has identified at least 4 broker-dealers that trade options and are members of one or more of the Exchange's affiliated options exchanges, but not Cboe Exchange, Inc. Indeed, the number of members at each exchange that trades options varies greatly. Particularly, the number of members of exchanges that trade options vary between approximately 9 and 171 broker-dealers.⁷¹ Even the number of

⁶⁸ Such market participant would be subject to the fees of that broker. The Exchange notes that such broker is not required to publicize, let alone justify or file with the Commission its fees, and as such could charge the market participant any fees it deems appropriate, even if such fees would otherwise be considered potentially unreasonable or uncompetitive fees.

⁶⁹ See SEC June 2020 Active Broker Dealer Report.

⁷⁰ *Id.* Approximately 10 broker-dealers are members of the Cboe Exchange, Inc. only, approximately 7 broker-dealers are members of only Nasdaq PHLX LLC, approximately 3 broker-dealers are members of only NYSE Arca, Inc., and approximately 3 broker-dealers are members of only NYSE American LLC.

⁷¹ See SEC June 2020 Active Broker Dealer Report. More specifically, 1 exchange has 9 members, 4 exchanges have between 36–50 members, 5 exchanges have between 50–100 members, 4 exchanges have between 100–150 members and 2 exchanges have more than 150 members. The Exchange notes however that some of these exchanges also trade equities and the

⁶¹ Floor Broker Trading Surcharges for SPX/SPXW and VIX are also not changing. The Exchange however, is creating a new table for Floor Broker Trading Surcharges and relocating such fees in the Fees Schedule in connection with the proposal to eliminate fees currently set forth in the "Trading Permit and Tier Appointment Fees" Table.

⁶² 15 U.S.C. 78f(b).

⁶³ 15 U.S.C. 78f(b)(5).

⁶⁴ 15 U.S.C. 78f(b)(4).

⁶⁵ 15 U.S.C. 78f(b)(5).

⁶⁶ See e.g., Affiliated Exchange Fee Schedules. See also e.g., BOX Options Fees Schedule, Section VI (Technology Fees) and Section IX (Participant Fees).

⁶⁷ See Cboe Global Markets U.S. Options Market Volume Summary (June 26, 2020), available at https://markets.cboe.com/us/options/market_statistics/.

members between the Exchange and its 3 other options exchange affiliates vary. Particularly, while the Exchange currently has 94 members, Cboe EDGX and Cboe C2 have 53 members that trade options and Cboe BZX has 63 members that trade options.

The rule structure for options exchanges are also fundamentally different from those of equities exchanges. In particular, options market participants are not forced to connect to (and purchase market data from) all options exchanges. For example, there are many order types that are available in the equities markets that are not utilized in the options markets, which relate to mid-point pricing and pegged pricing which require connection to the SIPs and each of the equities exchanges in order to properly execute those orders in compliance with best execution obligations. Additionally, in the options markets, the linkage routing and trade through protection are handled by the exchanges, not by the individual members. Thus not connecting to an options exchange or disconnecting from an options exchange does not potentially subject a broker-dealer to violate order protection requirements.⁷² Gone are the days when the retail brokerage firms (such as Fidelity, Schwab, and eTrade) were members of the options exchanges—they are not members of the Exchange or its affiliates, they do not purchase connectivity to the Exchange, and they do not purchase market data from the Exchange.

The Exchange is also not aware of any reason why any particular market participant could not simply drop its connections and cease being a TPH of the Exchange if the Exchange were to establish “unreasonable” and uncompetitive price increases for its connectivity alternatives. As further evidence of the fact that market participants can and do disconnect from exchanges based on connectivity pricing, R2G Services LLC (“R2G”) filed a comment letter after BOX Exchange LLC (“BOX”) proposed rule changes to increase its connectivity fees (SR-BOX-2018-24, SRBOX-2018-37, and SR-BOX-2019-04).⁷³ The R2G Letter stated,

Exchange is therefore unable to determine how many members at each exchange trade options.

⁷² The Exchange notes this discussion is consistent with the Fee Guidance suggestion that any discussion of alternatives should “include a discussion of how regulatory requirements, particularly best execution obligations, Regulation NMS Rule 611 (the Order Protection Rule), and/or the Options Order Protection and Locked/Crossed Market Plan (Options Linkage Plan), as applicable, affect the competitive analysis.”

⁷³ See Letter from Stefano Durdic, R2G, to Vanessa Countryman, Acting Secretary,

“[w]hen BOX instituted a \$10,000/month price increase for connectivity; we had no choice but to terminate connectivity into them as well as terminate our market data relationship. The cost benefit analysis just didn’t make any sense for us at those new levels.” Accordingly, this example shows that if an exchange sets too high of a fee for connectivity and/or market data services for its relevant marketplace, market participants can choose to disconnect from the Exchange. Moreover, the Exchange does not assess any termination fee for a market participant to drop its connectivity or membership, nor is the Exchange aware of any other costs that would be incurred by a market participant to do so. The Exchange notes that in fact, a number of firms currently do not participate on the Exchange or participate on the Exchange through sponsored access arrangements with other broker-dealers rather than by becoming a member. Additionally, as noted above, only 9 broker-dealers are members of all 16 options exchanges, which the Exchange believes demonstrates that, in addition to the absence of a rule requirement to connect to every option exchange, there is no prevailing business model that would practically require a broker-dealer to connect to every single options exchange.⁷⁴

Additionally, the Exchange notes that non-TPHs such as Service Bureaus and Extranets resell Cboe Options connectivity.⁷⁵ This indirect connectivity is another viable alternative for market participants to trade on the Exchange without connecting directly to the Exchange (and thus not pay the Exchange’s connectivity fees), which alternative is already being used by non-TPHs and further constrains the price that the Exchange is able to charge for

Commission, dated March 27, 2019 (the “R2G Letter”).

⁷⁴ The Exchange further notes that these 9 broker-dealers represent different market participants. Particularly, 5 of these broker-dealers are bulge bracket banks (of which 1 is also a market-maker), 2 are brokerage firms and 2 are clearing firms.

⁷⁵ Prior to migration, there were 13 firms that resold Cboe Options connectivity. Post-migration, the Exchange anticipated that there would be 19 firms that resell Cboe Options connectivity (both physical and logical) and as of January 2020 there are 15 firms that resell Cboe Options connectivity. The Exchange does not have specific knowledge as to what latency a market participant may experience using an indirect connection versus a direct connection and notes it may vary by the service provided by the extranet provider and vary between extranet providers. The Exchange believes however, that there are extranet providers able to provide connections with a latency that is comparable to latency experienced using a direct connection.

connectivity to its Exchange. The Exchange does not receive any connectivity revenue when connectivity is resold by a third-party, which often is resold to multiple customers, some of whom are agency broker-dealers that have numerous customers of their own.⁷⁶ Accordingly, in the event that a market participant views one exchange’s direct connectivity and access fees as more or less attractive than the competition, they can choose to connect to that exchange indirectly or may choose not to connect to that exchange and connect instead to one or more of the other 15 options markets. For example, two TPHs that connected directly to the Exchange pre-migration, now connect indirectly via an extranet provider. The Exchange notes that it has not received any comments that, and has no evidence to suggest, the two TPHs that transitioned from direct connections to an indirect connections post-migration were the result of an undue financial burden resulting from the proposed fee changes.⁷⁷ Rather, the Exchange believes the transitions demonstrate that indirect connectivity is in fact a viable option for market participants, therefore reflecting a competitive environment.⁷⁸ It further demonstrates the manner in which market participants connect to the Exchange is entirely within the discretion of market participants, who can consider the fees charged by the Exchange and by resellers when making decisions.

Additionally, pre-migration, in August 2019, the Exchange had 97 members (TPH organizations), of which nearly half connected indirectly to the Exchange.⁷⁹ Similarly, in December 2019, after a new broker-dealer became a member of the Exchange in late

⁷⁶ The Exchange notes that resellers are not required to publicize, let alone justify or file with the Commission their fees, and as such could charge the market participant any fees it deems appropriate (including connectivity fees higher than the Exchange’s connectivity fees), even if such fees would otherwise be considered potentially unreasonable or uncompetitive fees.

⁷⁷ The Exchange notes that TPHs are not required to specify to the Exchange why it opts to no longer be a TPH, or why it cancels its ports, nor is a non-TPH market participating required to specify to the Exchange why it opts to not be a TPH and directly connect to the Exchange.

⁷⁸ As shown above, the availability of 15 alternative options exchanges in addition to the viable option of indirect connectivity demonstrates that substitute connectivity products and services do exist supporting the assertion the proposed fees are constrained by competitive forces.

⁷⁹ The Exchange notes that one firm terminated in late September 2019, but that it believes it was unrelated to the migration and the proposed fee changes.

November 2019,⁸⁰ the Exchange had 97 members, of which nearly half of the participants connected indirectly to the Exchange. More specifically, in December 2019, 47 TPHs connected directly to the Exchange and accounted for approximately 66% of the Exchange's volume, 46 TPHs connected indirectly to the Exchange and accounted for approximately 29% of the Exchange's volume and 4 TPHs utilized both direct and indirect connections and accounted for approximately 5% of the Exchange's volume. In December 2019, TPHs that connected directly to the Exchange purchased a collective 179 physical ports (including legacy physical ports), 144 of which were 10 Gb ports and 35 of which were 1 Gb ports.⁸¹ The Exchange notes that of those market participants that do connect to the Exchange, it is the individual needs of each market participant that determine the amount and type of Trading Permits and physical and logical connections to the Exchange.⁸² With respect to physical connectivity, many TPHs were able to purchase small quantities of physical ports. For example, approximately 36% of TPHs that connected directly to the Exchange purchased only one to two 1 Gb ports, approximately 40% purchased only one to two 10 Gb ports, and approximately 40% had purchased a combined total of one to two ports (for both 1 Gb and 10 Gb). Further, no TPHs that connected directly to the Exchange had more than five 1 Gb ports, and only 8.5% of TPHs that connected directly to the Exchange had between six and ten 10 GB ports and only 8.5% had between ten and fourteen 10 Gb ports. There were also a combined total of 41 ports used for indirect connectivity (twenty-one 1 Gb ports and twenty 10 Gb ports).⁸³ The Exchange notes that all types of members connected indirectly to the Exchange including Clearing firms, Floor Brokers, order flow providers, and on-floor and off-floor Market-Makers, further reflecting the

⁸⁰ In February 2020, such member also became a member of the Exchange's affiliated options exchanges, which have similar physical and logical connectivity fees to the proposed fees in this filing.

⁸¹ Of the 4 TPHs that connected both directly and indirectly to the Exchange, 1 TPH had two 1 Gb Ports and the remaining 3 TPHs had a combined total of six 10 Gb ports.

⁸² To assist market participants that are connected or considering connecting to the Exchange, the Exchange provides detailed information and specifications about its available connectivity alternatives in the Cboe C1 Options Exchange Connectivity Manual, as well as the various technical specifications. See <http://markets.cboe.com/us/options/support/technical/>.

⁸³ The Exchange notes that it does not know how many, and which kind of, connections each TPH that indirectly connects to the Exchange has.

fact that each type of market participant has the option to participate on an exchange without direct connectivity. Indeed, market participants choose if and how to connect to a particular exchange and because it is a choice, the Exchange must set reasonable connectivity pricing, otherwise prospective members would not connect and existing members would disconnect or connect through a third-party reseller of connectivity.

Moreover, the Exchange notes that the Commission itself has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Particularly, 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."⁸⁴ The number of available exchanges to connect to ensures increased competition in the marketplace, and constrains the ability of exchanges to charge supracompetitive fees for access to its market. The Exchange is also not aware of any evidence that has been offered or demonstrated that a market share of approximately 17% provides the Exchange with anti-competitive pricing power. Additionally, the Exchange notes that its affiliated options exchanges have substantially similar physical and logical connectivity fees, notwithstanding a much lower market share ranging from approximately 2.5%–9%.⁸⁵ As discussed, if an exchange sets too high of a fee for connectivity and/or market data services for its relevant marketplace, market participants can choose to disconnect from the Exchange.

The Exchange also believes that competition in the marketplace constrains the ability of exchanges to charge supracompetitive fees for access to its market, even if such market, like the Exchange, offers proprietary products exclusive to that market. Notably, just as there is no regulatory requirement to become a member of any one options exchange, there is also no regulatory requirement for any market participant to trade any particular product, nor is there any requirement

⁸⁴ See Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) ("Regulation NMS Adopting Release").

⁸⁵ See Cboe Global Markets U.S. Options Market Volume Summary (June 26, 2020), available at https://markets.cboe.com/us/options/market_statistics/.

that any Exchange create or indefinitely maintain any particular product.⁸⁶ The Exchange also highlights that market participants may trade an Exchange's proprietary products through a third-party without directly or indirectly connecting to the Exchange. Additionally, market participants may trade any options product, including proprietary products, in the unregulated Over-the-Counter (OTC) markets for which there is no requirement for fees related to those markets to be public. Given the benefits offered by trading options on a listed exchange, such as increased market transparency and heightened contra-party creditworthiness due to the role of the Options Clearing Corporation as issuer and guarantor, the Exchange generally seeks to incentivize market participants to trade options on an exchange, which further constrains connectivity pricing. Market participants may also access other exchanges to trade other similar or competing proprietary or multi-listed products. Alternative products to the Exchange's proprietary products may include other options products, including options on ETFs or options futures, as well as particular ETFs or futures. For example, exclusively listed SPX options may compete with the following products traded on other markets: Multiply-listed SPY options (options on the ETF), E-mini S&P 500 Options (options on futures), and E-Mini S&P 500 futures (futures on index). Additionally, exclusively listed VIX options may compete with the following products traded on other markets: Multiply-listed VXX options (options on the ETF) and exclusively listed SPIKES options on the Miami International Securities Exchange, LLC ("MIAX").⁸⁷ Other options exchanges are also not precluded from creating new proprietary products that may achieve similar objectives to (and therefore

⁸⁶ If an option class is open for trading on another national securities exchange, the Exchange may delist such option class immediately. For proprietary products, the Exchange may determine to not open for trading any additional series in that option class; may restrict series with open interest to closing transactions, provided that, opening transactions by Market-Makers executed to accommodate closing transactions of other market participants and opening transactions by TPH organizations to facilitate the closing transactions of public customers executed as crosses pursuant to and in accordance with Rule 6.74(b) or (d) may be permitted; and may delist the option class when all series within that class have expired. See Cboe Rule 4.4, Interpretations and Policies .11.

⁸⁷ MIAX has described SPIKES options as "designed specifically to compete head-to-head against Cboe's proprietary VIX® product." See MIAX Press Release, *SPIKES Options Launched on MIAX*, February 21, 2019, available at https://www.miaxoptions.com/sites/default/files/press_release-files/MIAX_Press_Release_02212019.pdf.

compete with) the Exchange's existing proprietary products. For example, Nasdaq PHLX exclusively lists options on the Nasdaq-100, which options, like index options listed on the Exchange, offer investors an alternative method to manage and hedge portfolio exposure to the U.S. equity markets. Indeed, even though exclusively listed proprietary products may not be offered by competitors, a competitor could create similar products if demand were adequate. As noted above for example, MIAX created its exclusive product SPIKES specifically to compete against VIX options.⁸⁸ In connection with a recently proposed amendment to the National Market System Plan Governing the Consolidated Audit Trail ("CAT NMS Plan"),⁸⁹ the Commission discussed the existence of competition in the marketplace generally, and particularly for exchanges with unique business models. Specifically, the Commission contemplated the possibility of a forced exit by an exchange as a result of a proposed amendment that could reduce the amount of CAT funding a participant could recover if certain implementation milestones were missed. The Commission acknowledged that, even if an exchange were to exit the marketplace due to its proposed fee-related change, it would not significantly impact competition in the market for exchange trading services because these markets are served by multiple competitors.⁹⁰ The Commission explicitly stated that "[c]onsequently, demand for these services in the event of the exit of a competitor is likely to be swiftly met by existing competitors."⁹¹ The Commission further recognized that while some exchanges may have a unique business model that is not currently offered by competitors, a competitor could create similar business models if demand were adequate, and if they did not do so, the Commission believes it would be likely that new entrants would do so if the exchange with that unique business model was otherwise profitable.⁹² Similarly, although the Exchange may have proprietary products not offered by other competitors, not unlike unique business models, a competitor could create similar products to an existing proprietary product if demand were

adequate. As noted above, other exchanges, that have comparable connectivity fees, also currently offer exclusively listed products.⁹³ As such, the Exchange is still very much subject to competition and does not possess anti-competitive pricing power, even with its offering of proprietary products. Rather, the Exchange must still set reasonable connectivity pricing, otherwise prospective members would not connect, and existing members would disconnect or connect through a third-party reseller of connectivity, regardless of what products its offers.

For all the reasons discussed above, the Exchange believes its proposed fees are reasonable and that the Exchange was subject to significant competitive forces in setting its proposed fees. In addition, the Exchange believes its proposed fees are reasonable in light of the numerous benefits the new connectivity infrastructure provides market participants. As described, the post-migration connectivity architecture provides for a latency equalized infrastructure, improved system performance, and increased sustained order and quote per second capacity. As such, even where a fee for a particular type or kind of connectivity may be higher than it was to its pre-migration equivalent, such increase is reasonable given the increased benefits market participants are getting for a similar or modestly higher price. Moreover, as noted above, the objective of the proposed fee changes was not to generate an overall increase in access fee revenue, but rather adopt fees in connection with a new (and improved) connectivity infrastructure. Indeed, the Exchange tried to the best of its ability to approximate the overall connectivity revenue generated by the Exchange's pre-migration fees. Notably, the Exchange's pre-migration access fees were previously filed with the Commission and not suspended nor

disapproved.⁹⁴ The Exchange further believes that the reasonableness of its proposed connectivity fees is demonstrated by the very fact that such fees are in line with, and in some cases lower than, the costs of connectivity at other Exchanges,⁹⁵ including its own affiliated exchanges which have the same connectivity infrastructure as the Exchange currently does since migration.⁹⁶ The Exchange notes these fees were similarly filed with the Commission and not suspended nor disapproved.⁹⁷

⁹⁴ Although the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (the "Dodd-Frank Act") amended 19(b) of the Exchange Act to provide that SROs' fee changes become immediately effective on filing, the legislative history makes clear that while Congress intended to streamline SROs' rule filing procedures, the proposed change did not "[diminish] the SEC's authority to reject an improperly filed rule, disapprove a rule that is not consistent with the Exchange Act or [diminish] the applicable public notice and comment period." See S. Rep 111-176, at 106 (2010). The Commission therefore had every right to pursue a suspension and disapproval order of prior rule filings that adopted or amended connectivity fees that were in place prior to the migration if it had believed any proposed fees in those rule filings were not consistent with the Exchange Act. Additionally, the Commission did not request additional data or discussion in connection with prior rule filings regarding connectivity fees, as it has with respect to the proposed fees in this filing (and its previous versions). In the absence of such an order, the Exchange presumes that its pre-migration fees were reasonable and consistent with the Exchange Act.

⁹⁵ See e.g., Nasdaq PHLX and ISE Rules, General Equity and Options Rules, General 8. Phlx and ISE each charge a monthly fee of \$2,500 for each 1Gb connection, \$10,000 for each 10Gb connection and \$15,000 for each 10Gb Ultra connection. See also Nasdaq Price List—Trading Connectivity. Nasdaq charges a monthly fee of \$7,500 for each 10Gb direct connection to Nasdaq and \$2,500 for each direct connection that supports up to 1Gb. See also NYSE American Fee Schedule, Section V.B, and Arca Fees and Charges, Co-Location Fees. NYSE American and Arca each charge a monthly fee of \$5,000 for each 1Gb circuit, \$14,000 for each 10Gb circuit and \$22,000 for each 10Gb LX circuit.

⁹⁶ See e.g., Affiliated Exchange Fee Schedules, Physical Connectivity Fees. For example, Cboe BZX, Cboe EDGX and C2 each charge a monthly fee of \$2,500 for each 1Gb connection and \$7,500 for each 10Gb connection.

⁹⁷ For the same reason noted above, the Exchange presumes that the fees of other exchanges, including its affiliates, are reasonable, as required by the Exchange Act in the absence of any suspension or disapproval order by the Commission providing otherwise. The Exchange highlights the Exchange's affiliate C2 similarly underwent a migration of its trading platform to the same trading platform to which the Exchange migrated, overhauling its connectivity structure and adopting similar connectivity fees under similar circumstances as those proposed herein. See Securities Exchange Act Release No. 83201 (May 9, 2018), 83 FR 22546 (May 15, 2018) (SR-C2-2018-006). While the Commission had the opportunity to suspend that proposed rule change and institute proceedings to determine whether that proposed rule change should be approved or disapproved if the Commission believed C2 failed to meet its burden to demonstrate its proposal was reasonable,

Continued

⁸⁸ *Id.*

⁸⁹ See Securities Exchange Act Release No. 86901 (September 9, 2019), 84 FR 48458 (September 13, 2019) (File No. S7-13-19).

⁹⁰ *Id.*

⁹¹ *Id.*

⁹² *Id.*

⁹³ See e.g., Nasdaq PHLX LLC Rules, (Options 7 Pricing Schedule), Section 8A (Permit and Registration Fees) which provide for floor permit fees between \$4,000 to \$6,000 per permit and Section 9B (Port Fees), which provides various port fees ranging from \$500 to \$1,250 per port. See also Nasdaq PHLX LLC Rules, General 8 Connectivity, which provides for monthly physical connectivity fees including fees for 1 Gb physical connections priced at \$2,500 per port and for 10 Gb physical connections starting at \$10,000 per port and see MIAX Options Fees Schedule, Section 3b (Membership Fees, Monthly Trading Permit Fee), which provides for trading permit fees ranging from \$1,500 to \$22,000 per permit (which may include market-maker appointment costs) and Section 5 (System Connectivity Fees) which provides for monthly physical connectivity fees including fees for 1 Gb physical connections priced at \$1,400 per port and for 10 Gb physical connections priced at \$6,100 per port.

Furthermore, in determining the proposed fee changes discussed above, the Exchange reviewed the current competitive landscape, considered the fees historically paid by market participants for connectivity to the pre-migration system, and also assessed the impact on market participants to ensure that the proposed fees would not create an undue financial burden on any market participants, including smaller market participants. Indeed, the Exchange received no comments from any TPH suggesting they were unduly burdened by the proposed changes described herein, which were first announced via Exchange Notice nearly two months in advance of the migration (*i.e.*, now nine months ago), nor were any timely comment letters received by the Commission by the comment period submission deadline of November 12, 2019.⁹⁸ The Exchange also underscores the fact that no comment letters were received in response to its Second, Third or Fifth Proposed Rule Change, and that no individual market participant has provided any written comments specifically suggesting that the Exchange has failed to provide sufficient information in the Original Second, Third, Fourth or Fifth Proposed Rule Change to meet its burden to demonstrate its proposed fees are consistent with the requirements of the Exchange Act.

The Exchange also highlights that two market participants have in fact expanded their connectivity footprint since the implementation of the proposed fee changes. One of those market participants was a TPH that had discussed terminating its membership from the Exchange altogether prior to migration. However, after that TPH reviewed the notice the Exchange issued describing the proposed post-migration fees, the TPH relayed to the Exchange that it would instead remain a member and add logical connectivity in light of the cost savings it expected to realize due to the proposed changes. The Exchange believes this further demonstrates competition within the market for exchange connectivity, which as a result constrains fees the Exchange may charge for that connectivity. Another TPH, that prior to migration acted only as a proprietary

equitable and not unfairly discriminatory, it declined to do so. Additionally, the Exchange notes the Commission did not repeatedly request data regarding the proposed C2 connectivity fees as it has in connection with the Exchange's proposed migration fees.

⁹⁸ See Exchange Notice "Cboe Options Exchange Access and Capacity Fee Schedule Changes Effective October 1, 2019 and November 1, 2019" Reference ID C2019081900.

trading firm, added the trading function as a Market-Maker on the Exchange (which required the purchase of additional trading permits and connectivity). The Exchange also notes that since migration, one TPH terminated its membership with the Exchange but retained its membership with 10 other SROs.⁹⁹ The Exchange believes the fact that it lost only one TPH in the past nine months demonstrates the proposed fees are appropriate and reasonable and not unduly burdensome. While the TPH that did terminate did not specify to the Exchange why it ended its membership, if it had in fact determined that the Exchange's proposed connectivity fees did not make business sense for itself, for all the reasons discussed above, it was free to leave the Exchange at no cost and retain its membership with other SROs and/or pursue new memberships.

The proposed connectivity structure and corresponding fees, like the pre-migration connectivity structure and fees, continue to provide market participants flexibility with respect to how to connect to the Exchange based on each market participants' respective business needs. For example, the amount and type of physical and logical ports are determined by factors relevant and specific to each market participant, including its business model, costs of connectivity, how its business is segmented and allocated and volume of messages sent to the Exchange. Moreover, the Exchange notes that it does not have unlimited system capacity to support an unlimited number of order and quote entry per second. Accordingly, the proposed connectivity fees, and connectivity structure are designed to encourage market participants to be efficient with their respective physical and logical port usage. While the Exchange has no way of predicting with certainty the amount or type of connections market participants will in fact purchase, if any, the Exchange anticipates that like today, some market participants will continue to decline to connect and participate on the Exchange, some will participate on the Exchange via indirect connectivity, some will only purchase one physical connection and/or logical port connection, and others will purchase multiple connections.

In sum, the Exchange believes the proposed fees are reasonable and reflect a competitive environment, as the

⁹⁹ Two other Trading Permit Holders also terminated their respective memberships in the first quarter of 2020. The Exchange notes, however, that one TPH consolidated its membership with an affiliate and another TPH no longer appears to be a registered broker-dealer.

Exchange seeks to amend its access fees in connection with the migration of its technology platform, while still attracting market participants to continue to be, or become, connected to the Exchange.

Physical Ports

The Exchange believes increasing the fee for the new 10 Gb Physical Port is reasonable because unlike, the current 10 Gb Network Access Ports, the new Physical Ports provides a connection through a latency equalized infrastructure with faster switches and also allows access to both unicast order entry and multicast market data with a single physical connection. As discussed above, legacy Network Access Ports do not permit market participants to receive unicast and multicast connectivity. As such, in order to receive both connectivity types pre-migration, a market participant needed to purchase and maintain at least two 10 Gb Network Access Ports. The proposed Physical Ports not only provide latency equalization (*i.e.*, eliminate latency advantages between market participants based on location) as compared to the legacy ports, but also alleviate the need to pay for two physical ports as a result of needing unicast and multicast connectivity. Accordingly, market participants who historically had to purchase two separate ports for each of multicast and unicast activity, will be able to purchase only one port, and consequently pay lower fees overall. For example, pre-migration if a TPH had two 10 Gb legacy Network Access Ports, one of which received unicast traffic and the other of which received multicast traffic, that TPH would have been assessed \$10,000 per month (\$5,000 per port). Under the proposed rule change, using the new Physical Ports, that TPH has the option of utilizing one single port, instead of two ports, to receive both unicast and multicast traffic, therefore paying only \$7,000 per month for a port that provides both connectivity types. The Exchange notes that pre-migration, approximately 50% of TPHs maintained two or more 10 Gb Network Access Ports. While the Exchange has no way of predicting with certainty the amount or type of connections market participants will in fact purchase post-migration, the Exchange anticipated approximately 50% of the TPHs with two or more 10 Gb Network Access Ports to reduce the number of 10 Gb Physical Ports that they purchase and expected the remaining 50% of TPHs to maintain their current 10 Gb Physical Ports, but reduce the number of 1 Gb Physical Ports. Particularly, pre-

migration, a number of TPHs maintained two 10 Gb Network Access Ports to receive multicast data and two 1 Gb Network Access Ports for order entry (unicast connectivity). As the new 10 Gb Physical Ports are able to accommodate unicast connectivity (order entry), TPHs may choose to eliminate their 1 Gb Network Access Ports and utilize the new 10 Gb Physical Ports for both multicast and unicast connectivity. The Exchange notes that in February 2020, approximately 78% of TPHs that maintained a 1 Gb Network Access Port pre-migration, no longer maintained a 1 Gb Physical Port. Additionally, as of February 2020, approximately 44% reduced the quantity of 10 Gb Physical Ports they maintained as compared to pre-migration.

As discussed above, if a TPH deems a particular exchange as charging excessive fees for connectivity, such market participants may opt to terminate their connectivity arrangements with that exchange, and adopt a possible range of alternative strategies, including routing to the applicable exchange through another participant or market center or taking that exchange's data indirectly. Accordingly, if the Exchange charges excessive fees, it would stand to lose not only connectivity revenues but also revenues associated with the execution of orders routed to it, and, to the extent applicable, market data revenues. The Exchange believes that this competitive dynamic imposes powerful restraints on the ability of any exchange to charge unreasonable fees for physical connectivity. The Exchange also notes that the proposal represents an equitable allocation of reasonable dues, fees and other charges as its fees for physical connectivity are reasonably constrained by competitive alternatives, as discussed above. The proposed amounts are in line with, and in some cases lower than, the costs of physical connectivity at other Exchanges,¹⁰⁰ including the Cboe Affiliated Exchanges, which have the same connectivity infrastructure the Exchange has migrated to and some of which also

¹⁰⁰ See e.g., Nasdaq PHLX and ISE Rules, General Equity and Options Rules, General 8. Phlx and ISE each charge a monthly fee of \$2,500 for each 1Gb connection, \$10,000 for each 10Gb connection and \$15,000 for each 10Gb Ultra connection. See also Nasdaq Price List—Trading Connectivity. Nasdaq charges a monthly fee of \$7,500 for each 10Gb direct connection to Nasdaq and \$2,500 for each direct connection that supports up to 1Gb. See also NYSE American Fee Schedule, Section V.B, and Arca Fees and Charges, Co-Location Fees. NYSE American and Arca each charge a monthly fee of \$5,000 for each 1Gb circuit, \$14,000 for each 10Gb circuit and \$22,000 for each 10Gb LX circuit.

offer exclusive products.¹⁰¹ The Exchange does not believe it is unreasonable to assess fees that are in line with fees that have already been established for the same physical ports used to connect to the same connectivity infrastructure and common platform. The Exchange believes the proposed Physical Port fees are equitable and not unreasonably discriminatory as the connectivity pricing is associated with relative usage of the various market participants (including smaller participants) and the Exchange has not been presented with any evidence to suggest its proposed fee changes would impose a barrier to entry for participants, including smaller participants. In fact, as noted above, the Exchange is unaware of any market participant that has terminated direct connectivity solely as a result of the proposed fee changes. The Exchange also believes increasing the fee for 10 Gb Physical Ports and charging a higher fee as compared to the 1 Gb Physical Port is equitable as the 1 Gb Physical Port is 1/10th the size of the 10 Gb Physical Port and therefore does not offer access to many of the products and services offered by the Exchange (e.g., ability to receive certain market data products). Thus the value of the 1 Gb alternative is lower than the value of the 10 Gb alternative, when measured based on the type of Exchange access it offers. Moreover, market participants that purchase 10 Gb Physical Ports utilize the most bandwidth and therefore consume the most resources from the network. As such, the Exchange believes the proposed fees for the 1 and 10 Gb Physical Ports, respectively are reasonable and appropriately allocated.

Data Port Fees

The Exchange believes assessing the data port fee per data source, instead of per port, is reasonable because it may allow for market participants to maintain more ports at a lower cost and applies uniformly to all market participants. The Exchange believes the proposed increase is reasonable because, as noted above, market participants may pay lower fees as a result of charging per data source and not per data port. Indeed, while the Exchange has no way of predicting with certainty the impact of the proposed changes, the Exchange had anticipated approximately 76% of the 51 market participants who pay data port fees to pay the same or lower fees upon

¹⁰¹ See e.g., Affiliated Exchange Fee Schedules, Physical Connectivity Fees. For example, Cboe BZX, Cboe EDGX and C2 each charge a monthly fee of \$2,500 for each 1Gb connection and \$7,500 for each 10Gb connection.

implementation of the proposed change. As of December 2019, 46 market participants¹⁰² pay the proposed data port fees, of which approximately 78% market participants are paying the same or lower fees in connection with the proposed change. Monthly savings for firms paying lower fees range from \$500 to \$6,000 per month. The Exchange also anticipated that 19% of TPHs who pay data port fees would pay a modest increase of only \$500 per month. In December 2019, approximately 22% market participants paid higher fees, with the majority of those market participants paying a modest monthly increase of \$500 and only 3 firms paying either \$1,000 or \$1,500 more per month. Additionally, as discussed above, the Exchange's affiliate C2 has the same fee which is also assessed at the proposed rate and assessed by data source instead of per port. The proposed name change is also appropriate in light of the Exchange's proposed changes and may alleviate potential confusion.

Logical Connectivity

Port Fees

The Exchange believes it's reasonable to eliminate certain fees associated with legacy options for connecting to the Exchange and to replace them with fees associated with new options for connecting to the Exchange that are similar to those offered at its Affiliated Exchanges. In particular, the Exchange believes it's reasonable to no longer assess fees for CMI and FIX Login IDs because the Login IDs were retired and rendered obsolete upon migration and because the Exchange is proposing to replace them with fees associated with the new logical connectivity options. The Exchange believes that it is reasonable to harmonize the Exchange's logical connectivity options and corresponding connectivity fees now that the Exchange is on a common platform as its Affiliated Exchanges. Additionally, the Exchange notes the proposed fees are the same as, or in line with, the fees assessed on its Affiliated Exchanges for similar connectivity.¹⁰³ The proposed logical connectivity fees are also equitable and not unfairly discriminatory because the Exchange will apply the same fees to all market participants that use the same respective connectivity options.

The Exchange believes the proposed Logical Port fees are reasonable as it is the same fee for Drop Ports and the first

¹⁰² The Exchange notes the reduction in market participants that pay the data port fee is due to firm consolidations and acquisitions.

¹⁰³ See Affiliated Exchange Fee Schedules, Logical Port Fees.

five BOE/FIX Ports that is assessed for CMI and FIX Logins, which the Exchange is eliminating in lieu of logical ports. Additionally, while the proposed ports will be assessed the same monthly fees as current CMI/FIX Login IDs, the proposed logical ports provide for significantly more message traffic. Specifically, the proposed BOE/FIX Logical Ports will provide for 3 times the amount of quoting¹⁰⁴ capacity and approximately 165 times order entry capacity. Similarly, the Exchange believes the proposed BOE Bulk Port fees are reasonable because while the fees are higher than the CMI and FIX Login Id fees and the proposed Logical Port fees, BOE Bulk Ports offer significantly more bandwidth capacity than both CMI and FIX Login IDs and Logical Ports. Particularly, a single BOE Bulk Port offers 45 times the amount of quoting bandwidth than CMI/FIX Login IDs¹⁰⁵ and 5 times the amount of quoting bandwidth than Logical Ports will offer. Additionally, the Exchange believes that its fees for logical connectivity are reasonable, equitable, and not unfairly discriminatory as they are designed to ensure that firms that use the most capacity pay for that capacity, rather than placing that burden on market participants that have more modest needs. Although the Exchange charges a “per port” fee for logical connectivity, it notes that this fee is in effect a capacity fee as each FIX, BOE or BOE Bulk port used for order/quote entry supports a specified capacity (*i.e.*, messages per second) in the matching engine, and firms purchase additional logical ports when they require more capacity due to their business needs.

An obvious driver for a market participant’s decision to purchase multiple ports will be their desire to send or receive additional levels of message traffic in some manner, either by increasing their total amount of message capacity available, or by segregating order flow for different trading desks and clients to avoid latency sensitive applications from competing for a single thread of resources. For example, a TPH may purchase one or more ports for its market making business based on the amount of message traffic needed to support that business, and then purchase separate ports for proprietary trading or customer facing businesses so that those businesses have their own distinct connection, allowing the firm to

send multiple messages into the Exchange’s trading system in parallel rather than sequentially. Some TPHs that provide direct market access to their customers may also choose to purchase separate ports for different clients as a service for latency sensitive customers that desire the lowest possible latency to improve trading performance. Thus, while a smaller TPH that demands more limited message traffic may connect through a service bureau or other service provider, or may choose to purchase one or two logical ports that are billed at a rate of \$750 per month each, a larger market participant with a substantial and diversified U.S. options business may opt to purchase additional ports to support both the volume and types of activity that they conduct on the Exchange. While the Exchange has no way of predicting with certainty the amount or type of logical ports market participants will in fact purchase post-migration, the Exchange anticipated approximately 16% of TPHs to purchase one to two logical ports, and approximately 22% of TPHs to not purchase any logical ports. In December 2019, 13% of TPHs purchased one to two logical ports and 27% have not purchased any logical ports. At the same time, market participants that desire more total capacity due to their business needs, or that wish to segregate order flow by purchasing separate capacity allocations to reduce latency or for other operational reasons, would be permitted to choose to purchase such additional capacity at the same marginal cost. The Exchange believes the proposal to assess an additional Logical and BOE Bulk port fee for incremental usage per logical port is reasonable because the proposed fees are modestly higher than the proposed Logical Port and BOE Bulk fees and encourage users to mitigate message traffic as necessary. The Exchange notes one of its Affiliated Exchanges has similar implied port fees.¹⁰⁶

In sum, the Exchange believes that the proposed BOE/FIX Logical Port and BOE Bulk Port fees are appropriate as these fees would ensure that market participants continue to pay for the amount of capacity that they request, and the market participants that pay the most are the ones that demand the most resources from the Exchange. The Exchange also believes that its logical connectivity fees are aligned with the goals of the Commission in facilitating a competitive market for all firms that trade on the Exchange and of ensuring that critical market infrastructure has

“levels of capacity, integrity, resiliency, availability, and security adequate to maintain their operational capability and promote the maintenance of fair and orderly markets.”¹⁰⁷

The Exchange believes waiving the FIX/BOE Logical Port fee for one FIX Logical Port used to access PULSe and Silexx (for FLEX Trading) is reasonable because it will allow all TPHs using PULSe and Silexx to avoid having to pay a fee that they would otherwise have to pay. The waiver is equitable and not unfairly discriminatory because TPHs using PULSe are already subject to a monthly fee for the PULSe Workstation, which the Exchange views as inclusive of fees to access the Exchange. Moreover, while PULSe users today do not require a FIX/CMI Login Id, post-migration, due to changes to the connectivity infrastructure, PULSe users will be required to maintain a FIX Logical Port and as such incur a fee they previously would not have been subject to. Similarly, the Exchange believes that the waiver for Silexx (for FLEX trading) will encourage TPHs to transact business using FLEX Options using the new Silexx System and encourage trading of FLEX Options. Additionally, the Exchange notes that it currently waives the Login Id fees for Login IDs used to access the CFLEX system.

The Exchange believes its proposed fee for Purge Ports is reasonable as it is also in line with the amount assessed for purge ports offered by its Affiliated Exchanges, as well as other exchanges.¹⁰⁸ Moreover, the Exchange believes that offering purge port functionality at the Exchange level promotes robust risk management across the industry, and thereby facilitates investor protection. Some market participants, and, in particular, larger firms, could build similar risk functionality on their trading systems that permit the flexible cancellation of orders entered on the Exchange. Offering Exchange level protections however, ensures that such functionality is widely available to all firms, including smaller firms that may otherwise not be willing to incur the costs and development work necessary to support their own customized mass cancel functionality. The Exchange operates in a highly competitive market in which exchanges offer connectivity and related services as a means to

¹⁰⁷ See Securities Exchange Act Release No. 73639 (November 19, 2014), 79 FR 72251 (December 5, 2014) (File No. S7-01-13) (Regulation SCI Adopting Release).

¹⁰⁸ See Affiliated Exchange Fee Schedules, Logical Port Fees. See also, Nasdaq ISE Pricing Schedule, Section 7(C). ISE charges a fee of \$1,100 per month for SQF Purge Ports.

¹⁰⁴ Based on the purchase of a single Market-Maker Trading Permit or Bandwidth Packet.

¹⁰⁵ Based on the purchase of a single Market-Maker Trading Permit or Bandwidth Packet.

¹⁰⁶ See *e.g.*, Choe C2 Options Exchange Fees Schedule, Logical Connectivity Fees.

facilitate the trading activities of TPHs and other participants. As the proposed Purge Ports provide voluntary risk management functionality, excessive fees would simply serve to reduce demand for this optional product. The Exchange also believes that the proposed Purge Port fees are not unfairly discriminatory because they will apply uniformly to all TPHs that choose to use dedicated Purge Ports. The proposed Purge Ports are completely voluntary and, as they relate solely to optional risk management functionality, no TPH is required or under any regulatory obligation to utilize them. The Exchange believes that adopting separate fees for these ports ensures that the associated costs are borne exclusively by TPHs that determine to use them based on their business needs, including Market-Makers or similarly situated market participants. Similar to Purge Ports, Spin and GRP Ports are optional products that provide an alternative means for market participants to receive multicast data and request and receive a retransmission of such data. As such excessive fees would simply serve to reduce demand for these products, which TPHs are under no regulatory obligation to utilize. All TPHs that voluntarily select these service options (*i.e.*, Purge Ports, Spin Ports or GRP Ports) will be charged the same amount for the same respective services. All TPHs have the option to select any connectivity option, and there is no differentiation among TPHs with regard to the fees charged for the services offered by the Exchange.

Access Credits

The Exchange believes the proposal to adopt credits for BOE Bulk Ports is reasonable, equitable and not unfairly discriminatory because it provides an opportunity for TPHs to pay lower fees for logical connectivity. The Exchange notes that the proposed credits are in lieu of the current credits that Market-Makers are eligible to receive today for Trading Permits fees. Although only Market-Makers may receive the proposed BOE Bulk Port credits, Market-Makers are valuable market participants that provide liquidity in the marketplace and incur costs that other market participants do not incur. For example, Market-Makers have a number of obligations, including quoting obligations and fees associated with appointments that other market participants do not have. The Exchange also believes that the proposals provide incremental incentives for TPHs to strive for the higher tier levels, which provide increasingly higher benefits for

satisfying increasingly more stringent criteria, including criteria to provide more liquidity to the Exchange. The Exchange believes the value of the proposed credits is commensurate with the difficulty to achieve the corresponding tier thresholds of each program.

First, the Exchange believes the proposed BOE Bulk Port fee credits provided under AVP will incentivize the routing of orders to the Exchange by TPHs that have both Market-Maker and agency operations, as well as incent Market-Makers to continue to provide critical liquidity notwithstanding the costs incurred with being a Market-Maker. More specifically, in the options industry, many options orders are routed by consolidators, which are firms that have both order router and Market-Maker operations. The Exchange is aware not only of the importance of providing credits on the order routing side in order to encourage the submission of orders, but also of the operations costs on the Market-Maker side. The Exchange believes the proposed change to AVP continues to allow the Exchange to provide relief to the Market-Maker side via the credits, albeit credits on BOE Bulk Port fees instead of Trading Permit fees. Additionally, the proposed credits may incentivize and attract more volume and liquidity to the Exchange, which will benefit all Exchange participants through increased opportunities to trade as well as enhancing price discovery. While the Exchange has no way of predicting with certainty how many and which TPHs will satisfy the required criteria to receive the credits, the Exchange had anticipated approximately two TPHs (out of approximately 5 TPHs that are eligible for AVP) to reach VIP Tiers 4 or 5 and consequently earn the BOE Bulk Port fee credits for their respective Market-Maker affiliate. For the month of October 2019, two TPHs received access credits under Tier 5 and no TPHs received credits under Tier 4. The Exchange notes that it believes its reasonable, equitable and not unfairly discriminatory to no longer provide access credits for Market-Makers whose affiliates achieve VIP Tiers 2 or 3 as the Exchange has adopted another opportunity for all Market-Makers, not just Market-Makers that are part of a consolidator, to receive credits on BOE Bulk Port fees (*i.e.*, credits available via the proposed Market-Maker Access Credit Program). More specifically, limiting the credits under AVP to the top two tiers enables the Exchange to provide further credits under the new

Market-Maker Access Credit Program. Furthermore, the Exchange notes that it is not required to provide any credits at any tier level.

The Exchange believes the proposed BOE Bulk Port fee credits available for TPHs that reach certain Performance Tiers under the Liquidity Provider Sliding Scale Adjustment Table is reasonable as the credits provide for reduced connectivity costs for those Market-Makers that reach the required thresholds. The Exchange believe it's reasonable, equitable and not unfairly discriminatory to provide credits to those Market-Makers that primarily provide and post liquidity to the Exchange, as the Exchange wants to continue to encourage Market-Makers with significant Make Rates to continue to participate on the Exchange and add liquidity. Greater liquidity benefits all market participants by providing more trading opportunities and tighter spreads.

Moreover, the Exchange notes that Market-Makers with a high Make Rate percentage generally require higher amounts of capacity than other Market-Makers. Particularly, Market-Makers with high Make Rates are generally streaming significantly more quotes than those with lower Make Rates. As such, Market-Makers with high Make Rates may incur more costs than other Market-Makers as they may need to purchase multiple BOE Bulk Ports in order to accommodate their capacity needs. The Exchange believes the proposed credits for BOE Bulk Ports encourages Market-Makers to continue to provide liquidity for the Exchange, notwithstanding the costs incurred by purchasing multiple ports. Particularly, the proposal is intended to mitigate the costs incurred by traditional Market-Makers that focus on adding liquidity to the Exchange (as opposed to those that provide and take, or just take). While the Exchange cannot predict with certainty which Market-Makers will reach Performance Tiers 4 and 5 each month, based on historical performance it anticipated approximately 10 Market-Makers would achieve Tiers 4 or 5. In October 2019, 12 Market-Makers achieved Tiers 4 or 5. Lastly, the Exchange notes that it is common practice among options exchanges to differentiate fees for adding liquidity and fees for removing liquidity.¹⁰⁹

Bandwidth Packets and CMI CAS Server Fees

The Exchange believes it's reasonable to eliminate Bandwidth Packet fees and

¹⁰⁹ See *e.g.*, MIAX Options Fees Schedule, Section 1(a), Market Maker Transaction Fees.

the CMI CAS Server fee because TPHs will not pay fees for these connectivity options and because Bandwidth Packets and CAS Servers have been retired and rendered obsolete as part of the migration. The Exchange believes that even though it will be discontinuing Bandwidth Packets, the proposed incremental pricing for Logical Ports and BOE Bulk Ports will continue to encourage users to mitigate message traffic. The proposed change is equitable and not unfairly discriminatory because it will apply uniformly to all TPHs.

Access Fees

The Exchange believes the restructuring of its Trading Permits is reasonable in light of the changes to the Exchange's connectivity infrastructure in connection with the migration and the resulting separation of bandwidth allowance, logins and appointment costs from each Trading Permit. The Exchange also believes that it is reasonable to harmonize the Exchange's Trading Permit structure and corresponding connectivity options to more closely align with the structures offered at its Affiliated Exchanges once the Exchange is on a common platform as its Affiliated Exchanges.¹¹⁰ The proposed Trading Permit structure and corresponding fees are also in line with the structure and fees provided by other

exchanges. The proposed Trading Permit fees are also equitable and not unfairly discriminatory because the Exchange will apply the same fees to all market participants that use the same type and number of Trading Permits.

With respect to electronic Trading Permits, the Exchange notes that TPHs previously requested multiple Trading Permits because of bandwidth, login or appointment cost needs. As described above, in connection with migration, bandwidth, logins and appointment costs are no longer tied to Trading Permits or Bandwidth Packets and as such, the need to hold multiple permits and/or Bandwidth Packets is obsolete. As such, the Exchange believes the structure to require only one of each type of applicable electronic Trading Permit is appropriate. Moreover, the Exchange believes offering separate marketing making permits for off-floor and on-floor Market-Makers provides for a cleaner, more streamlined approach to trading permits and corresponding fees. Other exchanges similarly provide separate and distinct fees for Market-Makers that operate on-floor vs off-floor and their corresponding fees are similar to those proposed by the Exchange.¹¹¹

The Exchange believes the proposed fee for its MM EAP Trading Permits is reasonable as it is the same fee it assess today for Market-Maker Trading Permits

(i.e., \$5,000 per month per permit). Additionally, the proposed fee is in line with, and in some cases even lower than, the amounts assessed for similar access fees at other exchanges, including its affiliate C2.¹¹² The Exchange believes the proposed EAP fee is also reasonable, and in line with the fees assessed by other Exchanges for non-Market-Maker electronic access.¹¹³ The Exchange notes that while the Trading Permit fee is increasing, TPHs overall cost to access the Exchange may be reduced in light of the fact that a TPH no longer must purchase multiple Trading Permits, Bandwidth Packets and Login Ids in order to receive sufficient bandwidth and logins to meet their respective business needs. To illustrate the value of the new connectivity infrastructure, the Exchange notes that the cost that would be incurred by a TPH today in order to receive the same amount of order capacity that will be provided by a single Logical Port post-migration (i.e., 5,000 orders per second), is approximately 98% higher than the cost for the same capacity post-migration. The following examples further demonstrate potential cost savings/value added for an EAP holder with modest capacity needs and an EAP holder with larger capacity needs:

TPH THAT HOLDS 1 EAP, NO BANDWIDTH PACKETS AND 1 CMI LOGIN

	Current fee structure	Post-migration fee structure
EAP	\$1,600	\$3,000.
CMI Login/Logical Port	\$750	\$750..
Bandwidth Packets	0	N/A.
Total Bandwidth Available	30 orders/sec	5,000 orders/sec.
Total Cost	\$2,350	\$3,750.
Total Cost per message	\$78.33/order/sec	\$0.75/order/sec.

TPH THAT HOLDS 1 EAP, 4 BANDWIDTH PACKETS AND 15 CMI LOGINS

	Current fee structure	Post-migration fee structure
EAP	\$1,600	\$3,000.
CMI Login/Logical Port	\$11,250 (15@750)	\$750.
Bandwidth Packets	\$6,400 (4@\$1,600)	N/A.
Total Bandwidth Available	150 orders/sec	5,000 orders/sec.
Total Cost	\$19,250	\$3,750.
Total Cost per message	\$128.33/order/sec	\$0.75/order/sec.

¹¹⁰ For example, the Exchange's affiliate, C2, similarly provides for Trading Permits that are not tied to connectivity, and similar physical and logical port options at similar pricings. See Cboe C2 Options Exchange Fees Schedule. Physical connectivity and logical connectivity are also not tied to any type of permits on the Exchange's other options exchange affiliates.

¹¹¹ See e.g., PHLX Section 8A, Permit and Registration Fees. See also, BOX Options Fee Schedule, Section IX Participant Fees; NYSE

American Options Fees Schedule, Section III(A) Monthly ATP Fees and NYSE Arca Options Fees and Charges, OTP Trading Participant Rights. For similar Trading Floor Permits for Floor Market Makers, Nasdaq PHLX charges \$6,000; BOX charges up to \$5,500 for 3 registered permits in addition to a \$1,500 Participant Fee, NYSE Arca charges up to \$6,000; and NYSE American charges up to \$8,000.

¹¹² See e.g., Cboe C2 Options Exchange Fees Schedule. See also, NYSE Arca Options Fees and Charges, General Options and Trading Permit (OTP)

Fees, which assesses up to \$6,000 per Market Maker OTP and NYSE American Options Fee Schedule, Section III. Monthly ATP Fees, which assess up to \$8,000 per Market Maker ATP. See also, PHLX Section 8A, Permit and Registration Fees, which assesses up to \$4,000 per Market Maker Permit.

¹¹³ See e.g., PHLX Section 8A, Permit and Registration Fees, which assesses up to \$4,000 per Permit for all member and member organizations other than Floor Specialists and Market Makers.

The Exchange believes the proposal to adopt a new Clearing TPH Permit is reasonable because it offers TPHs that only clear transactions of TPHs a discount. Particularly, Clearing TPHs that also submit orders electronically to the Exchange would purchase the proposed EAP at \$3,000 per permit. The Exchange believe it's reasonable to provide a discount to Clearing TPHs that only clear transactions and do not otherwise submit electronic orders to the Exchange. The Exchange notes that another exchange similarly charges a separate fee for clearing firms.¹¹⁴

The Exchange believes the proposed fee structure for on-floor Market-Makers is reasonable as the fees are in line with those offered at other Exchanges.¹¹⁵ The Exchange believes that the proposed fee for MM Floor Permits as compared to MM EAPs is reasonable because it is only modestly higher than MM EAPs and Floor MMs don't have other costs that MM EAP holders have, such as MM EAP Appointment fees.

The Exchange believes its proposed fees for Floor Broker Permits are reasonable because the fees are similar to, and in some cases lower than, the fees the Exchange currently assesses for such permits. Specifically, based on the number of Trading Permits TPHs held upon migration, 60% of TPHs that hold Floor Broker Trading Permits will pay lower Trading Permit fees. Particularly, any Floor Broker holding ten or less Floor Broker Trading Permits will pay lower fees under the proposed tiers as compared to what they pay today. While the remaining 40% of TPHs holding Floor Broker Trading Permits (who each hold between 12–21 Floor Broker Trading Permits) will pay higher fees, the Exchange notes the monthly increase is de minimis, ranging from an increase of 0.6%–2.72%.¹¹⁶

The Exchange believes the proposed ADV Discount is reasonable because it provides an opportunity for Floor Brokers to pay lower FB Trading Permit fees, similar to the current rebate

program offered to Floor Brokers. The Exchange notes that while the new ADV Discount program includes only customer volume ("C" origin code) as compared to Customer and Professional Customer/Voluntary Professional, the amount of Professional Customer/Voluntary Professional volume was de minimis and the Exchange does not believe the absence of such volume will have a significant impact.¹¹⁷

Additionally, the Exchange notes that while the ADV requirements under the proposed ADV Discount program are higher than are required under the current rebate program, the proposed ADV Discount counts volume from all products towards the thresholds as compared to the current rebate program which excludes volume from Underlying Symbol List A (except RLG, RLV, RUI, and UKXM), DJX, XSP, and subcabinet trades. Moreover, the ADV Discount is designed to encourage the execution of orders in all classes via open outcry, which may increase volume, which would benefit all market participants (including Floor Brokers who do not hit the ADV thresholds) trading via open outcry (and indeed, this increased volume could make it possible for some Floor Brokers to hit the ADV thresholds). The Exchange believes the proposed discounts are equitable and not unfairly discriminatory because all Floor Brokers are eligible. While the Exchange has no way of predicting with certainty how many and which TPHs will satisfy the various thresholds under the ADV Discount, the Exchange anticipated approximately 3 Floor Brokers to receive a rebate under the program. In December 2019, 2 Floor Brokers received a rebate under the program.

The Exchange believes its proposed MM EAP Appointment fees are reasonable in light of the Exchange's elimination of appointment costs tied to Trading Permits. Other exchanges also offer a similar structure with respect to fees for appointment classes.¹¹⁸

Additionally, the proposed MM EAP Appointment fee structure results in approximately 36% electronic MMs paying lower fees for trading permit and appointment costs. For example, in order to have the ability to make electronic markets in every class on the Exchange, a Market-Maker would need 1 Market-Maker Trading Permit and 37 Appointment Units post-migration. Under the current pricing structure, in order for a Market-Maker to quote the entire universe of available classes, a Market-Maker would need 33 Appointment Credits, thus necessitating 33 Market-Maker Trading Permits. With respect to fees for Trading Permits and Appointment Unit Fees, under the proposed pricing structure, the cost for a TPH wishing to quote the entire universe of available classes is approximately 29% less (if they are not eligible for the MM TP Sliding Scale) or approximately 2% less (if they are eligible for the MM TP Sliding Scale). To further demonstrate the potential cost savings/value added, the Exchange is providing the following examples comparing current Market-Maker connectivity and access fees to projected connectivity and access fees for different scenarios. The Exchange notes that the below examples not only compare Trading Permit and Appointment Unit costs, but also the cost incurred for logical connectivity and bandwidth. Particularly, the first example demonstrates the total minimum cost that would be incurred today in order for a Market-Maker to have the same amount of capacity as a Market-Maker post-migration that would have only 1 MM EAP and 1 Logical Port (*i.e.*, 15,000 quotes/3 sec). The Exchange is also providing examples that demonstrate the costs of (i) a Market-Maker with small capacity needs and appointment unit of 1.0 and (ii) a Market-Maker with large capacity needs and appointment cost/unit of 30.0:

MARKET-MAKER THAT NEEDS CAPACITY OF 15,000/QUOTES/3 SECONDS

	Current fee structure	Post-migration fee structure
MM Permit/MM EAP	\$5,000	\$5,000.
Appointment Unit Cost	N/A (1 appointment cost)	\$0 (1 appointment unit).
CMI Login/Logical Port	\$750 ¹¹⁹	\$750.
Bandwidth Packets	\$5,500 (2@\$2,750)	N/A.
Total Bandwidth Available	15,000 quotes/3 sec	15,000 quotes/3 sec.

¹¹⁴ See *e.g.*, NYSE Arca Options Fees and Charges, General Options and Trading Permit (OTP) Fees and NYSE American Options Fee Schedule, Section III. Monthly ATP Fees.

¹¹⁵ See *e.g.*, PHLX Section 8A, Permit and Registration Fees, which assesses \$6,000 per permit for Floor Specialists and Market Makers.

¹¹⁶ The Floor Brokers whose fees are increasing have each committed to a minimum number of permits and therefore currently receive the rates set forth in the current Floor Broker TP Sliding Scale.

¹¹⁷ Furthermore, post-migration the Exchange will not have Voluntary Professionals.

¹¹⁸ See *e.g.*, PHLX Section 8. Membership Fees, B, Streaming Quote Trader ("SQT") Fees and C. Remote Market Maker Organization (RMO) Fee.

¹¹⁹ The maximum quoting bandwidth that may be applied to a single Login Id is 80,000 quotes/3 sec.

MARKET-MAKER THAT NEEDS CAPACITY OF 15,000/QUOTES/3 SECONDS—Continued

	Current fee structure	Post-migration fee structure
Total Cost	\$11,250	\$5,750.
Total Cost per message allowed	\$0.75/quote/3 sec	\$0.38/quote/3 sec.

MARKET MAKER THAT NEEDS CAPACITY OF NO MORE THAN 5,000 QUOTES/3 SECS

	Current fee structure	Post-migration fee structure
MM Permit/MM EAP	\$5,000	\$5,000.
Appointment Unit Cost	N/A (1 appointment cost)	\$0 (1 appointment unit).
CMI Login/Logical Port	\$750	\$750.
Bandwidth Packets	0	N/A.
Total Bandwidth Available	5,000 quotes/3 sec	15,000 quotes/3 sec.
Total Cost	\$5,750	\$5,750.
Total Cost per message allowed	\$1.15/quote/3 sec	\$0.38/quote/3 sec.

MARKET-MAKER THAT NEEDS 30 APPOINTMENT UNITS AND CAPACITY OF 300,000 QUOTES/3 SEC

	Current fee structure	Post-migration fee structure
MM Permits/MM EAP	\$105,000 (30 MM Permits assumes eligible for MM TP Sliding Scale) ¹²⁰ .	\$5,000.
Appointment Units Cost	N/A (30 appointment costs)	\$95,500 (30 appointment units).
CMI Logins/BOE Bulk Port	\$3,000 (4@ \$750) ¹²¹	\$3,000 (2 BOE Bulk@ \$1,500).
Bandwidth Packets	\$82,500(30@ \$2750)	N/A.
Total Bandwidth Available	300,000 quotes/3 sec	* 450,000 quotes/3 sec.
Total Cost	\$190,500	\$103,500.
Total Cost per message allowed	\$0.63/quotes/3 sec	\$0.23/quote/3 sec.

* Possible performance degradation at 15,000 messages per second.

The Exchange believes its proposal to provide separate fees for Tier Appointments for MM EAPs and MM Floor Permits as the Exchange will be issuing separate Trading Permits for on-floor and off-floor market making as discussed above. The proposal to eliminate the volume threshold for the electronic SPX Tier Appointment fee is reasonable as no TPHs in the past several months have electronically traded more than 1 SPX contract or less than 100 SPX contracts per month and therefore will not be negatively impacted by the proposed change, and because it aligns the electronic SPX Tier Appointment with the floor SPX Tier Appointment, which has no volume threshold. The Exchange believes the proposal to increase the electronic volume thresholds for VIX and RUT are reasonable as those that do not regularly trade VIX or RUT in open-outcry will continue to not be assessed the fee. In fact, any TPH that executes more than 100 contracts but less than 1,000 in the respective classes will no longer have to

pay the proposed Tier Appointment fee. As noted above, the Exchange is not proposing to change the amounts assessed for each Tier Appointment Fee. The proposed change is equitable and not unfairly discriminatory because it will apply uniformly to all TPHs.

Trading Permit Holder Regulatory Fee

The Exchange believes it's reasonable to eliminate the Trading Permit Holder Regulatory fee because TPHs will not pay this fee and because the Exchange is restructuring its Trading Permit structure. The Exchange notes that although it will less closely be covering the costs of regulating all TPHs and performing its regulatory responsibilities, it still has sufficient funds to do so. The proposed change is equitable and not unfairly discriminatory because it will apply uniformly to all TPHs.

The Exchange believes corresponding changes to eliminate obsolete language in connection with the proposed changes described above and to relocate and reorganize its fees in connection with the proposed changes maintain clarity in the Fees Schedule and alleviate potential confusion, thereby removing impediments to and perfecting the mechanism of a free and open market and a national market

system, and, in general, protecting investors and the public interest.

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.

With respect to intra-market competition, the Exchange does not believe that the proposed rule change would place certain market participants at the Exchange at a relative disadvantage compared to other market participants or affect the ability of such market participants to compete. As stated above, the Exchange does not believe its proposed pricing will impose a barrier to entry to smaller participants and notes that its proposed connectivity pricing is associated with relative usage of the various market participants. For example, market participants with modest capacity needs can buy the less expensive 1 Gb Physical Port and utilize only one Logical Port. Moreover, the pricing for 1 Gb Physical Ports and FIX/BOE Logical Ports are no different than are assessed today (i.e., \$1,500 and \$750 per port, respectively), yet the capacity and access associated with each is greatly increasing. While pricing may be

¹²⁰ For simplicity of the comparison, this assumes no appointments in SPX, VIX, RUT, XEO or OEX (which are not included in the TP Sliding Scale).

¹²¹ Given the bandwidth limit per Login Id of 80,000 quotes/3 sec, example assumes Market-Maker purchases minimum amount of Login IDs to accommodate 300,000 quotes/3 sec.

increased for larger capacity physical and logical ports, such options provide far more capacity and are purchased by those that consume more resources from the network. Accordingly, the proposed connectivity fees do not favor certain categories of market participants in a manner that would impose a burden on competition; rather, the allocation reflects the network resources consumed by the various size of market participants—lowest bandwidth consuming members pay the least, and highest bandwidth consuming members pay the most, particularly since higher bandwidth consumption translates to higher costs to the Exchange.

The Exchange also does not believe that the proposed rule change will result in any burden on inter-market competition that is not necessary or appropriate in furtherance of the purposes of the Act. As discussed in the Statutory Basis section above, options market participants are not forced to connect to (or purchase market data from) all options exchanges, as shown by the number of TPHs at Cboe and shown by the fact that there are varying number of members across each of Cboe's Affiliated Exchanges. The Exchange operates in a highly competitive environment, and as discussed above, its ability to price access and connectivity is constrained by competition among exchanges and third parties. As discussed, there are other options markets of which market participants may connect to trade options. There is also a possible range of alternative strategies, including routing to the exchange through another participant or market center or accessing the Exchange indirectly. For example, there are 15 other U.S. options exchanges, which the Exchange must consider in its pricing discipline in order to compete for market participants. In this competitive environment, market participants are free to choose which competing exchange or reseller to use to satisfy their business needs. As a result, the Exchange believes this proposed rule change permits fair competition among national securities exchanges. 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 written 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 pursuant to Section 19(b)(3)(A) of the Act¹²² and paragraph (f) of Rule 19b-4¹²³ thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will 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-2020-064 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-2020-064. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public

Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal 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-2020-064, and should be submitted on or before August 3, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹²⁴

J. Matthew DeLesDernier,
Assistant Secretary.

[FR Doc. 2020-14972 Filed 7-10-20; 8:45 am]

BILLING CODE 8011-01-P

SMALL BUSINESS ADMINISTRATION

Data Collection Available for Public Comments

ACTION: 60-Day notice and request for comments.

SUMMARY: The Small Business Administration (SBA) intends to request approval, from the Office of Management and Budget (OMB), for the collection of information described below. The Paperwork Reduction Act (PRA) requires Federal agencies to publish a notice in the **Federal Register** concerning each collection of information before submission to OMB and to allow 60 days for public comment in response to the notice. This notice complies with that requirement.

DATES: Submit comments on or before September 11, 2020.

ADDRESSES: Send all comments to Cynthia Pitts, Office of Disaster Assistance, Small Business Administration, 409 3rd Street, 6th Floor, Washington, DC 20416.

FOR FURTHER INFORMATION CONTACT: Cynthia Pitts, Director, Disaster Administrative Services, 202-205-7570, Cynthia.pitts@sba.gov or Curtis B. Rich, Management Analyst, 202-205-7030, curtis.rich@sba.gov.

SUPPLEMENTARY INFORMATION: Section 7(b) of the Small Business Act, 15 U.S.C. 636, as amended, authorizes the Small Business Administration to make disaster loans to businesses and

¹²² 15 U.S.C. 78s(b)(3)(A).

¹²³ 17 CFR 240.19b-4(f).

¹²⁴ 17 CFR 200.30-3(a)(12).

nonprofit organizations, including loans for economic injury. The *Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020*, Public Law 116–123 (March 6, 2020), amended the Small Business Act to make economic injury resulting from the current coronavirus pandemic (COVID–19) a disaster that is eligible for assistance under section 7(b) of the Small Business Act. The assistance available includes an “advance” on the loan (that does not have to be repaid) in an amount up to \$10,000. To expedite the processing time and provide immediate financial assistance, SBA obtained emergency approval from OMB to collect information from small businesses and nonprofit organizations seeking relief from the economic conditions created by the COVID–19 emergency. This approval expires on September 30, 2020. SBA will be requesting an extension of this approval to enable the agency to continue collecting the information necessary to process applications for assistance.

(a) Solicitation of Public Comments

SBA is requesting comments on (i) Whether the collection of information is necessary for the agency to properly perform its functions; (ii) whether the burden estimates are accurate; (iii) whether there are ways to minimize the burden, including through the use of automated techniques or other forms of information technology; and (iv) whether there are ways to enhance the quality, utility, and clarity of the information.

(b) Summary of Information Collection

Title: Economic Injury Disaster Loan Application (EIDL) COVID–19.

OMB Control Number: 3245–0406.

Respondents: Small businesses, including sole proprietors, independent contractors, and agricultural businesses, and nonprofit organizations.

Form Numbers: SBA Form 3501 through Form 3503.

(i) Form 3501, EID–COVID19 Application. This form is completed by all applicants for assistance. SBA estimates 15 million applicants, each needing approximately 30 minutes to complete the application. Based on one application per applicant, the total estimated burden is 7.5 million hours. The information requested includes business formation type and date; taxpayer’s identification number; number of employees; information about owners, including their criminal history, and suspensions and debarments.

(ii) Form 3502—Economic Injury Disaster Loan Supporting Information.

The requested information includes, where applicable, gross revenues for the 12 months prior to the disaster, costs of goods sold; lost rents due to the disaster; cost of operation for the 12 month period prior to the disaster; amount and description of compensation from other sources as a result of the disaster. The information supplements the Form 3501 information and thus is submitted by all applicants. SBA estimates 1 hour for completion time, for a total of 15 million hours.

(iii) Form 3503—Verification of Eligible Entity for Emergency EIDL Advance. This information is also submitted by all applicants to specifically request an advance on their loan and to certify to the accuracy of the information submitted on Form 3501 and 3502. SBA estimates each 15 million applicants will need about 10 minutes to complete the form for a total of 2.5 million hours.

Curtis Rich,

Management Analyst.

[FR Doc. 2020–14987 Filed 7–10–20; 8:45 am]

BILLING CODE 8026–03–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

NextGen Advisory Committee; Notice of Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: This notice announces a meeting of the NextGen Advisory Committee (NAC).

DATES: The meeting will be held virtual-only on August 6, 2020, from 1:00 p.m.–4:00 p.m. EDT. Requests to attend the meeting virtually must be received by July 23, 2020. Requests for accommodations for a disability must be received by July 16, 2020. If you wish to make a public statement during the meeting, you must submit a written copy of your remarks by July 23, 2020. Requests to submit written materials to be reviewed by NAC Members must be received no later than July 23, 2020.

ADDRESSES: The meeting will be a virtual meeting only. Virtual meeting information will be provided upon registration. Information on the NAC, including copies of previous meeting minutes will be available on the NAC internet website at https://www.faa.gov/about/office_org/headquarters_offices/ang/nac/. Members of the public interested in attending must send the

required information listed in the **SUPPLEMENTARY INFORMATION** to 9-AWA-ANG-NACRegistration@faa.gov.

FOR FURTHER INFORMATION CONTACT: Greg Schwab, NAC Coordinator, U.S. Department of Transportation, at gregory.schwab@faa.gov or 202–267–1201. Any requests or questions not regarding attendance registration should be sent to the person listed in this section.

SUPPLEMENTARY INFORMATION:

I. Background

NAC was created under the Federal Advisory Committee Act (FACA), under the authority of the U.S. Department of Transportation, to provide independent advice and recommendations to the FAA and to respond to specific taskings received directly from the FAA. The NAC recommends consensus-driven advice for FAA consideration relating to Air Traffic Management System modernization.

II. Agenda

At the meeting, the agenda will cover the following topics:

- NAC Chairman’s Report
- FAA Report
- NAC Subcommittee Chairman’s Report
 - Risk and Mitigations update for the following focus areas: Multiple Runway Operations, Data Communications, Performance Based Navigation, Surface and Data Sharing, and Northeast Corridor
- NAC Chairman Closing Comments

The detailed agenda will be posted on the NAC internet website at least one week in advance of the meeting.

III. Public Participation

This virtual meeting will be open to the public on a first-come, first served basis, as phone lines are limited. Members of the public who wish to attend are asked to register via email by submitting full legal name, country of citizenship, contact information (telephone number and email address), and name of your industry association, or applicable affiliation, to the email listed in the **ADDRESSES** section. When registration is confirmed, registrants will be provided the virtual meeting information/teleconference call-in number and passcode. Callers are responsible for paying associated long-distance charges.

Note: Only NAC Members, members of the public who have registered to make a public statement, and briefers will have the ability to speak. All other attendees will be listen only.

The U.S. Department of Transportation is committed to providing equal access to this meeting for all participants. If you need alternative formats or services because of a disability, such as sign language, interpretation, or other ancillary aids, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

There will be five minutes allotted for oral comments from each member of the public joining the meeting. To accommodate as many speakers as possible, the time for each commenter may be limited. Individuals wishing to reserve speaking time during the meeting must submit a request at the time of registration, as well as the name, address, and organizational affiliation of the proposed speaker. If the number of registrants requesting to make statements is greater than can be reasonably accommodated during the meeting, the FAA may conduct a lottery to determine the speakers. Speakers are required to submit a copy of their prepared remarks for inclusion in the meeting records and for circulation to NAC members to the person listed under the heading **FOR FURTHER INFORMATION CONTACT**. All prepared remarks submitted on time will be accepted and considered as part of the meeting's record.

Members of public may submit written statements for inclusion in the meeting records and circulation to the NAC members. Written statements need to be submitted to the person listed under the heading **FOR FURTHER INFORMATION CONTACT**. Comments received after the due date will be distributed to the members but may not be reviewed prior to the meeting. Any member of the public may present a written statement to the committee at any time.

Issued in Washington, DC, this 8th day of July 2020.

Dated: July 8, 2020.

Tiffany McCoy,

General Engineer, NextGen Office of Collaboration and Messaging, ANG-M, Office of the Assistant Administrator for NextGen, Federal Aviation Administration.

[FR Doc. 2020-15050 Filed 7-10-20; 8:45 am]

BILLING CODE 4910-9X-P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[Docket No. FHWA-2020-0013]

Agency Information Collection Activities: Request for Comments on the Renewal of a Previously Approved Information Collection

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice and request for comments.

SUMMARY: The FHWA invites public comments about our intention to request the Office of Management and Budget's (OMB) approval for a new information collection, which is summarized below under **SUPPLEMENTARY INFORMATION**. We are required to publish this notice in the **Federal Register** by the Paperwork Reduction Act of 1995.

DATES: Please submit comments by July 13, 2020.

ADDRESSES: You may submit comments identified by DOT Docket ID 2020-0013 by any of the following methods:

Website: For access to the docket to read background documents or comments received go to the Federal eRulemaking Portal: Go to <http://www.regulations.gov>. Follow the online instructions for submitting comments.

Fax: 1-202-493-2251.

Mail: Docket Management Facility, U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590-0001.

Hand Delivery or Courier: U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT:

Christine Thorkildsen, 518-487-1186, Office of Civil Rights, Federal Highway Administration, Department of Transportation, 1200 New Jersey Ave. SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Title: Federal-Aid Highway Construction Equal Employment Opportunity.

Background: Title 23, Part 140(a), requires the FHWA to ensure equal opportunity regarding contractors' employment practices on Federal-aid highway projects. To carry out this requirement, the contractors must submit employment workforce data to the State Transportation Agencies

(STAs) on all work being performed on Federal-aid contracts during all or any part of the last payroll period preceding the end of July. This report provides the employment workforce data on these contracts and includes the number of minorities, women, and non-minorities in specific highway construction job categories. This information is reported on Form PR-1391, Federal-Aid Highway Construction Contractors Summary of Employment Data. The statute also requires the STAs to submit a report to the FHWA summarizing the data entered on the PR-1391 forms. This summary data is provided on Form PR-1392, Federal-Aid Highway Construction Contractors Summary of Employment Data. The STAs and FHWA use this data to identify patterns and trends of employment in the highway construction industry, and to determine the adequacy and impact of the STA's and FHWA's contract compliance and on-the-job (OJT) training programs. The STAs use this information to monitor the contractors-employment and training of minorities and women in the traditional highway construction crafts. Additionally, the data is used by FHWA to provide summarization, trend analyses to Congress, DOT, and FHWA officials as well as others who request information relating to the Federal-aid highway construction EEO program. The information is also used in making decisions regarding resource allocation; program emphasis; marketing and promotion activities; training; and compliance efforts.

Respondents: 11,077 annual respondents for form PR-1391, and 53 STAs and Territory annual respondents for Form PR-1392 that, total of 11,130.

Frequency: Annually.

Estimated Average Burden per Response: FHWA estimates it takes 30 minutes for Federal-aid contractors to complete and submit Form PR-1391 and 8 hours for STAs to complete and submit Form PR-1392.

Estimated Total Amount Burden Hours: Form PR-1391—5,539 hours per year; Form PR-1392—416 hours per year, total of 5,955 hours annually.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including: (1) Whether the proposed collection is necessary for the FHWA's performance; (2) the accuracy of the estimated burdens; (3) ways for the FHWA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized, including the use of electronic technology, without reducing the quality of the collected information.

The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended; and 49 CFR 1.48.

Issued On: July 8, 2020.

Michael Howell,

Information Collections Officer.

[FR Doc. 2020-15020 Filed 7-10-20; 8:45 am]

BILLING CODE 4910-22-P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD-2020-0094]

Request for Comments of a Previously Approved Information Collection: War Risk Insurance, Applications and Related Information

AGENCY: Maritime Administration, DOT.

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, this notice announces that the Information Collection Request (ICR) abstracted below is being forwarded to the Office of Management and Budget (OMB) for review and comments. A **Federal Register** Notice with a 60-day comment period soliciting comments on the following information collection was published on April 28, 2020.

DATES: Comments must be submitted on or before August 12, 2020.

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 "Currently under 30-day Review—Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: Michael Yarrington, 202-366-1915, Office of Marine Insurance, Maritime Administration, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC, 20590.

SUPPLEMENTARY INFORMATION:

Title: War Risk Insurance, Applications and Related Information.
OMB Control Number: 2133-0011.

Type of Request: Renewal of a Previously Approved Information Collection.

Background: The U.S. Government's War Risk Insurance program is a standby emergency program for national defense and national security. It

becomes effective upon and simultaneously with the automatic termination of ocean marine commercial war risk insurance policies. Those policies are automatically terminated upon the outbreak of war, whether declared or not, between any of the five great powers (United States of America, United Kingdom, France, People's Republic of China, the Russian Federation) or upon the hostile detonation of a weapon of war employing atomic or nuclear fission.

The War Risk Insurance program makes it possible for applicants to obtain war risk insurance from the U.S. Government when such insurance is unavailable on reasonable terms from the commercial market. The program is mutually beneficial to the United States and to the shipowner in that it assures continued flow of essential U.S. trade and provides protection for the ship owner from loss by risks of war.

Respondents: Vessel owners or charterers interested in participating in MARAD's war risk insurance program.

Affected Public: Business or other for profit.

Total Estimated Number of Responses: 20.

Frequency of Collection: Annually.

Estimated time per Respondent: 12.8 hours.

Total Estimated Number of Annual Burden Hours: 256.

Public Comments Invited: Comments are invited on: whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; the accuracy of the Department's estimate of the burden of the proposed information collection; 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 respondents, including the use of automated collection techniques or other forms of information technology.

(AUTHORITY: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.93)

* * *

Dated: July 7, 2020.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2020-14959 Filed 7-10-20; 8:45 am]

BILLING CODE 4910-81-P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA-2019-0131; Notice 1]

FCA US LLC, Receipt of Petition for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Receipt of petition.

SUMMARY: FCA US LLC (f/k/a Chrysler Group LLC) "FCA" has determined that certain model year (MY) 2004-2020 Chrysler, Dodge, Jeep, Fiat, and Alfa Romeo motor vehicles do not comply with Federal Motor Vehicle Safety Standard (FMVSS) No. 101, *Controls and Displays*. FCA filed a noncompliance report dated November 15, 2019, and later amended it on December 9, 2019. FCA US subsequently petitioned NHTSA on December 9, 2019, for a decision that the subject noncompliance is inconsequential as it relates to motor vehicle safety. This document announces receipt of FCA's petition.

DATES: Send comments on or before August 12, 2020.

ADDRESSES: Interested persons are invited to submit written data, views, and arguments on this petition. Comments must refer to the docket and notice number cited in the title of this notice and submitted by any of the following methods:

- *Mail:* Send comments by mail addressed to the U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590.

- *Hand Delivery:* Deliver comments by hand to the U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590. The Docket Section is open on weekdays from 10 a.m. to 5 p.m. except for Federal Holidays.

- *Electronically:* Submit comments electronically by logging onto the Federal Docket Management System (FDMS) website at <https://www.regulations.gov/>. Follow the online instructions for submitting comments.

- Comments may also be faxed to (202) 493-2251.

Comments must be written in the English language, and be no greater than 15 pages in length, although there is no limit to the length of necessary

attachments to the comments. If comments are submitted in hard copy form, please ensure that two copies are provided. If you wish to receive confirmation that comments you have submitted by mail were received, please enclose a stamped, self-addressed postcard with the comments. Note that all comments received will be posted without change to <https://www.regulations.gov>, including any personal information provided.

All comments and supporting materials received before the close of business on the closing date indicated above will be filed in the docket and will be considered. All comments and supporting materials received after the closing date will also be filed and will be considered to the fullest extent possible.

When the petition is granted or denied, notice of the decision will also be published in the **Federal Register** pursuant to the authority indicated at the end of this notice.

All comments, background documentation, and supporting materials submitted to the docket may be viewed by anyone at the address and times given above. The documents may also be viewed on the internet at <https://www.regulations.gov> by following the online instructions for accessing the dockets. The docket ID number for this petition is shown in the heading of this notice.

DOT's complete Privacy Act Statement is available for review in a **Federal Register** notice published on April 11, 2000, (65 FR 19477–78).

SUPPLEMENTARY INFORMATION:

I. Overview

FCA has determined that certain MY 2004–2020 Chrysler, Dodge, Jeep, Fiat, and Alfa Romeo motor vehicles do not comply with paragraph S5.2.1 of FMVSS No. 101, *Controls and Displays* (49 CFR 571.101). FCA filed a noncompliance report dated November 15, 2019, and later amended it on December 9, 2019, pursuant to 49 CFR 573, *Defect and Noncompliance Responsibility and Reports*. FCA subsequently petitioned NHTSA on December 9, 2019, for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential as it relates to motor vehicle safety, pursuant to 40 U.S.C. 30118 and 49 U.S.C. 30120, *Exemption for Inconsequential Defect or Noncompliance*.

This notice of receipt of FCA's petition is published under 49 U.S.C. 30118 and 30120 and does not represent any agency decision or other exercise of

judgment concerning the merits of the petition.

II. Vehicles Involved

Approximately 2,507,693 MY 2004–2020 Chrysler, Dodge, Jeep, Fiat, and Alfa Romeo motor vehicles, manufactured between November 25, 2002, and November 9, 2019, are potentially involved.

III. Noncompliance

FCA explains that the noncompliance is that the subject vehicles are equipped with speedometers that allow the driver to configure the speedometer to display the vehicle's speed in kilometers-per-hour (km/h) only and therefore do not meet the requirements set forth in paragraph S5.2.1 and Table 1, Column 3 of FMVSS No. 101.

IV. Rule Requirements

Paragraph S5.2.1 and Table 1, Column 3 of FMVSS No. 101 provides that each passenger car, multipurpose passenger vehicle, truck and bus that is fitted with a control, a telltale, or an indicator listed in Table 1 or Table 2 must meet the requirements of FMVSS No. 101 for the location, identification, color, and illumination of that control, telltale or indicator. Each control, telltale and indicator that is listed in column 1 of Table 1 or Table 2 must be identified by the symbol specified for it in column 2 or the word or abbreviation specified for it in column 3 of Table 1 or Table 2. Specifically, the speedometer must only allow the speed to be displayed in miles per hour (MPH) or km/h and MPH.

V. Summary of FCA's Petition

The following views and arguments presented in this section, V. Summary of FCA's Petition, are the views and arguments provided by FCA. They have not been evaluated by the Agency and do not reflect the views of the Agency.

FCA described the subject noncompliance and stated that the noncompliance is inconsequential as it relates to motor vehicle safety. FCA submitted the following views and arguments in support of the petition:

1. FCA states that the vehicles are initially delivered for first-sale in a compliant state (vehicle speed displayed in MPH) and that it is only through vehicle operator interaction that the settings can be changed from MPH to km/h. FCA believes that this adjustment cannot be accomplished inadvertently.

2. FCA states that the two speedometer settings are clearly and continuously identified as “km/h” or “MPH”. In addition, the two speedometer scales are noticeably

different, and that if a previous vehicle operator changed the units, a subsequent vehicle operator would be able to tell in a glance that the scale is not in MPH.

3. FCA states that the vehicle speed in km/h is 1.6 times greater than speed in MPH [in terms of numeric value displayed by the speedometer—1km/h is approximately 0.62 MPH]. FCA believes that if a vehicle operator changes the display to km/h and then later forgets that the change had been made, the operator will recognize that the vehicle is moving at a slower speed than intended and adjust the speed to match the road and vehicle conditions. This should alert the operator to (at the next appropriate opportunity) perform the appropriate steps to adjust the speedometer.

4. FCA also states that the owner's manuals for all of the affected vehicles contain instructions to change the speedometer display. Therefore, if a vehicle operator needs assistance to reconfigure the display to MPH, instructions are available.

5. FCA further states that the owner's manuals contain toll-free numbers to the FCA customer helplines. Therefore, if a vehicle operator notices that the speed is unintentionally displayed in km/h and does not know how to re-set the speed to display in MPH, e.g., as set by a previous operator, the vehicle operator can easily contact FCA for assistance.

6. FCA has not received any customer contacts regarding this issue, even though this condition exists as in approximately 2.5 million vehicles, some of which have been in service for over 16 years.

7. FCA is not aware of any crashes, injuries, or customer complaints associated with this condition.

8. FCA states that NHTSA has previously granted inconsequential treatment for FMVSS No. 101 noncompliance for display of the vehicle speed in km/h only. An example of the Agency granting a similar inconsequentiality petition for display of the vehicle speed in km/h only is:

- BMW of North America, LLC, a subsidiary of BMW AG, 80 FR 61884 (October 14, 2015).

9. It is FCA's belief that the information described above satisfies the intent of 49 CFR part 556 and operators can safely utilize their vehicles for the intended purposes. FCA believes that pursuant to 49 CFR part 556, 49 U.S.C. 30118(d) and § 30120(h), the FMVSS 101 S5.2.1, this display of the vehicle speed in km/h only noncompliance is inconsequential to motor vehicle safety and FCA should be exempted from the notification and

remedy requirements of 49 U.S.C. Chapter 301, "Motor Vehicle Safety" for the reasons supporting exemption cited above.

NHTSA notes that the statutory provisions (49 U.S.C. 30118(d) and 30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or noncompliance and to remedy the defect or noncompliance. Therefore, any decision on this petition only applies to the subject vehicles that FCA no longer controlled at the time it determined that the noncompliance existed. However, any decision on this petition does not relieve vehicle distributors and dealers of the prohibitions on the sale, offer for sale, or introduction or delivery for introduction into interstate commerce of the noncompliant vehicles under their control after FCA notified them that the subject noncompliance existed.

Authority: 49 U.S.C. 30118, 30120; delegations of authority at 49 CFR 1.95 and 501.8

Otto G. Matheke III,
Director, Office of Vehicle Safety Compliance.

[FR Doc. 2020-15006 Filed 7-10-20; 8:45 am]

BILLING CODE 4910-59-P

DEPARTMENT OF TRANSPORTATION

[Docket No. DOT-OST-2020-0084]

Information Collection; Improving Customer Experience (OMB Circular A-11, Section 280 Implementation)

AGENCY: Department of Transportation.

ACTION: Notice; request for comment.

SUMMARY: The Department of Transportation (DOT) as part of its continuing effort to reduce paperwork and respondent burden, is announcing an opportunity for public comment on a new proposed collection of 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, and to allow 60 days for public comment in response to the notice. This notice solicits comments on new collection proposed by the Agency.

DATES: *Submit comments on or before:* September 11, 2020.

ADDRESSES: Submit comments identified by Information Collection, Improving Customer Experience (OMB Circular A-11, Section 280

Implementation), by any of the following methods:

- **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.

- **Mail:** Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Ave. SE, West Building Ground Floor, Room W12-140, Washington, DC 20590-0001.

- **Hand Delivery or Courier:** West Building Ground Floor, Room W12-140, 1200 New Jersey Ave. SE, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal Holidays.

- **Fax:** (202) 493-2251.

Instructions: You must include the agency name and docket number DOT-OST-2018-0151. Please submit comments only and cite Information Collection, Improving Customer Experience (OMB Circular A-11, Section 280 Implementation), in all correspondence related to this collection. All comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided. To confirm receipt of your comment(s), please check [regulations.gov](https://www.regulations.gov), approximately two-to-three business days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

Privacy Act: Anyone is able to search the electronic form of all comments received in any of our 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.). You may review DOT's complete Privacy Act statement in the **Federal Register** published on January 17, 2008 (73 FR 3316-3317).

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> or to the street address listed above. Follow the online instructions for accessing the docket.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Claire W. Barrett, Chief Privacy & Information Governance Officer, Office of the Chief Information Officer, Office of the Secretary, US Department of Transportation, 1200 New Jersey Ave. SE, Washington, DC 20590, via email to PRA@dot.gov, or via phone at 202.366.8135.

SUPPLEMENTARY INFORMATION:

A. Purpose

Under the PRA, (44 U.S.C. 3501-3520) Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA 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, DOT is publishing notice of the proposed collection of information set forth in this document.

Whether seeking a loan, Social Security benefits, veteran's benefits, or other services provided by the Federal Government, individuals and businesses expect Government customer services to be efficient and intuitive, just like services from leading private-sector organizations. Yet the 2016 American Consumer Satisfaction Index and the 2017 Forrester Federal Customer Experience Index show that, on average, Government services lag nine percentage points behind the private sector.

A modern, streamlined and responsive customer experience means: Raising government-wide customer experience to the average of the private sector service industry; developing indicators for high-impact Federal programs to monitor progress towards excellent customer experience and mature digital services; and providing the structure (including increasing transparency) and resources to ensure customer experience is a focal point for agency leadership. To support this, OMB Circular A-11 Section 280 established government-wide standards for mature customer experience organizations in government and measurement. To enable Federal programs to deliver the experience taxpayers deserve, they must undertake three general categories of activities: Conduct ongoing customer research, gather and share customer feedback, and test services and digital products.

These data collection efforts may be either qualitative or quantitative in nature or may consist of mixed methods. Additionally, data may be collected via a variety of means, including but not limited to electronic

or social media, direct or indirect observation (*i.e.*, in person, video and audio collections), interviews, questionnaires, surveys, and focus groups. DOT will limit its inquiries to data collections that solicit strictly voluntary opinions or responses. Steps will be taken to ensure anonymity of respondents in each activity covered by this request.

The results of the data collected will be used to improve the delivery of Federal services and programs. It will include the creation of personas, customer journey maps, and reports and summaries of customer feedback data and user insights. It will also provide government-wide data on customer experience that can be displayed on *performance.gov* to help build transparency and accountability of Federal programs to the customers they serve.

Method of Collection

DOT will collect this information by electronic means when possible, as well as by mail, fax, telephone, technical discussions, and in-person interviews. DOT may also utilize observational techniques to collect this information.

Data

Form Number(s): None.
Type of Review: New.

B. Annual Reporting Burden

Affected Public: Collections will be 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. For the purposes of this request, "customers" are individuals, businesses, and organizations that interact with a Federal Government agency or program, either directly or via a Federal contractor. This could include individuals or households; businesses or other for-profit organizations; not-for-profit institutions; State, local or tribal governments; Federal government; and Universities.

Estimated Number of Respondents: 2,001,550.

Estimated Time per Response: Varied, dependent upon the data collection method used. The possible response time to complete a questionnaire or survey may be 3 minutes or up to 1.5 hours to participate in an interview.

Estimated Total Annual Burden Hours: 101,125.

Estimated Total Annual Cost to Public: \$0.

C. Public Comments

DOT invites comments on: (a) Whether the proposed collection of

information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: July 2, 2020.

Claire W. Barrett,

Chief Privacy & Information Governance Officer.

[FR Doc. 2020-14757 Filed 7-10-20; 8:45 am]

BILLING CODE 4910-9X-P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

FEDERAL RESERVE SYSTEM

FEDERAL DEPOSIT INSURANCE CORPORATION

Joint Report: Differences in Accounting and Capital Standards Among the Federal Banking Agencies as of December 31, 2019; Report to Congressional Committees

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury; Board of Governors of the Federal Reserve System (Board); and Federal Deposit Insurance Corporation (FDIC).

ACTION: Report to Congressional Committees.

SUMMARY: The OCC, the Board, and the FDIC (collectively, the agencies) have prepared this report pursuant to section 37(c) of the Federal Deposit Insurance Act. Section 37(c) requires the agencies to jointly submit an annual report to the Committee on Financial Services of the U.S. House of Representatives and to the Committee on Banking, Housing, and Urban Affairs of the U.S. Senate describing differences among the accounting and capital standards used by the agencies for insured depository institutions. Section 37(c) requires that this report be published in the **Federal Register**. The agencies have not

identified any material differences among the agencies' accounting and capital standards applicable to the insured depository institutions they regulate and supervise.

FOR FURTHER INFORMATION CONTACT:

OCC: Andrew Tschirhart, Risk Expert, Capital Policy, (202) 649-6370, Office of the Comptroller of the Currency, 400 7th Street SW, Washington, DC 20219.

Board: Juan Climent, Manager, Capital and Regulatory Policy, (202) 872-7526, and Donald Gabbai, Lead Financial Institution Policy Analyst, (202) 452-3358, Division of Supervision and Regulation, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW., Washington, DC 20551.

FDIC: Benedetto Bosco, Chief, Capital Policy Section, (202) 898-6853, Richard Smith, Capital Policy Analyst, Capital Policy Section, (202) 898-6931, Division of Risk Management Supervision, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.

SUPPLEMENTARY INFORMATION: The text of the report follows:

Report to the Committee on Financial Services of the U.S. House of Representatives and to the Committee on Banking, Housing, and Urban Affairs of the U.S. Senate Regarding Differences in Accounting and Capital Standards Among the Federal Banking Agencies

Introduction

Under section 37(c) of the Federal Deposit Insurance Act (section 37(c)), the Office of the Comptroller of the Currency (OCC), the Board of Governors of the Federal Reserve System (Board), and the Federal Deposit Insurance Corporation (FDIC) (collectively, the agencies) must jointly submit an annual report to the Committee on Financial Services of the U.S. House of Representatives and the Committee on Banking, Housing, and Urban Affairs of the U.S. Senate that describes any differences among the accounting and capital standards established by the agencies for insured depository institutions (institutions).¹

In accordance with section 37(c), the agencies are submitting this joint report, which covers differences among their accounting or capital standards existing as of December 31, 2019, applicable to institutions.² In recent years, the

¹ See 12 U.S.C. 1831n(c)(1). This report must be published in the **Federal Register**. See 12 U.S.C. 1831n(c)(3).

² Although not required under section 37(c), this report includes descriptions of certain of the

agencies have acted together to harmonize their accounting and capital standards and eliminate as many differences as possible. As of December 31, 2019, the agencies have not identified any material differences among the agencies' accounting standards applicable to institutions.

In 2013, the agencies revised the risk-based and leverage capital rules for institutions (capital rules),³ which harmonized the agencies' capital rules in a comprehensive manner.⁴ Since 2013, the agencies have revised the capital rules on several occasions, further reducing the number of differences in the agencies' capital rules.⁵ Today, only a few differences remain, which are statutorily mandated for certain categories of institutions or which reflect certain technical, generally nonmaterial differences among the agencies' capital rules. No new material differences were identified in the capital standards applicable to institutions in this report compared to the previous report submitted by the agencies pursuant to section 37(c).

Differences in Accounting Standards Among the Federal Banking Agencies

As of December 31, 2019, the agencies have not identified any material differences among themselves in the accounting standards applicable to institutions.

Board's capital standards applicable to depository institution holding companies where such descriptions are relevant to the discussion of capital standards applicable to institutions.

³ See 78 FR 62018 (October 11, 2013) (final rule issued by the OCC and the Board); 78 FR 55340 (September 10, 2013) (interim final rule issued by the FDIC). The FDIC later issued its final rule in 79 FR 20754 (April 14, 2014). The agencies' respective capital rules are at 12 CFR part 3 (OCC), 12 CFR part 217 (Board), and 12 CFR part 324 (FDIC). These capital rules apply to institutions, as well as to certain bank holding companies and savings and loan holding companies. See 12 CFR 217.1(c).

⁴ The capital rules reflect the scope of each agency's regulatory jurisdiction. For example, the Board's capital rule includes requirements related to bank holding companies, savings and loan holding companies, and state member banks, while the FDIC's capital rule includes provisions for state nonmember banks and state savings associations, and the OCC's capital rule includes provisions for national banks and federal savings associations.

⁵ See e.g., 84 FR 35234 (July 22, 2019). The OCC and FDIC revised their capital rules to conform with language in the Board's capital rule related to the qualification criteria for additional tier 1 capital instruments and the definition of corporate exposures. As a result, these differences, which were included in the previous report submitted by the agencies pursuant to section 37(c), have been eliminated.

Differences in Capital Standards Among the Federal Banking Agencies

The following are the remaining technical differences among the capital standards of the agencies' capital rules.⁶

Definitions

The agencies' capital rules largely contain the same definitions.⁷ The differences that exist generally serve to accommodate the different needs of the institutions that each agency charters, regulates, and/or supervises.

The agencies' capital rules have differing definitions of a pre-sold construction loan. The capital rules of all three agencies provide that a pre-sold construction loan means any "one-to-four family residential construction loan to a builder that meets the requirements of section 618(a)(1) or (2) of the Resolution Trust Corporation Refinancing, Restructuring, and Improvement Act of 1991 (12 U.S.C. 1831n), and, in addition to other criteria, the purchaser has not terminated the contract."⁸ The Board's definition provides further clarification that, if a purchaser has terminated the contract, the institution must immediately apply a 100 percent risk weight to the loan and report the revised risk weight in the next quarterly Consolidated Reports of Condition and Income (Call Report).⁹ Similarly, if the purchaser has terminated the contract, the OCC and FDIC capital rules would immediately disqualify the loan from receiving a 50 percent risk weight, and would apply a 100 percent risk weight to the loan. The change in risk weight would be reflected in the next quarterly Call Report. Thus, the minor wording difference between the agencies should have no practical consequence.

Capital Components and Eligibility Criteria for Regulatory Capital Instruments

While the capital rules generally provide uniform eligibility criteria for regulatory capital instruments, there are some textual differences among the agencies' capital rules. All three agencies' capital rules require that, for an instrument to qualify as common equity tier 1 or additional tier 1 capital, cash dividend payments be paid out of net income and retained earnings, but the Board's capital rule also allows cash dividend payments to be paid out of

⁶ Certain minor differences, such as terminology specific to each agency for the institutions that it supervises, are not included in this report.

⁷ See 12 CFR 3.2 (OCC); 12 CFR 217.2 (Board); 12 CFR 324.2 (FDIC).

⁸ 12 CFR 3.2 (OCC); 12 CFR 217.2 (Board); 12 CFR 324.2 (FDIC).

⁹ 12 CFR 217.2.

related surplus.¹⁰ In addition, both the Board's capital rule and the FDIC's capital rule include an additional sentence noting that institutions regulated by each agency are subject to restrictions independent of the capital rule on paying dividends out of surplus and/or that would result in a reduction of capital stock.¹¹ These additional sentences do not create differences in substance between the agencies' capital standards, but rather note that restrictions apply under separate regulations. The provision in the Board's capital rule that allows dividends to be paid out of related surplus is a difference in substance among the agencies' capital rules. However, due to the restrictions on institutions regulated by the Board in separate regulations, this additional language in the Board's rule has a practical impact only on bank holding companies and savings and loan holding companies and is not a difference as applied to institutions. As a result, the agencies apply the criteria for determining eligibility of regulatory capital instruments in a manner that ensures consistent outcomes for institutions.

In addition, the Board's capital rule includes a requirement that a bank holding company or a savings and loan holding company must obtain prior approval before redeeming regulatory capital instruments.¹² This requirement applies only to a bank holding company or a savings and loan holding company and is, therefore, not included in the OCC and FDIC capital rules. However, all three agencies require institutions to obtain prior approval before redeeming regulatory capital instruments.¹³ The additional provision in the Board's rule, therefore, only has a practical impact on bank holding companies and savings and loan holding companies and is not a difference as applied to institutions.

Capital Deductions

There is a technical difference between the FDIC's capital rule and the OCC's and Board's capital rules with regard to an explicit requirement for deduction of examiner-identified losses.

¹⁰ 12 CFR 217.20(b)(1)(v) and 217.20(c)(1)(viii) (Board).

¹¹ See 12 CFR 217.20(b)(1)(v) and 217.20(c)(1)(viii) (Board); 12 CFR 324.20(b)(1)(v) and 324.20(c)(1)(viii) (FDIC). Although not referenced in the capital rule, the OCC has similar restrictions on dividends; see 12 CFR 5.55 and 12 CFR 5.63.

¹² 12 CFR 217.20(f).

¹³ See 12 CFR 5.46, 5.47, 5.55, and 5.56 (OCC); 12 CFR 208.5 (Board); 12 CFR 303.241 and 12 CFR 390.345 (incorporated into 12 CFR 303.241, effective Feb. 20, 2020 (85 FR 3232 (Jan. 21, 2020))) (FDIC).

The agencies require their examiners to determine whether their respective supervised institutions have appropriately identified losses. The FDIC's capital rule, however, explicitly requires FDIC-supervised institutions to deduct identified losses from common equity tier 1 capital elements, to the extent that the institutions' common equity tier 1 capital would have been reduced if the appropriate accounting entries had been recorded.¹⁴ Generally, identified losses are those items that an examiner determines to be chargeable against income, capital, or general valuation allowances.

For example, identified losses may include, among other items, assets classified as loss, off-balance-sheet items classified as loss, any expenses that are necessary for the institution to record in order to replenish its general valuation allowances to an adequate level, and estimated losses on contingent liabilities. The Board and the OCC expect their supervised institutions to promptly recognize examiner-identified losses, but the requirement is not explicit under their capital rules. Instead, the Board and the OCC apply their supervisory authorities to ensure that their supervised institutions charge off any identified losses.

Subsidiaries of Savings Associations

There are special statutory requirements for the agencies' capital treatment of a savings association's investment in or credit to its subsidiaries as compared with the capital treatment of such transactions between other types of institutions and their subsidiaries. Specifically, the Home Owners' Loan Act (HOLA) distinguishes between subsidiaries of savings associations engaged in activities that are permissible for national banks and those engaged in activities that are not permissible for national banks.¹⁵ When subsidiaries of a savings association are engaged in activities that are not permissible for national banks,¹⁶ the parent savings association generally must deduct the parent's investment in and extensions of

credit to these subsidiaries from the capital of the parent savings association. If a subsidiary of a savings association engages solely in activities permissible for national banks, no deduction is required and investments in and loans to that organization may be assigned the risk weight appropriate for the activity.¹⁷ As the appropriate federal banking agencies for federal and state savings associations, respectively, the OCC and the FDIC apply this capital treatment to those types of institutions. The Board's regulatory capital framework does not apply to savings associations and, therefore, does not include this requirement.

Tangible Capital Requirement

Federal statutory law subjects savings associations to a specific tangible capital requirement but does not similarly do so with respect to banks. Under section 5(t)(2)(B) of HOLA, savings associations are required to maintain tangible capital in an amount not less than 1.5 percent of total assets.¹⁸ The capital rules of the OCC and the FDIC include a requirement that savings associations maintain a tangible capital ratio of 1.5 percent.¹⁹ This statutory requirement does not apply to banks and, thus, there is no comparable regulatory provision for banks. The distinction is of little practical consequence, however, because under the Prompt Corrective Action (PCA) framework, all institutions are considered critically undercapitalized if their tangible equity falls below 2 percent of total assets.²⁰ Generally speaking, the appropriate federal banking agency must appoint a receiver within 90 days after an institution becomes critically undercapitalized.²¹

¹⁷ A deduction from capital is only required to the extent that the savings association's investment exceeds the generally applicable thresholds for deduction of investments in the capital of an unconsolidated financial institution.

¹⁸ See 12 U.S.C. 1464(t)(1)(A)(ii) and (t)(2)(B).

¹⁹ See 12 CFR 3.10(a)(6) (OCC); 12 CFR 324.10(a)(6) (FDIC). The Board's regulatory capital framework does not apply to savings associations and, therefore, does not include this requirement.

²⁰ See 12 U.S.C. 1831o(c)(3); see also 12 CFR 6.4 (OCC); 12 CFR 208.45 (Board); 12 CFR 324.403 (FDIC).

²¹ 12 U.S.C. 1831o(h)(3)(A).

Enhanced Supplementary Leverage Ratio

The agencies adopted enhanced supplementary leverage ratio standards that took effect beginning on January 1, 2018.²² These standards require certain bank holding companies to exceed a 5 percent supplementary leverage ratio to avoid limitations on distributions and certain discretionary bonus payments and also require the subsidiary institutions of these bank holding companies to meet a 6 percent supplementary leverage ratio to be considered "well capitalized" under the PCA framework.²³ The rule text establishing the scope of application for the enhanced supplementary leverage ratio differs among the agencies. The Board applies the enhanced supplementary leverage ratio standards to bank holding companies identified as global systemically important bank holding companies as defined in 12 CFR 217.2 and those bank holding companies' Board-supervised institution subsidiaries.²⁴ The OCC and the FDIC apply enhanced supplementary leverage ratio standards to the institution subsidiaries under their supervisory jurisdiction of a top-tier bank holding company that has more than \$700 billion in total assets or more than \$10 trillion in assets under custody.²⁵ The distinction is of little practical consequence at this time because the set of bank holding companies identified by each agency's regulations is the same.

Brian P. Brooks,

Acting Comptroller of the Currency.

Board of Governors of the Federal Reserve System.

Ann E. Misback,

Secretary of the Board.

Federal Deposit Insurance Corporation.

Dated at Washington, DC, on or about July 2, 2020.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2020-14991 Filed 7-10-20; 8:45 am]

BILLING CODE 4810-33-P; 6210-01-P; 6714-01-P

²² See 79 FR 24528 (May 1, 2014).

²³ See 12 CFR 6.4(c)(1)(iv)(B) (OCC); 12 CFR 208.43(b)(1)(iv)(B) (Board); 12 CFR 324.403(b)(1)(v) (FDIC).

²⁴ See 80 FR 49082 (August 14, 2015).

²⁵ See 12 CFR 6.4(c)(1)(iv)(B) (OCC); 12 CFR 324.403(b)(1)(v) (FDIC).

¹⁴ 12 CFR 324.22(a)(9).

¹⁵ See 12 U.S.C. 1464(t)(5).

¹⁶ Subsidiaries engaged in activities not permissible for national banks are considered non-includable subsidiaries.

DEPARTMENT OF THE TREASURY

United States Mint

Pricing for the 2020 Women’s Suffrage Centennial Silver Dollar

AGENCY: United States Mint, Department of the Treasury.

ACTION: Notice.

SUMMARY: The United States Mint is announcing pricing for the 2020 Women’s Suffrage Centennial Silver Dollar products as follows:

Product	Introductory Price	Regular Price
Proof Silver Dollar	\$69.00	\$74.00
Uncirculated Silver Dollar	64.00	69.00
Proof Silver Dollar and Medal Set	N/A	120.00

FOR FURTHER INFORMATION CONTACT: Rosa Matos, Program Manager for Sales and Marketing; United States Mint; 801 9th Street NW; Washington, DC 20220; or call 202-354-7500.

Authority: Public Law 116-71.

Eric Anderson,
Executive Secretary, United States Mint.
[FR Doc. 2020-15075 Filed 7-10-20; 8:45 am]

BILLING CODE P



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Part II

Environmental Protection Agency

40 CFR Part 63

National Emission Standards for Hazardous Air Pollutants: Integrated Iron and Steel Manufacturing Facilities Residual Risk and Technology Review; Final Rule

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 63**

[EPA-HQ-OAR-2002-0083; FRL-10008-45-OAR]

RIN 2060-AT03

National Emission Standards for Hazardous Air Pollutants: Integrated Iron and Steel Manufacturing Facilities Residual Risk and Technology Review**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule.

SUMMARY: This action finalizes the residual risk and technology review (RTR) conducted for the Integrated Iron and Steel Manufacturing Facilities source category regulated under national emission standards for hazardous air pollutants (NESHAP). The Agency found that risks due to emissions of air toxics from this source category are acceptable and that the current NESHAP provides an ample margin of safety to protect public health. Under the technology review, we found no developments in practices, processes, or control technologies that necessitate revision of the standards. In addition, we are taking final action to establish emission standards for mercury in response to a 2004 administrative petition for reconsideration which minimizes emissions by limiting the amount of mercury per ton of metal scrap used. We also are removing exemptions for periods of startup, shutdown, and malfunction (SSM) consistent with a 2008 court decision, and clarifying that the emissions standards apply at all times; adding electronic reporting of performance test results and compliance reports; and making minor corrections and clarifications for a few other rule provisions.

DATES: This final rule is effective on July 13, 2020. The incorporation by reference (IBR) of certain publications listed in the rule is approved by the Director of the Federal Register as of July 13, 2020.

ADDRESSES: The U.S. Environmental Protection Agency (EPA) has established a docket for this action under Docket ID No. EPA-HQ-OAR-2002-0083. All documents in the docket are listed on the <https://www.regulations.gov/> website. Although listed, some information is not publicly available, e.g., 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 electronically through <https://www.regulations.gov/>. Out of an abundance of caution for members of the public and our staff, the EPA Docket Center and Reading Room was closed to public visitors on March 31, 2020, to reduce the risk of transmitting COVID-19. Our Docket Center staff will continue to provide remote customer service via email, phone, and webform. There is a temporary suspension of mail delivery to the EPA, and no hand deliveries are currently accepted. For further information and updates on EPA Docket Center services and the current status, please visit us online at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: For questions about this final action, contact Dr. Donna Lee Jones, Sector Policies and Programs Division (D243-02), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541-5251; fax number: (919) 541-4991; and email address: jones.donnalee@epa.gov. For specific information regarding the risk assessment methodology, contact Ted Palma, Health and Environmental Impacts Division (C539-02), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541-5470; fax number: (919) 541-0840; and email address: palma.ted@epa.gov. For information about the applicability of the NESHAP to a particular entity, contact Maria Malave, Office of Enforcement and Compliance Assurance, U.S. Environmental Protection Agency, WJC South Building (Mail Code 2227A), 1200 Pennsylvania Avenue NW, Washington DC 20460; telephone number: (202) 564-7027; and email address: malave.maria@epa.gov.

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

ACI activated carbon injection
ADL above detection limit
AISI American Iron and Steel Institute
ANSI American National Standards Institute
ASME American Society of Mechanical Engineers
ASTM American Society for Testing and Materials
BDL below detection limit
BF blast furnace

BOPF basic oxygen process furnace
CAA Clean Air Act
CDX Central Data Exchange
CEDRI Compliance and Emissions Data Reporting Interface
CFR Code of Federal Regulations
COS carbonyl sulfide
DCOT Digital Camera Opacity Technique
DLL detection level limited
EAF electric arc furnace
EPA Environmental Protection Agency
ERT Electronic Reporting Tool
ESP electrostatic precipitators
HAP hazardous air pollutant(s)
HCl hydrochloric acid
HCN hydrogen cyanide
HI hazard index
HMTDS hot metal transfer, desulfurization, and skimming
HQ hazard quotient
IBR incorporation by reference
ICR information collection request
km kilometers
lbs pounds
MACT maximum achievable control technology
MIR maximum individual risk
NAICS North American Industry Classification System
NESHAP national emission standards for hazardous air pollutants
NRDC Natural Resources Defense Council
NVMSRP National Vehicle Mercury Switch Recovery Program
OAQPS Office of Air Quality Planning and Standards
OMB Office of Management and Budget
PDF portable document format
PM particulate matter
PM_{2.5} particulate matter at or below 2.5 micrometers.
ppm parts per million
REL reference exposure level
RFA Regulatory Flexibility Act
RTR residual risk and technology review
SSM startup, shutdown, and malfunction
TOSHI target organ-specific hazard index
tpy tons per year
UFIP unmeasured fugitive and intermittent particulate
UMRA Unfunded Mandates Reform Act
UPL upper prediction limit
U.S. United States
VCS voluntary consensus standards
VOC volatile organic compound

Background information. On August 16, 2019, the EPA proposed the results of the RTR and various amendments for the Integrated Iron and Steel Manufacturing Facilities NESHAP (84 FR 42704). In this action, we are finalizing decisions and revisions for the rule. We summarize some of the more significant comments we timely received regarding the proposed rule and provide our responses in this preamble. A summary of all other public comments on the proposal and the EPA's responses to those comments is available in the *Summary of Public Comments and Responses for the Risk and Technology Review for Integrated Iron and Steel Manufacturing Facilities* (Docket ID No. EPA-HQ-OAR-2002-

0083). A “redline” (track changes) version of the regulatory language that incorporates the changes in this action is available in the docket.

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

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- J. National Technology Transfer and Advancement Act (NTTAA) and 1 CFR part 51
- K. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations
- L. Congressional Review Act (CRA)

I. General Information

A. Does this action apply to me?

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

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

Source category	NESHAP	NAICS code ¹
Integrated Iron and Steel Manufacturing	40 CFR part 63, subpart FFFFF	331110

¹ North American Industry Classification System.

Table 1 of this preamble is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by the final action for the source category listed. To determine whether your facility is affected, you should examine the applicability criteria in the appropriate NESHAP. If you have any questions regarding the applicability of any aspect of this NESHAP, please contact the appropriate person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section of this preamble.

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

In addition to being available in the docket, an electronic copy of this final action will also be available on the internet. Following signature by the EPA Administrator, the EPA will post a copy of this final action at: <https://www.epa.gov/stationary-sources-air-pollution/integrated-iron-and-steel-manufacturing-national-emission-standards>.

pollution/integrated-iron-and-steel-manufacturing-national-emission-standards. Following publication in the **Federal Register**, the EPA will post the **Federal Register** version and key technical documents at this same website.

Additional information is available on the RTR website at <https://www.epa.gov/stationary-sources-air-pollution/risk-and-technology-review-national-emissions-standards-hazardous>. This information includes an overview of the RTR program, links to project websites for the RTR source categories.

C. Judicial Review and Administrative Reconsideration

Under Clean Air Act (CAA) section 307(b)(1), judicial review of this final action is available only by filing a petition for review in the United States Court of Appeals for the District of Columbia Circuit (the Court) by

September 11, 2020. Under CAA section 307(b)(2), the requirements established by this final rule may not be challenged separately in any civil or criminal proceedings brought by the EPA to enforce the requirements.

Section 307(d)(7)(B) of the CAA further provides that only an objection to a rule or procedure which was raised with reasonable specificity during the period for public comment (including any public hearing) may be raised during judicial review. This section also provides a mechanism for the EPA to reconsider the rule if the person raising an objection can demonstrate to the Administrator that it was impracticable to raise such objection within the period for public comment or if the grounds for such objection arose after the period for public comment (but within the time specified for judicial review) and if such objection is of central relevance to the outcome of the rule. Any person seeking to make such a demonstration should

submit a Petition for Reconsideration to the Office of the Administrator, U.S. EPA, Room 3000, WJC South Building, 1200 Pennsylvania Ave. NW, Washington, DC 20460, with a copy to both the person(s) listed in the preceding **FOR FURTHER INFORMATION CONTACT** section, and the Associate General Counsel for the Air and Radiation Law Office, Office of General Counsel (Mail Code 2344A), U.S. EPA, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

II. Background

A. What is the statutory authority for this action?

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

For these MACT standards, the statute specifies certain minimum stringency requirements, which are referred to as MACT floor requirements, and which may not be based on cost considerations. See CAA section 112(d)(3). For new sources, the MACT floor cannot be less stringent than the emission control achieved in practice by the best-controlled similar source. The MACT standards for existing sources can be less stringent than floors for new sources, but they cannot be less stringent than the average emission

limitation achieved by the best-performing 12 percent of existing sources in the category or subcategory (or the best-performing five sources for categories or subcategories with fewer than 30 sources). In developing MACT standards, we must also consider control options that are more stringent than the floor under CAA section 112(d)(2). We may establish standards more stringent than the floor, based on the consideration of the cost of achieving the emissions reductions, any non-air quality health and environmental impacts, and energy requirements.

In the second stage of the regulatory process, the CAA requires the EPA to undertake two different analyses, which we refer to as the technology review and the residual risk review. Under the technology review, we must review the technology-based standards and revise them “as necessary (taking into account developments in practices, processes, and control technologies)” no less frequently than every 8 years, pursuant to CAA section 112(d)(6). Under the residual risk review, we must evaluate the risk to public health remaining after application of the technology-based standards and revise the standards, if necessary, to provide an ample margin of safety to protect public health or to prevent, taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental effect. The residual risk review is required within 8 years after promulgation of the technology-based standards, pursuant to CAA section 112(f). In conducting the residual risk review, if the EPA determines that the current standards provide an ample margin of safety to protect public health, it is not necessary to revise the MACT standards pursuant to CAA section 112(f).¹ For more information on the statutory authority for this rule, see 84 FR 42704, August 16, 2019.

B. What is the Integrated Iron and Steel Manufacturing Facilities source category and how does the NESHAP regulate HAP emissions from the source category?

The EPA promulgated the Integrated Iron and Steel Manufacturing Facilities NESHAP on May 20, 2003 (68 FR 27646). The standards are codified at 40 Code of Federal Regulations (CFR) part 63, subpart FFFFF. The rule was

¹The Court has affirmed this approach of implementing CAA section 112(f)(2)(A): *NRDC v. EPA*, 529 F.3d 1077, 1083 (DC Cir. 2008) (“If EPA determines that the existing technology-based standards provide an ‘ample margin of safety,’ then the Agency is free to readopt those standards during the residual risk rulemaking.”).

amended on July 13, 2006 (71 FR 39579). The amendments added a new compliance option, revised emission limitations, reduced the frequency of repeat performance tests for certain emission units, added corrective action requirements, and clarified monitoring, recordkeeping, and reporting requirements. All documents used to develop the previous 2003 and 2006 final rules can be found in either the legacy docket, A-2000-44, or the electronic docket, EPA-HQ-OAR-2002-0083.

The Integrated Iron and Steel Manufacturing Facilities industry consists of facilities that produce steel from iron ore pellets, coke, metal scrap, and other raw materials using furnaces and other processes. The Integrated Iron and Steel Manufacturing Facilities source category includes sinter production, iron preparation, iron production, and steel production. The source category covered by this MACT standard currently includes 11 facilities.

The main sources of air toxics emissions from Integrated Iron and Steel Manufacturing Facilities are the blast furnace (BF); basic oxygen process furnace (BOPF); hot metal transfer, desulfurization, and skimming (HMTDS) operations; ladle metallurgy operations; sinter plant windbox; sinter plant discharge end; and sinter cooler. All 11 facilities have BFs, BOPFs, HMTDS operations, and ladle metallurgy operations. However, only three facilities have sinter plants. See 40 CFR 63.7852 for definitions of the emission units at integrated iron and steel manufacturing facilities.

The NESHAP includes emission limits for particulate matter (PM) and opacity standards (both of which are surrogates for PM HAP) for furnaces and sinter plants. The NESHAP also includes an emission limit for volatile organic compounds (VOC) for the sinter plant windbox exhaust stream or, as an alternative, an operating limit for the oil content of the sinter plant feedstock. The VOC and oil content limits serve as surrogates for all organic HAP emitted from the windbox.

C. What changes did we propose for the Integrated Iron and Steel Manufacturing Facilities source category in our August 16, 2019, proposal?

On August 16, 2019, the EPA published a proposed rule in the **Federal Register** for the Integrated Iron and Steel Manufacturing Facilities NESHAP, 40 CFR part 63, subpart FFFFF, that took into consideration the RTR analyses (84 FR 42704). In the proposed rule, we also proposed a numerical emissions standard for

mercury and an alternative compliance option based on limiting the amount of mercury in the metal scrap used by these facilities. In addition, we proposed the removal of exemptions for periods of SSM consistent with a 2008 court decision, and clarifying that the emissions standards apply at all times; the addition of electronic reporting of performance test results and compliance reports; and minor corrections and clarifications for a few other rule provisions.

D. Regulatory Background

In 2003, the EPA promulgated standards pursuant to CAA section 112(d)(2) and (3) for HAP emissions from the Integrated Iron and Steel Manufacturing Facilities source category. In 2004, the Sierra Club submitted an administrative petition for reconsideration on several issues, including adding standards for mercury, dioxins/furans, polycyclic aromatic hydrocarbons, benzene, and other organic HAP. In 2005, the EPA granted reconsideration to evaluate a possible mercury emission limit, but denied the petition for reconsideration to the extent it requested reconsideration of other issues. The Sierra Club sought judicial review of the 2003 NESHAP as well as the EPA's 2005 denial of the petition for reconsideration. In February 2010, the EPA asked the Court for a voluntary remand without vacatur of both the 2003 rule and the EPA's 2005 reconsideration denial letter. The Court granted this request and the rule and the letter denying reconsideration were remanded to the Agency.

III. What is included in this final rule?

This action finalizes the EPA's determinations pursuant to the RTR provisions of CAA section 112 for the Integrated Iron and Steel Manufacturing Facilities source category. This action also finalizes amendments to the NESHAP, including the addition of mercury emission limits, changes to SSM provisions, addition of electronic reporting, and minor corrections and clarifications to a number of other rule provisions. This final action also includes some changes to the August 2019 proposed requirements based on consideration of comments received during the public comment period described in section IV of this preamble.

A. What are the final rule amendments based on the risk review for the Integrated Iron and Steel Manufacturing Facilities source category?

The EPA proposed no changes to the Integrated Iron and Steel Manufacturing Facilities NESHAP based on the risk

review conducted pursuant to CAA section 112(f). In this action, we are finalizing our proposed determination that risks from this source category are acceptable, the standards provide an ample margin of safety to protect public health, and more stringent standards are not necessary to prevent an adverse environmental effect. Section IV.A.3 of this preamble provides a summary of key comments we received regarding the risk review and our responses to those comments.

B. What are the final rule amendments based on the technology review for the Integrated Iron and Steel Manufacturing Facilities source category?

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

C. What are the final rule amendments for mercury for the Integrated Iron and Steel Manufacturing Facilities source category?

The EPA is promulgating emissions standards for mercury for the Integrated Iron and Steel Manufacturing Facilities source category pursuant to CAA sections 112(d)(2) and (3).

We are promulgating a MACT floor limit of 0.00026 pounds (lbs) of mercury per ton of scrap processed as an input-based limit for all existing BOPFs and related units at existing integrated iron and steel facilities pursuant to CAA section 112(d)(3) for existing sources. We are finalizing the mercury emission limit for existing sources as proposed. We are providing two options to

demonstrate compliance with the input-based emission limit in the final rule: (1) Subsequent to an initial performance test required within 1 year of the effective date of the rule, conduct performance testing twice per permit cycle, (*i.e.*, mid-term and at initial or end term for permitted facilities, or every 2.5 years for facilities without a permit) at all BOPF-related units and convert the sum of the results to input-based units (*i.e.*, lbs of mercury per ton of scrap input) and document the results in a test report that can be submitted electronically to the delegated authority with the results (see section IV.E below); or (2) certify annually that the facility obtains all of their scrap from National Vehicle Mercury Switch Recovery Program (NVMSRP) participants (or similar program as approved by the delegated authority), or certify that the

scrap processed by the facility does not contain mercury switches. Existing sources will have 1 year to comply with the mercury emission limits.

Pursuant to CAA section 112(d)(3), the standard for new sources shall not be less stringent than the emission control that is achieved in practice by the best controlled similar source. We are promulgating a new source MACT limit of 0.000081 lbs of mercury per ton of scrap processed as an input-based limit for any new BOPF and related units, or any new integrated iron and steel facility. With regard to compliance, new sources will have the same options to demonstrate compliance as existing sources. These new source limits apply to BOPFs for which construction or reconstruction commenced after August 16, 2019.

The mercury emission limits, promulgated pursuant to CAA sections 112(d)(2) and (3), have been added to Table 1 in the NESHAP. In addition, 40 CFR 63.7791 (and related sections 40 CFR 63.7820, 63.7821, 63.7825, 63.7826, 63.7833, 63.7840, and 63.7841) describes the specific compliance deadlines and compliance options related to the control of mercury. Based on consideration of public comments discussed in section IV.C below, we made some minor revisions to the proposed deadlines, compliance options, and testing requirements in 40 CFR 63.7791, 63.7820(e), 63.7821(e), 63.7825, 63.7833(h), 63.7833(i), 63.7840(e), 63.7840(f), and 63.7841(b)(9)–(11). The specific revisions are described in section IV.C.5 of this preamble.

D. What are the final rule amendments addressing emissions during periods of SSM?

In this action, we are finalizing revisions to the SSM provisions of the NESHAP to ensure that they are consistent with the Court decision in *Sierra Club v. EPA*, 551 F. 3d 1019 (DC Cir. 2008), which vacated two provisions that exempted sources from the requirement to comply with otherwise applicable CAA section 112(d) emission standards during periods of SSM. We also are finalizing various other changes to modify reporting and monitoring as a result of the SSM revisions. Our analyses and changes related to these issues are discussed below. In addition, we are making minor revisions to aspects of the proposed SSM requirements in response to comments. These changes are discussed below in IV.D.5.

We are finalizing the proposed revision of 40 CFR 63.7810(a) to eliminate the SSM exemption. The

revision will apply after January 11, 2021. In addition, we are updating the references in Table 4 (the General Provisions Applicability Table) of 40 CFR part 63, subpart FFFFF, including the references to 40 CFR 63.6(f)(1) and (h)(1)—the provisions vacated by *Sierra Club v. EPA*. Consistent with *Sierra Club v. EPA*, the standards in this rule will apply at all times. We are also revising 40 CFR part 63, subpart FFFFF, Table 4 to change several references related to requirements that apply during periods of SSM. For example, we are eliminating the incorporation of the General Provisions' requirement that sources develop an SSM plan. We also are eliminating and revising certain recordkeeping and reporting requirements related to the SSM exemption.

The EPA has attempted to ensure that the provisions we eliminated are inappropriate, unnecessary, or redundant in the absence of the SSM exemption. In promulgating the standards in this rule, the EPA has taken into account startup and shutdown periods and, for the reasons explained below, has not proposed alternate standards for those periods. The integrated iron and steel industry has not identified (and there are no data indicating) any specific problems with removing the SSM provisions.

1. 40 CFR 63.7810(d) General Duty

We are promulgating revisions to the General Provisions table (Table 4) of 40 CFR part 63, subpart FFFFF by adding an entry for 40 CFR 63.6(e)(1)(i), which describes the general duty to minimize emissions, and including a “No” for new or reconstructed sources which commenced construction or reconstruction after August 16, 2019. For all other affected sources, we include “Yes on or before January 11, 2021 and No thereafter.” in column 3. Some of the language in that section is no longer necessary or appropriate in light of the elimination of the SSM exemption. We are instead adding general duty regulatory text at 40 CFR 63.7810(d) that reflects the general duty to minimize emissions while eliminating the reference to periods covered by an SSM exemption. The current language in 40 CFR 63.6(e)(1)(i) characterizes what the general duty entails during periods of SSM. With the elimination of the SSM exemption, there is no need to differentiate between normal operations, startup and shutdown, and malfunction events in describing the general duty. Therefore, the language the EPA is promulgating for 40 CFR 63.7810(d) does not include that language from 40 CFR 63.6(e)(1)

after January 11, 2021 for each such source, and after July 13, 2020 for new and reconstructed sources for which construction or reconstruction commenced after August 16, 2019.

We are also finalizing revisions to the General Provisions table (Table 4) of 40 CFR part 63, subpart FFFFF by adding an entry for 40 CFR 63.6(e)(1)(ii) and including “No, for new or reconstructed sources which commenced construction or reconstruction after August 16, 2019.” For all other affected sources, we are adding “Yes, on or before January 11, 2021 and No thereafter.” in column 3. 40 CFR 63.6(e)(1)(ii) imposes requirements that are not necessary with the elimination of the SSM exemption or are redundant with the general duty requirement being added at 40 CFR 63.7810(d).

2. SSM Plan

We are finalizing revisions to the General Provisions table (Table 4) of 40 CFR part 63, subpart FFFFF by adding an entry for 40 CFR 63.6(e)(3) and including “No, for new or reconstructed sources which commenced construction or reconstruction after August 16, 2019. For all other affected sources, Yes, on or before January 11, 2021 and No thereafter.” in column 3. Generally, the paragraphs under 40 CFR 63.6(e)(3) require development of an SSM plan and specify SSM recordkeeping and reporting requirements related to the SSM plan. As the EPA is removing the SSM exemptions, the affected units will be subject to an emission standard during such events. The applicability of a standard during such events will ensure that sources have ample incentive to plan for and achieve compliance and, thus, the SSM plan requirements are no longer necessary. For that same reason, we are revising 40 CFR 63.7810(c) to remove the SSM plan requirement 180 days after publication in the **Federal Register** for sources that commenced construction or reconstruction on or before August 16, 2019, and to remove the SSM plan requirement upon publication in the **Federal Register** for all sources that commenced construction or reconstruction after August 16, 2019.

3. Compliance With Standards

We are finalizing revisions to the General Provisions table (Table 4) of 40 CFR part 63, subpart FFFFF by adding an entry for 40 CFR 63.6(f)(1) and including “No” in column 3. The exemption at 40 CFR 63.6(f)(1), which exempted sources from non-opacity standards during periods of SSM, was vacated by the Court in *Sierra Club v. EPA*, as discussed above.

We also are finalizing revisions to the General Provisions table (Table 4) of 40 CFR part 63, subpart FFFFF by adding an entry for 40 CFR 63.6(h)(1) and including “No” in column 3. The exemption at 40 CFR 63.6(h)(1), which exempted sources from opacity standards during periods of SSM, was also vacated by the Court in *Sierra Club v. EPA*. Consistent with *Sierra Club v. EPA*, the EPA is finalizing revisions to standards in this rule to ensure that a CAA section 112 standard applies at all times.

4. 40 CFR 63.7822 and 63.7823 Performance Testing

We are finalizing revisions to the General Provisions table (Table 4) of 40 CFR part 63, subpart FFFFF by adding an entry for 40 CFR 63.7(e)(1) and including “No, for new or reconstructed sources which commenced construction or reconstruction after August 16, 2019. For all other affected sources, Yes, on or before January 11, 2021 and No thereafter.” in column 3. In section 40 CFR 63.7(e)(1), performance testing requirements are described. The EPA is instead adding a performance testing requirement at 40 CFR 63.7822(a) and 63.7823(a). The performance testing requirements we are adding differ from the General Provisions performance testing provisions in several respects. The regulatory text we are adding does not include the language in 40 CFR 63.7(e)(1) that restated the SSM exemption and precluded SSM periods from being considered “representative” for purposes of performance testing. In 40 CFR 63.7(e)(1), performance tests conducted under this subpart should not be conducted during SSM because conditions during SSM are often not representative of normal operating conditions. During SSM periods, both emission and flow rate profiles can be highly variable and unsuitable for the emission measurement methods. The EPA is promulgating language that requires the owner or operator to record the process information that is necessary to document operating conditions during the test and include in this record an explanation to support that such conditions represent normal operation. In 40 CFR 63.7(e), the owner or operator is required to make available to the Administrator on request such records “as may be necessary to determine the condition of the performance test,” but does not specifically require the information to be recorded. The regulatory text the EPA is adding to this provision builds onto that requirement and makes explicit the requirement to record the information.

5. Monitoring

We are finalizing revisions to the General Provisions table (Table 4) of 40 CFR part 63, subpart FFFFFF by adding entries for 40 CFR 63.8(c)(1)(i) and (iii) and including “No, for new or reconstructed sources which commenced construction or reconstruction after August 16, 2019. For all other affected sources, Yes, on or before January 11, 2021 and No thereafter.” in column 3. The cross-references to the general duty and SSM plan requirements in those subparagraphs are not necessary in light of other requirements of 40 CFR 63.8 that require good air pollution control practices (40 CFR 63.8(c)(1)) and that set out the requirements of a quality control program for monitoring equipment (40 CFR 63.8(d)).

We are finalizing revisions to the General Provisions table (Table 4) of 40 CFR part 63, subpart FFFFFF by adding an entry for 40 CFR 63.8(d)(3) and including “No, for new or reconstructed sources which commenced construction or reconstruction after August 16, 2019. For all other affected sources, Yes, on or before January 11, 2021 and No thereafter.” in column 3. The final sentence in 40 CFR 63.8(d)(3) refers to the General Provisions’ SSM plan requirement which is no longer applicable. The EPA is adding to the rule at 40 CFR 63.7842(b)(3) text that is identical to 40 CFR 63.8(d)(3) except that the final sentence is replaced with the following sentence: “The program of corrective action should be included in the plan required under 40 CFR 63.8(d)(2).”

6. 40 CFR 63.7842 Recordkeeping

We are finalizing revisions to the General Provisions table (Table 4) of 40 CFR part 63, subpart FFFFFF by adding an entry for 40 CFR 63.10(b)(2)(i) and including “No, for new or reconstructed sources which commenced construction or reconstruction after August 16, 2019. For all other affected sources, Yes, on or before January 11, 2021 and No thereafter.” in column 3. 40 CFR 63.10(b)(2)(i) describes the recordkeeping requirements during startup and shutdown. These recording provisions are no longer necessary because the EPA is requiring that recordkeeping and reporting applicable to normal operations would apply to startup and shutdown. In the absence of special provisions applicable to startup and shutdown, such as a startup and shutdown plan, there is no reason to retain additional recordkeeping for startup and shutdown periods.

We are finalizing revisions to the General Provisions table (Table 4) of 40 CFR part 63, subpart FFFFFF by adding an entry for 40 CFR 63.10(b)(2)(ii) and including “No, for new or reconstructed sources which commenced construction or reconstruction after August 16, 2019. For all other affected sources, Yes, on or before January 11, 2021 and No thereafter.” in column 3. 40 CFR 63.10(b)(2)(ii) describes the recordkeeping requirements during a malfunction. The EPA is adding such requirements to 40 CFR 63.7842. The regulatory text we are adding differs from the General Provisions it is replacing in that the General Provisions requires the creation and retention of a record of the occurrence and duration of each malfunction of process, air pollution control, and monitoring equipment. The EPA is finalizing this requirement to apply to any failure to meet an applicable standard and is requiring the source to record the date, time, and duration of the failure rather than the “occurrence.” The EPA is also adding to 40 CFR 63.7842(a)(3) a requirement that sources keep records that include a list of the affected sources or equipment and actions taken to minimize emissions, an estimate of the quantity of each regulated pollutant emitted over the standard for which the source failed to meet the standard, and a description of the method used to estimate the emissions. Examples of such methods would include product-loss calculations, mass balance calculations, measurements when available, or engineering judgment based on known process parameters. The EPA is requiring that sources keep records of this information to ensure that there is adequate information to allow the EPA to determine the severity of any failure to meet a standard, and to provide data that may document how the source met the general duty to minimize emissions when the source has failed to meet an applicable standard.

We are finalizing revisions to the General Provisions table (Table 4) of 40 CFR part 63, subpart FFFFFF by adding an entry for 40 CFR 63.10(b)(2)(iv) and including “No, for new or reconstructed sources which commenced construction or reconstruction after August 16, 2019. For all other affected sources, Yes, on or before January 11, 2021 and No thereafter.” in column 3. When applicable, the provision requires sources to record actions taken during SSM events when actions were inconsistent with their SSM plan. The requirement is no longer appropriate because SSM plans would no longer be

required. The requirement previously applicable under 40 CFR 63.10(b)(2)(iv) to record actions to minimize emissions and record corrective actions during SSM is now applicable at all times by 40 CFR 63.7842(a)(4).

We are finalizing revisions to the General Provisions table (Table 4) of 40 CFR part 63, subpart FFFFFF by adding an entry for 40 CFR 63.10(b)(2)(v) and including “No, for new or reconstructed sources which commenced construction or reconstruction after August 16, 2019. For all other affected sources, Yes, on or before January 11, 2021 and No thereafter.” in column 3. When applicable, the provision requires sources to record actions taken during SSM events to show that actions taken were consistent with their SSM plan. The requirement is no longer appropriate because SSM plans would no longer be required.

We are finalizing revisions to the General Provisions table (Table 4) of 40 CFR part 63, subpart FFFFFF by adding an entry for 40 CFR 63.10(c)(15) and including “No, for new or reconstructed sources which commenced construction or reconstruction after August 16, 2019. For all other affected sources, Yes, on or before January 11, 2021 and No thereafter.” in column 3. Because the SSM plan requirement is being eliminated, 40 CFR 63.10(c)(15) no longer applies. When applicable, the provision allowed an owner or operator to use the affected source’s SSM plan or records kept to satisfy the recordkeeping requirements of the SSM plan, specified in 40 CFR 63.6(e), to also satisfy the requirements of 40 CFR 63.10(c)(10) through (12). The EPA is eliminating this requirement because SSM plans would no longer be required, and, therefore, 40 CFR 63.10(c)(15) no longer serves any useful purpose for affected units.

7. 40 CFR 63.7841 Reporting

We are finalizing revisions to the General Provisions table (Table 4) of 40 CFR part 63, subpart FFFFFF by adding an entry for 40 CFR 63.10(d)(5)(i) and including “No, for new or reconstructed sources which commenced construction or reconstruction after August 16, 2019. For all other affected sources, Yes, on or before January 11, 2021 and No thereafter.” in column 3. 40 CFR 63.10(d)(5)(i) describes the reporting requirements for startups, shutdowns, and malfunctions. To replace the General Provisions reporting requirement, the EPA is adding reporting requirements to 40 CFR 63.7841(b)(4). The replacement language differs from the General Provisions requirement in that it eliminates

periodic SSM reports as a stand-alone report. We are adding language that requires sources that fail to meet an applicable standard at any time to report the information concerning such events in the semiannual reporting period compliance report already required under this rule. We are requiring the report to contain the date, time, duration, and the cause of such events (including unknown cause, if applicable), a list of the affected source or equipment, an estimate of the quantity of each regulated pollutant emitted over any emission limit, and a description of the method used to estimate the emissions. Examples of such methods would include product-loss calculations, mass balance calculations, measurements when available, or engineering judgment based on known process parameters. The EPA is promulgating this requirement to ensure that there is adequate information to determine compliance, to allow the EPA to determine the severity of the failure to meet an applicable standard, and to provide data that may document how the source met the general duty to minimize emissions during a failure to meet an applicable standard.

We are no longer requiring owners or operators to determine whether actions taken to correct a malfunction are consistent with an SSM plan, because plans are no longer required. These final amendments, therefore, eliminate from this section the cross-reference to 40 CFR 63.10(d)(5)(i) that contains the description of the previously required SSM report format and submittal schedule. These specifications are no longer necessary because the SSM events would be reported in otherwise required periodic reports with similar format and submittal requirements.

We are finalizing revisions to the General Provisions table (Table 4) of 40 CFR part 63, subpart FFFFF by adding an entry for 40 CFR 63.10(d)(5)(ii) and including “No, for new or reconstructed sources which commenced construction or reconstruction after August 16, 2019. For all other affected sources, Yes, on or before January 11, 2021 and No thereafter.” in column 3. 40 CFR 63.10(d)(5)(ii) describes an immediate report for startups, shutdown, and malfunctions when a source failed to meet an applicable standard but did not follow the SSM plan. We are no longer requiring owners and operators to report when actions taken during an SSM event were not consistent with an SSM plan, because such plans are no longer required.

E. What are the final rule amendments addressing electronic reporting?

Through this final rule, the EPA is requiring that owners and operators of integrated iron and steel manufacturing facilities submit the required electronic copies of performance test results and semiannual reports through the EPA’s Central Data Exchange (CDX) using the Compliance and Emissions Data Reporting Interface (CEDRI). A description of the electronic data submission process is provided in the memorandum titled *Electronic Reporting Requirements for New Source Performance Standards (NSPS) and National Emission Standards for Hazardous Air Pollutants (NESHAP) Rules* (Docket ID Item No. EPA–HQ–OAR–2002–0083–0909).

This final rule requires that performance test results collected using test methods that are supported by the EPA’s Electronic Reporting Tool (ERT), as listed on the ERT website at the time of the test, be submitted in the format generated through the use of the ERT, and that other performance test results be submitted in portable document format (PDF) using the attachment module of the ERT. Similarly, performance evaluation results of continuous monitoring systems that measure relative accuracy test audit pollutants that are supported by the ERT at the time of the test, should be submitted in the format generated through the use of the ERT; other performance evaluation results should be submitted in PDF using the attachment module of the ERT. For semiannual compliance reports, the final rule requires that owners and operators use the appropriate spreadsheet template to submit information to CEDRI. The draft template for these reports is included in the docket for this rulemaking and the final template will be available on the CEDRI homepage (<https://www.epa.gov/electronic-reporting-air-emissions/cedri>).

Additionally, the EPA has identified two broad circumstances in which electronic reporting extensions may be provided. In both circumstances, the decision to accept the claim of needing additional time to report is within the discretion of the Administrator, and reporting should occur as soon as possible. The EPA is providing these potential extensions to protect owners and operators from noncompliance in cases where they cannot successfully submit a report by the reporting deadline for reasons outside of their control. The situation where an extension may be warranted due to

outages of the EPA’s CDX or CEDRI which precludes an owner or operator from accessing the system and submitting required reports is addressed in 40 CFR 63.7841(e). The situation where an extension may be warranted due to a force majeure event, which is defined as an event that would be or has been caused by circumstances beyond the control of the affected facility, its contractors, or any entity controlled by the affected facility that prevents an owner or operator from complying with the requirement to submit a report electronically as required by this rule is addressed in 40 CFR 63.7841(f). Examples of such events are acts of nature, acts of war or terrorism, or equipment failure or safety hazards beyond the control of the facility.

The electronic submittal of the reports addressed in this rulemaking will increase the usefulness of the data contained in those reports, is in keeping with current trends in data availability and transparency, will further assist in the protection of public health and the environment, will improve compliance by facilitating the ability of regulated facilities to demonstrate compliance with requirements, and by facilitating the ability of delegated state, local, tribal, and territorial air agencies and the EPA to assess and determine compliance, and will ultimately reduce burden on regulated facilities, delegated air agencies, and the EPA. Electronic reporting also eliminates paper-based, manual processes, thereby saving time and resources, simplifying data entry, eliminating redundancies, minimizing data reporting errors, and providing data quickly and accurately to the affected facilities, air agencies, the EPA, and the public. Moreover, electronic reporting is consistent with the EPA’s plan to implement Executive Order 13563 and is in keeping with the EPA’s Agency-wide policy developed in response to the White House’s Digital Government Strategy. For more information on the benefits of electronic reporting, see the memorandum titled *Electronic Reporting Requirements for New Source Performance Standards (NSPS) and National Emission Standards for Hazardous Air Pollutants (NESHAP) Rules* (Docket ID Item No. EPA–HQ–OAR–2002–0083–0909).

We are also making minor revisions to aspects of the proposed electronic reporting requirements in response to comments. These rule changes are discussed in section IV.E.5 of this preamble.

F. What other changes are being made to the NESHAP?

1. IBR Under 1 CFR Part 51

We are promulgating regulatory text that includes IBR. In accordance with requirements of 1 CFR 51.5, the EPA is incorporating by reference the three documents listed below and amending 40 CFR 63.14 to identify the provisions for which these documents are IBR approved for this rule:

- ANSI/ASME PTC 19.10–1981, Flue and Exhaust Gas Analyses [Part 10, Instruments and Apparatus], issued August 31, 1981, IBR approved for 40 CFR 63.7822(b), 63.7824(e) and 63.7825(b). This method determines quantitatively the gaseous constituents of exhausts resulting from stationary combustion sources. The gases addressed in the method are oxygen, carbon dioxide, carbon monoxide, nitrogen, sulfur dioxide, sulfur trioxide, nitric oxide, nitrogen dioxide, hydrogen sulfide, and hydrocarbons. The method is approved for this rule for oxygen and carbon dioxide measurements, with the caveats described in section VI.J of this preamble.

- ASTM D7520–16, Standard Test Method for Determining the Opacity of a Plume in the Outdoor Ambient Atmosphere, approved April 1, 2016, IBR approved for 40 CFR 63.7823(c), 63.7823(d), 63.7823(e), and 63.7833(g). This method describes procedures to determine the opacity of a plume, using digital imagery and associated hardware and software, where opacity is caused by PM emitted from a stationary point source in the outdoor ambient environment. The opacity of emissions is determined by the application of a digital camera opacity technique (DCOT) that consists of a digital still camera, analysis software, and the output function's content to obtain and interpret digital images to determine and report plume opacity. The method is approved for this rule with caveats described in section VI.J of this preamble.

- Fabric Filter Bag Leak Detection Guidance, EPA–454/R–98–015, Office of Air Quality Planning and Standards (OAQPS), September 1997, IBR approved for 40 CFR 63.7831(f). This document provides guidance on the use of triboelectric monitors as fabric filter bag leak detectors. The document includes fabric filter and monitoring system descriptions; guidance on monitor selection, installation, setup, adjustment, and operation; and quality assurance procedures.

2. Technical and Editorial Rule Corrections and Clarifications

In this final rule, the EPA is making a number of technical and editorial changes to the NESHAP to reflect corrections and clarifications. These revisions are described in section IV.G.3 of this preamble.

G. What are the effective and compliance dates of the standards?

This final rule is effective on July 13, 2020. Because most of these amendments provide corrections and clarifications to the current rule and do not impose new requirements on the industry, existing sources are required to comply with the amendments 180 days after publication of the final rule, except where indicated otherwise, as in the provisions for mercury. Sources constructed on or before August 16, 2019 must comply with the mercury emission limits within 1 year of publication of the final rule. New BOPF or new facilities constructed or reconstructed after August 16, 2019, must comply with the new source mercury emission limit on the effective date of the final rule, or upon startup, whichever is later. Electronic reporting for the compliance report is required beginning either 180 days after promulgation of the final rule or 180 days after the spreadsheet template is available in CEDRI, whichever is later. Electronic reporting of performance tests is required upon promulgation of the final rule.

IV. What is the rationale for our final decisions and amendments for the Integrated Iron and Steel Manufacturing Facilities source category?

For each significant issue, this section provides a description of what we proposed and what we are finalizing for each issue, the EPA's rationale for the final decisions and amendments, a summary of key comments and responses, and impact on final rule language, if applicable. For all comments not discussed in this preamble, comment summaries and the EPA's responses can be found in the *Summary of Public Comments and Responses for the Risk and Technology Review for Integrated Iron and Steel Manufacturing Facilities* document, which is available in the docket.

A. Residual Risk Review for the Integrated Iron and Steel Manufacturing Facilities Source Category

1. What did we propose pursuant to CAA section 112(f) for the Integrated Iron and Steel Manufacturing Facilities source category?

On August 16, 2019 (84 FR 42704), the EPA proposed that risks posed by emissions from the source category are acceptable, that the current NESHAP provides an ample margin of safety to protect public health, and that additional standards are not necessary to prevent an adverse environmental effect. The estimated cancer risks were below the presumptive limit of acceptability and the noncancer risk results indicate there is minimal likelihood of adverse noncancer health effects due to HAP emissions from this source category. The proposed decision on ample margin of safety was based on weighing factors relevant to this particular source category, including the risk posed by point sources and the costs and cost-effectiveness of additional controls to reduce risk further, as well as uncertainties in the assessment of unmeasured fugitive and intermittent particulate (UFIP),² including uncertainties in the baseline emissions estimates used in estimating risk posed by UFIP emissions, the costs and effectiveness of the work practices we considered to reduce these emissions, and the amount of risk reduction that could be achieved with the work practices.

The EPA sets standards under CAA section 112(f)(2) using “a two-step standard-setting approach, with an analytical first step to determine an ‘acceptable risk’ that considers all health information, including risk estimation uncertainty, and includes a presumptive limit on maximum individual risk (MIR) of approximately 1-in-10 thousand.” (54 FR 38045, September 14, 1989). In the proposal, the EPA estimated risks based on actual and allowable emissions from integrated iron and steel sources, and we considered these in determining acceptability. A more thorough discussion of the risk assessment is included in the *Residual Risk Assessment for the Integrated Iron and Steel Manufacturing Source Category in Support of the Risk and Technology Review 2020 Final Rule* document, available in the docket for this rule

² The UFIP sources are BF bleeder valve unplanned openings (also known as slips), BF bleeder valve planned openings, BF bell leaks, BF casthouse fugitives, BF iron beaching, BF slag handling and storage operations, and BOPF shop fugitives.

(Docket ID No. EPA-HQ-OAR-2002-0083).

In the proposed rule, as presented in Table 2 below, based on modeling point source actual emissions from the source category for all 11 facilities, we estimated inhalation cancer risk to the individual most exposed was 10-in-1 million. The estimated incidence of cancer due to inhalation exposures due to the point sources for the source category was 0.03 excess cancer cases per year, or one excess case every 33 years. We estimated that approximately 64,000 people face an increased cancer risk greater than or equal to 1-in-1 million due to inhalation exposure to HAP emissions from the point sources for this source category. The Agency estimated that the maximum chronic

noncancer target organ-specific hazard index (TOSHI) from inhalation exposure due to point sources for this source category was 0.1. In the screening assessment of worst-case acute inhalation impacts due to point sources, we estimated a maximum hazard quotient (HQ) of 0.3 (due to arsenic) based on the reference exposure level (REL). With regard to multipathway human health risks, we estimated the cancer risk for the highest exposed individual to be 40-in-1 million (due to dioxins/furans emissions from sinter plants) and the maximum chronic noncancer hazard quotient (HQ) to be less than 1 for all the persistent and bioaccumulative HAP. Based on the results of the environmental risk screening analysis, we do not expect an

adverse environmental effect as a result of HAP emissions from point source emissions from this source category.

As shown in Table 2, based on allowable emissions, the estimated inhalation cancer risk to the individual most exposed from point sources in the source category is 70-in-1 million and the estimated incidence of cancer due to inhalation exposures to these allowable emissions is 0.3 excess cancer cases per year, or one excess case every 3 years. An estimated 6 million people would face an increased cancer risk greater than or equal to 1-in-1 million due to inhalation exposure to allowable HAP emissions from this source category. The maximum chronic noncancer TOSHI from inhalation exposure is 0.9 based on allowable emissions.

TABLE 2—RISK SUMMARY FOR THE INTEGRATED IRON AND STEEL MANUFACTURING SOURCE CATEGORY POINT SOURCE EMISSIONS

Emissions	Inhalation cancer risk		Population cancer risk			Max chronic individual noncancer risk		Max acute noncancer risk		Multipathway assessment
	Maximum individual risk (in 1 million)	Risk driver	Cancer incidence (cases per year)	≥10 in 1 million	≥1 in 1 million	Hazard index (TOSHI)	Risk driver	Hazard quotient	Risk driver	Risk driver and health endpoints
Baseline Actual Emissions: Source Category.	10	chromium (VI) compounds.	0.03	60	64,000	0.1 (developmental).	arsenic and lead compounds.	0.7	arsenic compounds.	Cancer (dioxins/furans) site-specific MIR = 40-in-1 million; Noncancer (mercury) site-specific HQ = 0.5
Baseline Allowable Emissions: Source Category.	70	arsenic compounds, chromium (VI) compounds, nickel compounds, cadmium compounds.	0.3	79,500	5,900,000	0.9 (developmental).	arsenic and lead compounds.	

We also estimated risk posed by both point source and nonpoint (*i.e.*, UFIP) emissions from an actual facility in the category that we selected as an example facility. Of the facilities in the category, the example facility has the largest production capacity, the highest estimated HAP emissions from steel-making sources (*i.e.*, facility emissions not including sinter plant emissions), and the highest estimated UFIP emissions. The example facility is also the facility with the highest potential population exposure (4 million people within 50 kilometers of the facility). The EPA conducted a risk assessment using conservative emissions estimates to evaluate the potential exposures and risks due to all the emissions for this one example facility. We performed the risk analysis for the example facility to assess the potential change in the magnitude of risk when risk from UFIP

emissions is added to risk posed by point-source emissions. The estimated risks due to actual emissions from nonpoint (*i.e.*, UFIP) and point sources for the example facility are presented in Table 3.

When UFIP sources were included in the EPA's risk analysis, the estimated HAP emissions increased from 3 tpy to 53 tpy and the estimated inhalation cancer risk to the individual most exposed to actual emissions from the example facility increased from 2-in-1 million to 20-in-1 million. The estimated population with risks greater than or equal to 1-in-1 million increased from 3,000 to 4,000,000, and the population with risks greater than or equal to 10-in-1 million increased from 0 to 9,000. The maximum chronic noncancer TOSHI from inhalation exposures remained at less than 1, but the acute HQ increased from 0.3 to 3

based on the REL (for arsenic). The two UFIP sources that are the greatest contributors to the inhalation risk in terms of MIR were the BF casthouse and BOPF shop, which are currently regulated by opacity limits in the rule. Based on allowable emissions, the estimated inhalation cancer risk to the individual most exposed increased from 30-in-1 million to 50-in-1 million with the inclusion of emissions from UFIP sources.

There is considerable uncertainty in the estimated risk due to UFIP sources for the example facility due to the uncertainties in the estimated UFIP emissions and release parameters. Nevertheless, if UFIP emissions were quantified for the entire source category, the source category risks and the number of individuals with cancer risk exceeding 1-in-1 million would be expected to increase for each facility.

Although it is problematic to estimate from our risk assessment results (shown in Tables 2 and 3) what the increase in risk might be for each facility in the entire industry without quantifying UFIP emissions for each facility, based upon results from the example facility, we concluded that it is likely that the cancer MIR based on allowable

emissions at all other facilities would be less than 90-in-1 million (70-in-1 million from point sources and up to 20-in-1 million from UFIP emissions) and the maximum chronic noncancer HI would be less than 1. For information on the development of emission estimates from the example facility, see the memorandum titled *Development of*

Emissions Estimates for Fugitive or Intermittent HAP Emission Sources for an Example Integrated Iron and Steel Facility for Input to the RTR Risk Assessment (Docket ID Item No. EPA-HQ-OAR-2002-0083-0956), hereafter called the “Example Facility memorandum.”

TABLE 3—INHALATION RISK RESULTS—EXAMPLE FACILITY WITH AND WITHOUT UFIP EMISSIONS

Emissions	Example facility sources	Inhalation chronic cancer				Inhalation chronic noncancer		Acute noncancer	
		MIR (in 1-M)	Incidence	Pop >1-in-1 million	Pop >10-in-1 million	HI (TOSHI)	Target organ	HQ	Pollutant
Actual	Point Sources <i>Only</i>	2	0.010	3,000	0	0.03	Developmental	0.3	Arsenic Arsenic
	Point Sources & UFIP Emissions	20	0.12	4,000,000	9,000	0.3	Developmental	3	
Allowables	Point Sources <i>Only</i>	30	0.13	4,000,000	11,000	0.3	Developmental
	Point Sources & UFIP Emissions	50	0.24	4,000,000	90,000	0.7	Developmental

Although we did not assess multipathway risks for the example facility used to represent a “worst case” for UFIP emissions, the highest exposed individual for dioxins/furans in the point source modeling was not due to the example facility. Furthermore, none of the UFIP sources are known to emit dioxins/furans emissions. In addition, because mercury is emitted as a gas, UFIP emissions, which are PM, did not add to mercury emissions. See the Example Facility memorandum cited above for more information on the estimated emissions from the model facility.

Furthermore, it is important to note that after the EPA completed its risk modeling, the American Iron and Steel Institute (AISI) provided additional, more recent test data for the example facility that suggest arsenic emissions are lower than the level we estimated based on the 2011 information collection request (ICR) data that we used in our analysis (Docket ID Item No. EPA-HQ-OAR-2002-0083-0804). The AISI also conducted their own risk assessment using the new data and using the same modeling methodology that the EPA uses. The results presented by AISI (described in the EPA’s proposal preamble at 84 FR 42704) indicate the MIR when the UFIP emissions are included could be about 60 percent lower than the estimated value in the EPA’s risk characterization presented above (*i.e.*, 8-in-1 million compared to the EPA’s estimate of 20-in-1 million) and that population risks also could be substantially lower than the EPA’s estimate presented above in this preamble, with an estimated 500,000 people with risks greater than or equal to 1-in-1 million compared to the estimate of 4,000,000 in the EPA’s risk characterization. Therefore, we conclude the emissions used in our risk

assessment are likely conservative (upper-end) estimates.

In determining whether risks are acceptable for this source category, the EPA considered all available health information and risk estimation uncertainty that includes the uncertainty in the data from both point sources and the estimated UFIP emissions. (See proposal at 84 FR 42716, section III.C.8, *How do we consider uncertainties in risk assessment?*) A more thorough discussion of the uncertainties is included in the *Residual Risk Assessment for the Integrated Iron and Steel Manufacturing Source Category in Support of the Risk and Technology Review 2020 Final Rule*, available in the docket for this rule (Docket ID No. EPA-HQ-OAR-2002-0083).

The risk results indicate that the inhalation cancer risks to the individual most exposed could be more than 70-in-1-million but less than 90-in-1 million, as a worst case, based on the highest allowable emissions due to point sources among the industry facilities plus the conservative estimate of risk from UFIP emissions, and also considering the uncertainties in the example facility analysis as discussed above and in the proposal (84 FR 42716). This worst case risk is still below the presumptive limit of 100-in-1 million risk. In addition, there were no facilities with an estimated maximum chronic noncancer HI greater than or equal to 1 from point sources. The maximum acute HQ for all pollutants was less than 1 when we only considered point source emissions, and up to 3 based on the REL for arsenic when including exposures to estimated emissions from UFIP emissions at the example facility.

For the acute screening analyses, to better characterize the potential health risks associated with estimated worst-

case acute exposures to HAP, the EPA examined a wider range of acute health metrics, where available, including the California Reference Exposure Levels (RELs) and emergency response levels, such as Acute Exposure Guideline Levels and Emergency Response Planning Guidelines. This is in acknowledgement that there are generally more data gaps and uncertainties in acute reference values than there are in chronic reference values. The maximum acute HQ is estimated to be no more than 3 from arsenic emissions, based on the acute REL. However, for arsenic, the only available acute health metric is the REL. By definition, the acute REL represents a health-protective level of exposure, with effects not anticipated below those levels, even for repeated exposures; however, the level of exposure that would cause health effects is not specifically known. As the exposure concentration increases above the acute REL, the potential for effects increases. In addition, the acute screening assessment includes the conservative (health protective) assumptions that every process releases its peak hourly emissions at the same hour, that the near worst-case dispersion conditions occur at that same hour, and that an individual is present at the location of maximum concentration for that hour. Further, the HQ value was not refined to an off-site location, which, in many cases, may be significantly lower than that estimated at an on-site receptor. Thus, because of the conservative nature of the acute inhalation screening assessment as well as the conservative bias in the UFIP emission estimates, the EPA anticipates that emissions from the Integrated Iron and Steel Manufacturing Facilities source category pose minimal risk of adverse acute health effects.

As part of the ample margin of safety analysis performed for the proposal, we

evaluated additional potential technologies for controlling point source emissions to further reduce risk from these sources, taking into consideration costs, energy, safety, and other relevant factors. We evaluated the installation of a wet electrostatic precipitator (ESP) on the exhaust of the current air pollution control devices for the BF casthouse primary units to reduce chromium VI and arsenic emissions, respectively. We also evaluated the installation of activated carbon injection (ACI) systems onto current control devices for the sinter plant windbox to reduce emissions of dioxins/furans. Details of the estimated costs and emissions reductions associated with these control measures can be found in the memorandum titled *Ample Margin of Safety for Point Sources in the II&S Industry* (Docket ID Item No. EPA-HQ-OAR-2002-0083-0952).

We estimated the MIR could be reduced by 95, 95, and 98 percent, respectively, from 10-in-1 million, 70-in-1 million, and 40-in-1 million for BF chromium actual emissions, BOPF arsenic allowable emissions, and sinter plant dioxins/furans actual emissions as toxic equivalents, respectively. However, we did not propose any of these control scenarios because of the relatively high capital and annualized costs compared to a relatively low amount of emissions reduced. Cost-effectiveness estimates were determined to be \$1.9 billion/ton (\$940,000/lb), \$46 million/ton (\$23,000/lb), and \$188 billion/ton (\$94 million/lb) for BF chromium, BOPF arsenic, and sinter plant dioxins/furans, respectively. None of these options were considered cost effective.

We also considered potential work practices to reduce UFIP emissions as part of the ample margin of safety analysis. The EPA identified work practices that could achieve HAP reductions from the seven UFIP sources, such as more frequent measurements (e.g., opacity, internal furnace conditions) to identify problems earlier, increased maintenance, applying covers on equipment, developing operating plans to minimize emissions, optimizing positioning of ladles with respect to hood faces, and earlier repair of equipment. We estimated these work practices would achieve a range of 50- to 90-percent reduction in UFIP emissions (i.e., control efficiency) from these sources, based on EPA staff judgment as to the potential effectiveness of the work practices. In analyzing post-control scenarios, we assumed the work practices would achieve 70-percent reduction in emissions (the midpoint between 50 and

90 percent), corresponding to an estimate of 185 tpy of HAP reduced, assuming work practices were required for all seven UFIP sources. A description of the uncontrolled UFIP emissions and an estimate of emissions after implementation of work practices are provided in the Example Facility memorandum cited above.

To estimate the risk reductions that could be achieved from the UFIP sources via work practices, we developed a model input file to reflect the estimated emissions reductions that would be achieved under two control options and modeled two post-control scenarios for the example facility to estimate risk reductions. We analyzed two options: Option 1 would establish work practice standards for two of the UFIP sources (BF casthouse fugitives and BOPF shop fugitives), which contribute about 70 percent of the MIR and are currently regulated via opacity standards; Option 2 would establish work practice standards for all seven of the UFIP sources. Potential work practices for the two UFIP sources in Option 1 were the same in Option 2. We assumed a control efficiency of 70 percent for the work practices as the average of an assumed range of 50-percent to 90-percent control efficiency for the work practices. Details of the work practices for UFIP and estimated costs of the work practices can be found in the memorandum titled *Ample Margin of Safety for Nonpoint Sources in the II&S Industry* (Docket ID Item No. EPA-HQ-OAR-2002-0083-0953).

Based on this modeling assessment, we estimated Option 1 would reduce the MIR from 20-in-1 million to about 10-in-1 million for the example facility, the estimated population with risks greater than or equal to 1-in-1 million would decrease from 4,000,000 to 1,500,000, and the estimated population with risks greater than or equal to 10-in-1 million would decrease from 9,000 to 800. In addition, the maximum acute HQ would decrease from 3 to 2. This option also would achieve reductions in PM with a diameter of 2.5 micrometers or less (PM_{2.5}). For Option 2, we estimated the work practices would reduce the MIR from 20-in-1 million to about 9-in-1 million for the example facility, the estimated population with risks greater than or equal to 1-in-1 million would decrease from 4,000,000 to 800,000, and the estimated population with risks greater than or equal to 10-in-1 million would decrease from 9,000 to 0. Also, the maximum acute HQ would decrease from 3 to 0.9. This option would also achieve reductions in PM_{2.5}.

We estimated the total capital costs of Option 1 for the source category would be approximately \$1.4 million, annualized costs would be approximately \$1.7 million per year, and HAP reductions would be approximately 173 tpy of HAP, which corresponds to a cost-effectiveness value of approximately \$10,000/ton. This estimate was based on cost estimates for individual emission units that were projected to the entire industry based on the number of units of each type at each facility. For Option 2 for the source category, we estimated the total capital costs would be approximately \$8.7 million, annualized costs would be approximately \$3 million per year, and HAP reductions would be approximately 185 tpy, which corresponds to a cost-effectiveness value of approximately \$16,000/ton HAP.

Considering all of the health and environmental risk information and factors discussed above, including the substantial uncertainties regarding our estimates of UFIP emissions, and the costs and cost effectiveness of the work practices, the EPA proposed that risks from the Integrated Iron and Steel Manufacturing Facilities source category are acceptable and that revision of the standards is not required in order to provide an ample margin of safety to protect public health or to prevent an adverse environmental effect.

2. How did the risk review change for the Integrated Iron and Steel Manufacturing Facilities source category?

No changes were made to the risk review in the final rule. As mentioned above, we received new arsenic performance test data and an industry conducted risk assessment for the example facility from industry shortly before proposal suggesting arsenic emissions and risks are about 60 percent lower than our estimates.³ (See 84 FR 42720 (August 16, 2019) for more discussion). However, we did not rerun the risk model after proposal because of the court-ordered schedule to complete the final rule⁴ and because it would not affect the outcome of the final rule. We proposed risks were acceptable and the NESHAP provided an ample margin of safety to protect public health. Based on

³ Letter and attachment from P. Balsarak, AISI, Washington, DC, to C. French, U.S. EPA, Research Triangle Park, NC. 34 pages. February 4, 2019. (Docket ID Item No. EPA-HQ-OAR-2002-0083-1014).

⁴ The EPA is required by court order to complete the RTR for the Integrated Iron and Steel Manufacturing Facilities source category by May 5, 2020. *Calif. Communities Against Toxics v. Wheeler*, No. 1:15-cv-00512, Order (D.D.C. March 13, 2017, as modified February 20, 2020).

consideration of comments and information received through the comment period, we continue to conclude risks are acceptable and that the NESHAP provides an ample margin of safety to protect public health.

3. What key comments did we receive on the risk review, and what are our responses?

This section provides a summary of key comments and responses regarding the risk review. A summary of all other public comments on the proposal related to the risk review and the EPA's responses to those comments is available in the document, *Summary of Public Comments and Responses for the Risk and Technology Review for Integrated Iron and Steel Manufacturing Facilities* (Docket ID No. EPA-HQ-OAR-2002-0083). With regard to UFIP emissions and potential work practices, key comments and responses in regard to risk are discussed below. Other key comments and responses are discussed under the sections in this preamble on technology review (Section IV.B of this preamble) and UFIP (Section IV.F). The remainder of the UFIP comments and responses are discussed in the response to comment document cited above.

Comment: One commenter stated the EPA has failed to provide an ample margin of safety. The commenter stated at the ample margin stage, the EPA refuses to address the fact that the health risks are quite high. The EPA must consider how to assure an ample margin of safety to protect public health from the systemic harm implied by this risk value. Yet, the EPA does not discuss or find that it is providing any margin, much less an ample one, to protect people from the emissions causing the carcinogenic, chronic noncancer, and acute risks it also found.

In contrast, a different commenter stated the conservative residual risk estimates in the proposal are already well below the presumptively acceptable risk threshold, despite being artificially inflated due to inaccurate emissions inputs and modeling parameters. Thus, the Agency's proposed determination that no additional regulatory requirements are necessary to provide an ample margin of safety or to prevent adverse environmental effect in light of relevant factors including safety and costs is unquestionably reasonable and appropriate.

Response: We acknowledge the comments supporting the EPA's ample margin of safety analysis and the determination that risks are acceptable and no additional regulatory requirements are necessary to provide

an ample margin of safety or to prevent adverse environmental effect. A summary of the EPA's ample margin of safety analysis is provided in section IV.A.1 of this preamble and in the proposal preamble (84 FR 42704). Further details are provided in the memorandum titled *Ample Margin of Safety Analysis for Point Sources in the Integrated Iron and Steel Industry* (Docket ID Item No. EPA-HQ-OAR-2002-0083-0952). In this memorandum, we estimate the remaining risk after implementation of potential control technologies and work practices along with the costs of these controls and work practices.

The EPA disagrees with the comments that the EPA failed to satisfy the CAA requirement to provide an ample margin of safety and only addressed whether cost-effective measures were identified for reducing HAP emissions. The EPA uses "a two-step standard-setting approach, with an analytical first step to determine an 'acceptable risk' that considers all health information, including risk estimation uncertainty, and includes a presumptive limit on MIR of approximately 1-in-10 thousand," as stated in the Benzene NESHAP (54 FR 38045), followed by a second step to set a standard that provides an "ample margin of safety," in which the EPA considers whether the emissions standards provide an ample margin of safety to protect public health in consideration of all health information, including the number of persons at risk levels higher than, approximately, 1-in-1 million, as well as other relevant factors, including costs and economic impacts, technological feasibility, and other factors relevant to each particular decision.

As explained above, we determined, based on our risk analysis, the risks from the source category are acceptable and that no additional regulatory requirements are necessary to provide an ample margin of safety to protect public health.

Regarding potential controls for point sources (described in section IV.A.1 of this preamble), we determined these controls would reduce risks, but were not cost effective. The calculated cost-effectiveness values were \$940,000/lb, \$23,000/lb, and \$94 million/lb for HAP removed from BF (chromium VI), BOPF (arsenic), and sinter plants (dioxins/furans), respectively.

With regard to the UFIP and potential work practices, consistent with our explanation in the proposed rule (see 84 FR 42704), based on consideration of all our analyses and related information, including the risk results, costs, and uncertainties, we have determined that

no additional standards are required under CAA section 112(f) and that the current NESHAP provides an ample margin of safety to protect public health. This decision is based largely on the substantial uncertainties in the estimates of the baseline HAP emissions from UFIP emission sources, costs of the work practices, HAP risk reductions that would be achieved by the work practices, and uncertainties raised by industry in their comments regarding potential effects of the work practices on the facilities' operations, safety, and economics.

Comment: One commenter stated the multipathway risk did not include UFIP sources. Since the EPA only considered UFIP emissions from the one facility, the commenter inquired about the population that resides in the area impacted by all four mills along a short 20 mile stretch of northwest Indiana. The commenter questioned whether the cumulative risk from inhalation from total point, and UFIP sources for people who live within the impacted areas from all of these mills together was addressed because it does not appear to have been assessed in this proposal. The commenter asserted the EPA has significantly underestimated the exposure for people who live near more than one of the four mills in an approximately 20-mile area of northwest Indiana. The commenter stated the EPA's risk model results, when UFIP emissions are included for the example facility alone, increase by an order of magnitude. The commenter asserted that by itself this should have made it imperative that the EPA consider UFIP sources as important as point sources in quantifying emissions and risks and considering control measures in the final rule.

Another commenter stated documents in the rule docket show serious, harmful, and major releases of pollution, demonstrated in photographs and in high opacity or visible smoke, and in inspections and communications with enforcement officials. The commenter asserted that this information shows the need for stronger standards under each provision of the CAA. The commenter concluded that by not including UFIP emissions in its multipathway assessment, the EPA has underestimated health risks and the already high health threats communities are facing. The commenter stated the EPA has recognized that its residual risk assessment fails to account for several types of pollution that the EPA calls UFIP emissions. The commenter stated the EPA is also refusing to complete a risk assessment for all sources, including the UFIP emission points, and

this is unlawful. The commenter asserted the EPA needs to complete a new risk assessment study, where they include all of the risk factors, to protect the health of Americans that are living around these steel facilities.

Response: The commenter is correct that the UFIP emissions were considered later in the process of developing the RTR and, therefore, were not included in the quantitative multipathway analysis. The EPA would not have been able to meet the RTR court-ordered deadline if the multipathway analysis was repeated to include UFIP emissions or if the risk assessment was repeated to include UFIP emissions from all facilities. However, we qualitatively considered the potential impact of UFIP emissions on the multipathway analysis and concluded that including UFIP emissions would not have affected the results or conclusions of the analysis. Specifically, the HAP driving the risks in the multipathway analysis were dioxins/furans from sinter plants (with a cancer risk estimate for the highest exposed individual of 40-in-1 million from the fisher scenario). In contrast, the UFIP HAP emissions are particulate HAP metals (such as arsenic) from the BF and BOPF related sources, and do not include dioxins/furans. The combined metal HAP from all point sources at the three facilities in the multipathway analysis showed a significantly lower risk (with a cancer risk estimate of 2-in-1 million from arsenic emissions from the gardener scenario) as compared to the risk estimated from dioxins/furans noted above. Therefore, even if we took estimated arsenic emissions from UFIP sources into account in the multipathway analysis, the multipathway risks from the gardener scenario would almost certainly remain lower than the dioxins/furans risk from the fisher scenario. Thus, we have no reason to believe that including arsenic emissions from UFIP sources in the multipathway analysis would alter our conclusion from the multipathway analysis.

Obtaining measurements of UFIP emissions via source testing to combine with the point source emissions was not possible due to the court-ordered deadline and, more importantly, because measurement of UFIP sources would be very difficult, if not impossible, for some sources. To balance the difficulty of obtaining reasonably accurate information on HAP emissions from UFIP sources with the importance of gaining some understanding of the potential risk from UFIP, we modeled a very large facility

with the highest expected UFIP (and HAP) emissions, which is also close to a large urban area to estimate the potential upper-end risks due to such emissions. Using the example facility analysis was also a time-saving measure in lieu of estimating UFIP emissions for the entire industry via emission factors.

Comment: One commenter stated the EPA found that a list of effective controls, work practices, and monitoring methods for UFIP sources could achieve HAP reductions from the seven UFIP sources. The commenter stated the EPA's findings are extensive, and are noted as being available, with emissions "preventable," with many practices identified as "having no or minimal cost" (ample margin of safety memorandum at 7), and that some facilities are actually using currently. See, e.g., *Id.* at 7–15. The commenter further stated the EPA found that the experience of its regional staff provided the reason for consideration of these controls. The commenter continued that the EPA recognized some iron and steel sources have had serious compliance problems in the past and highlighted some provisions, like stronger monitoring, that would reduce and prevent those problems. The commenter stated the EPA also provided photographs (at undisclosed locations) that show huge visual releases of HAP metals and other pollution into the air from bell leaks, beaching, and BF slips. The commenter noted that the EPA staff took to research, compile, and discuss the important pollution control methods is appreciated.

The commenter stated the Ferroalloys and Secondary Lead Smelting NESHAP each include a number of methods or variations on the methods described in the Integrated Iron and Steel Manufacturing Facilities RTR proposal to reduce metal HAP emissions from UFIP—such as requiring total or partial building enclosure with negative pressure. In addition, the commenter asserted the EPA has recognized the need to prohibit uncontrolled releases of HAP to the atmosphere from planned or unplanned openings at other kinds of facilities. For example, the commenter noted that the EPA, in a long list of CAA section 112 rulemakings in recent years, has repeatedly prohibited uncontrolled HAP releases that vented directly to the atmosphere rather than being routed to a control device.

The commenter stated the EPA ultimately proposes not to require any of the work practices, referring to "uncertainties regarding the effect the work practice standards would have on facility operations, economics, and safety." The commenter stated the

EPA's own analyses and direct observations all support better characterizing UFIP emissions and implementing the basic cost-effective control measures and work practices the EPA has already explored to some extent. To not do so, the commenter asserted, would be to ignore the EPA's own analyses of the impacts to human health and the environment of the UFIP emissions from the mills in these highly affected areas, and miss the opportunity to implement easy cost and industry-friendly actions that would go far to reduce impacts to the nearby communities, land, and waterways. The commenter asserted the EPA may not lawfully or rationally refuse to set emission standards that reflect the emission reduction methods available.

Response: We agree with the commenter that work practices to reduce UFIP emissions are available. However, due to the substantial uncertainties regarding the emissions estimates, the uncertainties regarding the costs and effectiveness of the work practices, and potential negative effects of the work practices on facility operations, economics, and safety that were asserted by industry representatives (see below in their detailed comments), the EPA is not promulgating any work practice requirements for UFIP sources in this final rule at this time. Because we conducted a risk assessment for the largest facility in the source category to examine a worst-case scenario for UFIP sources in the industry (as described in detail in section IV.A of this preamble) and determined that risks posed by emissions from the source category were acceptable, and due to the uncertainties and other factors described above, we conclude that the NESHAP provides an ample margin of safety and additional standards, such as work practices described above, are not necessary. In addition, because of the same uncertainties and potential impacts described above for the UFIP sources and work practices, we also are not promulgating any work practice standards under CAA section 112(d)(6) for the two regulated UFIP sources in this action.

Comment: One commenter stated the EPA is right to conclude that additional control technologies, including wet ESPs for BF casthouses and BOPF shops and ACI systems for sinter plant windboxes would not provide cost-effective emissions reductions, given the extremely high costs associated with small incremental additional reductions of HAP.

The commenter asserted that the EPA's "very high" cost estimates are

actually low, *i.e.*, underestimated, and that the removal rate estimates are high, *i.e.*, overestimated. The values that the EPA calculated are so clearly not cost effective, however, that further analysis of these costs and reduction levels is unnecessary to reject them under an ample margin of safety analysis. The EPA's proposed determination is, thus, well within the substantial discretion afforded to it under the Court's *Vinyl Chloride* decision and should be finalized.

Response: We acknowledge the comments supporting the EPA's proposed determination that no new standards are required to provide an ample margin of safety to protect public health and that the costs of the control technologies evaluated and emission reductions estimated in the ample margin of safety analysis were not in the range generally determined to be cost effective by the EPA. The costs of additional controls are disproportionately high considering the reductions in risk that are achievable.

Comment: One commenter stated it is arbitrary for the EPA to find risk acceptable in view of additional evidence of uncertainty in the record. The EPA should find the current health risks to be unacceptable because of the omissions, underestimates, and uncertainties its own risk assessment contains. The EPA has failed to show, based on evidence in the record, that the risks are not significantly higher than the values it has presented. The EPA has failed to justify its acceptability determination when such major gaps are present.

Response: As stated in the proposal rulemaking, the estimated combined worst-case, upper-end risks (point and UFIP) are below the presumptive limit of acceptability of 100-in-1-million and the noncancer results indicate there is minimal likelihood of adverse noncancer health effects due to HAP emissions from this source category. As we explained in the proposal preamble, the EPA's risk results indicate that the inhalation cancer risks to the individual most exposed are less than 90-in-1 million, as a worst case, considering the highest allowable risk due to point sources among the industry facilities plus the conservative estimate of risk from UFIP emissions due, in part, to the use of the largest facility as the example facility. Furthermore, we conclude that by using the UFIP emissions estimate from the example facility plus the highest allowable point source risk to represent the worst case risk scenario for the industry mitigates any potential concerns regarding the lack of UFIP emissions estimates and associated

UFIP associated risks for each individual facility. Furthermore, we did not receive any data or information through the public comment process that would change our proposed determination that risks are acceptable.

Comment: One commenter stated the EPA's ICR did not collect emissions data information on UFIP sources or all HAP emitted, controlled and uncontrolled. The EPA assessed additional particulate and metal HAP emissions from UFIP sources not addressed in the ICR through estimates based on "literature values for PM from these or other similar emission points and ratios of HAP to PM developed from the ICR data." The commenter also stated the EPA's "actual" analysis of risk is based on an emission inventory that is largely calculated from emission factors and engineering judgment. The commenter asserted that it is well-documented that emission factors underestimate emissions for a variety of reasons including inherent bias in the factors themselves and the inability to account for equipment malfunctions and environmental conditions. The commenter stated the EPA cannot rationally base emission estimates or risk assessments on data it has strong reason to doubt. The commenter stated the EPA must collect actual emissions data to support its emissions estimates. The commenter argues that, to the extent actual data is not collected, the Agency must adjust the emissions inventory using these same conclusions from the technology review and the large body of scientific evidence that show emissions factors underestimate emissions, in order to ensure that the inventory better represents reality and reflects actual emissions.

One commenter stated that the proposal's UFIP source analysis (*i.e.*, effort to quantify UFIP emissions) is based on no sampling or engineering analysis, but on very dated studies and emission factors that are poorly rated. While it is more difficult to characterize the emissions from UFIP sources, the commenter asserted that methods do exist that can help in properly characterizing UFIP emissions. The commenter stated these include grab sampling followed by HAP characterization, use of process knowledge, and engineering assessment/modeling. The commenter asserted that each of these methods could have been used by the EPA to better characterize potential HAP emissions from UFIP.

Response: The commenter is correct that EPA did not require HAP testing from these UFIP sources in the ICR in 2011. The EPA did not have a good

understanding of the UFIP sources at the time of the ICR in 2011. Furthermore, it would have been quite difficult to reliably measure the UFIP emissions at that time due to the nature of such emissions and lack of test methods to reliably quantify emissions from these sources for use in the RTR. However, note that we did not use an inventory for any analyses in this RTR, for UFIP or otherwise.

The HAP to PM ratios that were used along with the estimates of PM emissions from UFIP to calculate HAP emissions estimates for UFIP sources for the risk assessment for this action were obtained from ICR source tests and are as good, in terms of quality and, therefore, accuracy, if not better than the grab samples that the commenter suggests because the ICR stack tests were performed continuously over a period of hours providing a composite profile of HAP emissions, whereas grab samples would have been instantaneous and only reflect a discrete moment in time. The EPA used all of the other methods recommended by the commenter to estimate emissions from UFIP sources, specifically: HAP characterization, use of process knowledge, and engineering assessment/modeling, as described in the technical memorandum titled Development of Emissions Estimates for Fugitive or Intermittent HAP Emission Sources for an Example Integrated Iron and Steel Facility for Input to the RTR Risk Assessment (Docket ID Item No. EPA-HQ-OAR-2002-0083-0956), hereafter called the "Example Facility" memorandum.

The emission factors used in the example facility analysis were, in most cases, from a number of test reports from various and different facilities that were evaluated and combined into one overall emission factor for each of the seven UFIP sources. Environmental conditions and malfunctions are not included in data used to develop EPA emission factors and the latter are never included in any part of an emission factor analysis. In addition, we have no evidence that based on current industry operation the EPA's emission factors are biased low, in general, *i.e.*, for typical or average conditions. Engineering judgment was used when portions of the emission estimates were missing and was conservative in nature. An analysis using limited ambient emission data previously obtained by the EPA in the vicinity of the example facility, included in the "Example Facility" memorandum (Section 7 and Appendix G), indicates the EPA's emissions estimates for UFIP at the example facility are plausible.

4. What is the rationale for our final approach and final decisions for the risk review?

Based on consideration of comments, and all of the health risk information, factors, results, and uncertainties discussed above and in the proposal (84 FR 42704), we conclude the risks due to HAP emissions from this source category acceptable. Furthermore, based on the analyses described in the proposal and elsewhere in this preamble, including the evaluation of potential controls and work practices to reduce emissions and risks, and the costs, effectiveness, and uncertainties of those controls and work practices, and after evaluating comments, we conclude the NESHAP provides an ample margin of safety to protect public health. Finally, based on our evaluation of environmental risks, we conclude that more stringent standards are not necessary to prevent an adverse environmental effect. Therefore, we are not promulgating any additional control requirements pursuant to CAA section 112(f)(2), but instead are readopting the existing standards.⁵

B. Technology Review for the Integrated Iron and Steel Manufacturing Facilities Source Category

1. What did we propose pursuant to CAA section 112(d)(6) for the Integrated Iron and Steel Manufacturing Facilities source category?

In the proposed technology review, we evaluated the cost effectiveness of upgrading fume/flame suppressants used for control of fugitive PM and HAP metal emissions from BF to use of baghouses as control devices. We also evaluated process modifications found in European literature to further reduce dioxins/furans emissions from sinter plants; these potential process controls for dioxins/furans emissions were in addition to the add-on control devices considered for sinter plants under the ample margin of safety analysis for point sources described above. The technology reviews for these two emissions sources were discussed in detail in the proposal (84 FR 42704) and the technical memorandum titled *Technology Review for the Integrated Iron and Steel NESHAP* (Docket ID Item No. EPA-HQ-OAR-2002-0083-0964).

In the proposed technology review, the EPA also evaluated potential work

practices to reduce nonpoint source emissions from the BF casthouse and BOPF shop (84 FR 42704). However, the EPA did not propose any of these work practices primarily because there are significant uncertainties in the technical assessment of UFIP emissions that includes estimates of the baseline UFIP emissions, the estimated HAP reductions that would be achieved by the work practices, and the costs of the work practices. In addition, there also are uncertainties in the effect the work practices would have on facility operations, economics, and safety.

Based on all our analyses and uncertainties described above, the EPA proposed to find that there are no developments in practices, processes, or control technologies that necessitate revising the standards for these two UFIP sources under CAA section 112(d)(6).

Considering all the information evaluated in our technology reviews for upgrading fume/flame suppressants control on BF's, sinter plant process modifications, and the potential work practices to reduce UFIP emissions from BF casthouse and BOP shop, we did not identify any developments in practices, processes, or technologies that warrant revision of the NESHAP for the currently regulated point or nonpoint sources under section 112(d)(6) of the CAA and, therefore, did not propose any changes to the NESHAP pursuant to section 112(d)(6) of the CAA.

a. Upgrading Fume/Flame Suppressants at BF's to Baghouses

Emissions from BF's are controlled in the integrated iron and steel industry in one of two fundamentally different ways: (1) Fume and flame suppression techniques or (2) conventional ventilation practices that route exhaust air to control devices such as baghouses. Fume suppression consists of blowing natural gas over the open equipment which retards vaporization and prevents emissions. With flame suppression, the natural gas is ignited with accompanying oxygen consumption that suppresses the formation of metal oxide emissions. The use of fume/flame suppressants for control of fugitive BF casthouse emissions is estimated to have 75-percent control, whereas control with baghouses is estimated to have 95-percent control.

There are a total of eight BF's with fume/flame suppressants distributed at four facilities among the 21 BF's total at 11 integrated iron and steel facilities. Per-unit capital costs for converting from fume/flame suppressant control to baghouses was estimated to be \$18 million with \$2.7 million in annual unit

costs, where some facilities have two or three units. Total industry costs are estimated to be \$140 million in capital costs and \$22 million in annual costs. The estimated cost effectiveness of upgrading the fume/flame suppressant control to ventilation and baghouses at all eight BF's is \$7 million/ton of metal HAP with 3 tpy of HAP removed, and \$160,000/ton PM with 120 tpy of PM removed. We concluded these controls were not cost effective and, therefore, we did not propose to require baghouses to be installed on BF's as a result of the technology review.

b. Process Modifications To Control Dioxins/Furans at Sinter Plants

There are three facilities in the Integrated Iron and Steel Manufacturing Facilities source category that have sinter plants. The sinter plants are currently regulated by PM and opacity limits on the windbox exhaust stream, sinter cooler, and discharge end of sinter plants. In addition, the sinter plant windbox is regulated for organic HAP with compliance demonstrated by either meeting a VOC limit or a limit on oil content of the sinter feed. Dioxins/furans are components of the organic HAP but because of their higher toxicity, they often are evaluated separately under control scenarios. Therefore, our technology review included exploration of potential control measures that could further reduce dioxins/furans from sinter plants.

For the proposal, we conducted a literature search and reviewed various technical publications (largely from Europe and other countries in the Stockholm Convention⁶) regarding potential control technologies and practices to reduce dioxins/furans from sinter plants and found a number of potential options that could potentially be applied at sinter plants in the U.S.^{7 8 9} These options include urea injection to inhibit dioxins/furans formation; partial

⁶ *Stockholm Convention on Persistent Organic Pollutants (Pops), Texts and Annexes*. Revised in 2017. Published by the Secretariat of the Stockholm Convention, Geneva, Switzerland. May 2018. Available at: <http://www.pops.int>.

⁷ Ooi, T. C. and L. Lu. *Formation and mitigation of PCDD/Fs in iron ore sintering*. *Chemosphere* 85:291-299. 2011.

⁸ Boscolo, M.E., Padoano, and S. Tommasi. *Identification of possible dioxin emission reduction strategies in preexisting iron ore sinter plants*. Institute of Materials, Minerals and Mining. Published by Maney on behalf of the Institute. Ironmaking and Steelmaking. 15:35:11. The Charlesworth Group, Wakefield, UK. October 19, 2007.

⁹ Lanzerstorfer, C. *State of the Art in Air Pollution Control for Sinter Plants*. Chapter 18, in *Ironmaking and Steelmaking Processes*. P. Cavaliere, Ed. Springer International Publishing, Springer Nature, Switzerland AG. 2016.

⁵ The Court upheld this approach to CAA section 112(f)(2) in *NRDC v. EPA*, 529 F.3d 1077, 1083 (D.C. Cir. 2008): "If EPA determines that the existing technology-based standards provide an 'ample margin of safety,' then the Agency is free to readopt those standards during the residual risk rulemaking."

windbox exhaust gas recirculation; post-exhaust windbox chemical spray (monoethanolamine and triethanolamine dissolved in water and sprayed onto exhaust); and elimination of certain inputs (e.g., no ESP dust). The European Union also included these measures in their 2013 Best Available Technology evaluation.¹⁰

As far as we knew at proposal, none of these technologies or practices were currently used at sinter plants in the U.S. However, based on the literature cited above, we believe some of these technologies or measures may be used to control dioxins/furans in other countries (such as in Europe and other countries complying with the Stockholm Convention).

We were not able to estimate the costs of these control methods due to lack of cost information in the literature, nor were we able to estimate the feasibility for U.S. facilities. Based on the analysis set forth in the proposal, we did not propose to require process modifications to control dioxins/furans at sinter plants as a result of the technology review.

c. Work Practices as a Potential Measure To Reduce UFIP Emissions From BF Casthouses and BOPF Shops

As described in the proposal, we evaluated potential work practices to reduce uncaptured fugitive emissions from BF casthouses and BOPF shops under our technology review. The estimated capital costs for work practices for these two nonpoint sources were \$1.4 million and annualized costs were \$1.7 million. We estimated these work practices would achieve about 173 tpy reduction in metal HAP, at an average combined cost effectiveness of \$10,000 per ton.

After considering all the information and analyses, we proposed to find that there were no developments in practices, processes, or control technologies that necessitate revising the standards for these two UFIP sources under CAA section 112(d)(6). This decision was based largely on the considerable uncertainties in the technical assessment of UFIP emissions that includes estimates of the baseline UFIP emissions, the HAP emission reductions that would be achieved by the work practices, and the costs of the

work practices. In addition, as indicated by the industry in their comments, there are also uncertainties with regard to the effect the work practices would have on facility operations, economics, and safety.

2. How did the technology review change for the Integrated Iron and Steel Manufacturing Facilities source category?

No changes were made to the technology review in the final rule from that proposed for the Integrated Iron and Steel Manufacturing Facilities source category (84 FR 42704).

3. What key comments did we receive on the technology review, and what are our responses?

This section provides a summary of key comments and responses regarding the technology review. Related comments and responses in regard to UFIP emissions are discussed in sections IV.A.3 and IV.F.3 of this preamble. A summary of all other public comments on the proposal and the EPA's responses to those comments is available in the *Summary of Public Comments and Responses for the Risk and Technology Review for Integrated Iron and Steel Manufacturing Facilities* (Docket ID No. EPA-HQ-OAR-2002-0083).

Comment: One commenter stated the record contradicts the EPA's conclusion of no developments for point sources. The evidence shows, "that there are many techniques to control dioxins/furans emissions from sinter plants," through process modifications controls such as windbox gas recirculation or chemical treatment of windbox exhaust, and these are in use at European facilities. Tech. Review Memo at 21. The commenter said that the EPA found chemical treatment could achieve 40- to 90-percent control and that the EPA concluded that the cost effectiveness and success of application of these techniques in the U.S. is not known. *Id.* at 19–20. The commenter stated that the EPA gave no justification for why the application should be different in the U.S., however, nor any evidence showing that these could not be applied or should not be applied in the U.S. The commenter also claimed that the European Union actually requires BAT for control of dioxins/furans emissions and stated that the EPA has no lawful or rational basis to refuse to revise the emission standards to "tak[e] into account" these techniques when they are plainly "developments" within the meaning of CAA section 112(d)(6). *Id.* at 20.

The commenter stated the EPA's claims about the cost effectiveness of ACI in the proposal were made in the context of its separate CAA section 112(f) analysis (84 FR at 42725) and that the EPA did not evaluate ACI in the context of its CAA section 112(d)(6) analysis. *Id.* at 42729. The commenter also claimed that the EPA's findings under CAA section 112(f)(2) cannot possibly satisfy the Agency's obligations under the separate and different requirements of CAA section 112(d)(6). Stating what the EPA believes ACI costs does not show that ACI is not cost effective and is irrelevant under CAA section 112(d)(6). Equally irrelevant is whether or not ACI would reduce health risks. The focus under CAA section 112(d)(6), is how much reduction is achievable and not the EPA's views about risk or the value of reducing it.

The commenter stated moreover, the Agency grossly underestimates this technology's cost effectiveness by considering it only for one HAP at a time, as if iron and steel sources would have to purchase and install ACI once to control dioxins/furans, and again to control other pollutants. 84 FR 42726 (August 16, 2019). The commenter stated the EPA's irrational failure to recognize the actual benefits of ACI on multiple HAP is arbitrary and unlawful.

In addition, the commenter asserted that the Agency pretends that cost effectiveness must be measured in dollars per ton even for pollutants like mercury and dioxins/furans for which such a measure is "ridiculous." The commenter explained that dioxins/furans are measured in millionths of a gram, and they are toxic in the millionths of a gram. Further, the commenter elaborated that all the industries in the nation do not emit a single ton of dioxins/furans in a year. The commenter posited that giving the cost effectiveness for ACI in dollars per ton of dioxins/furans is meaningless and that by doing so the EPA is simply obscuring the facts by using absurdly irrelevant units to make ACI look as though it is not cost effective to support its rejection of an extremely effective and cost-effective technology.

The commenter stated failing to present all of the underlying information the EPA relied on for its CAA section 112(d)(6) determination—including, e.g., the title V permits to which it refers—makes it impossible for the public and for a reviewing court to evaluate the EPA's conclusory determination that there are "no developments" requiring revision.

In contrast, a different commenter stated as part of the technology review, the EPA considered a number of process

¹⁰ *Best Available Techniques (BAT) Reference Document for Iron and Steel Production*. Industrial Emissions Directive 2010/75/EU (Integrated Pollution Prevention and Control). R. Remus, M. A. Aguado-Monsonet, S. Roudier, and L. D. Sancho. European Commission, Joint Research Centre, Institute for Prospective Technological Studies. European IPPC Bureau, Seville, Spain. Luxembourg Publications Office of the European Union. doi:10.2791/97469. 2013.

modifications to provide additional reductions of dioxins/furans emissions from sinter plants but appropriately chose not to propose to require them based on inadequate information. The commenter stated that the EPA reasonably determined not to focus on additional control technologies for sinter plants during the technology review, which are already subject to limits on organic HAP emissions (through either a VOC limit or an oil content limit for the sinter feed). Based on the incredibly high estimated cost-effectiveness numbers, the commenter stated that the EPA proposes that these additional control technologies would not be cost effective and proposes not to require them. Although the commenter stated that the EPA's cost estimates appear unrealistically low and the estimated emissions reductions too high, even with those flawed assumptions the commenter stated that the EPA calculated such staggeringly high cost-effectiveness values that further analysis is unnecessary to establish that these controls are not appropriate to impose pursuant to the technology review. The commenter stated the process modifications the EPA evaluated are not used at any facility in the Integrated Iron and Steel Manufacturing Facilities source category but, rather, were identified during the EPA's literature review from primarily European sources. Sinter plant emissions are already regulated by PM and opacity limits, as well as a VOC limit or limit on sinter feed oil content to regulate organic HAP emissions, including dioxins/furans. The commenter stated that the EPA nonetheless looked to identify the potential process changes in its literature review to yield further dioxins/furans emission reductions. The commenter stated that none of the process changes that the EPA identified warrant revision of the 40 CFR part 63, subpart FFFFF standards for sinter plants. The industry reviewed the materials from the EPA's literature review described in the proposal; however, the commenter stated that the EPA did not provide adequate information to properly evaluate the potential effectiveness, costs, or other issues associated with the process changes discussed therein. Because there has not been a meaningful opportunity to review and comment on any potential requirement the EPA could impose on the basis of that insufficiently clear literature, the commenter stated that none should be adopted in the final rule.

Response: At proposal, we evaluated ACI as a means of reducing dioxins/furans emissions from sinter plants and used the information and data we collected to inform both our ample margin of safety analysis under CAA section 112(f) and our technology review under CAA section 112(d)(6). In addition, we investigated potential process modifications to reduce emissions for the sinter plants under CAA section 112(d)(6). None of the process technologies or practices identified to control dioxins/furans in European sinter plants are currently used at sinter plants in the U.S. Therefore, we were not able to estimate the costs of these control methods due to lack of cost information in the literature, nor were we able to determine the feasibility for U.S. facilities or whether the European facilities that are applying these process modifications are similar enough to U.S. facilities to enable adoption of the same control techniques. Considering all the information in our technology reviews, we did not identify any developments in practices, processes, or technologies that warrant revision of the NESHAP for sinter plants.

We agree with the first commenter that dioxins/furans are commonly expressed in grams. However, in the RTR proposal (84 FR 42704), we provided the emissions for dioxins/furans in measurement units typically used for most other HAP (*i.e.*, tons and lbs) for consistency purposes. Changing measurement units does not change the relative impact of this analysis compared to previous EPA analyses for dioxins/furans.

We agree with the first commenter that we did not specifically discuss ACI for dioxins/furans in the technology review sections of our RTR proposal preamble. However, in the memorandum titled *Technology Review for the Integrated Iron and Steel NESHAP* (Docket ID Item No. EPA-HQ-OAR-2002-0083-0964), we explained (on page 17 of 22) that although add-on controls are available, the focus for the technology review was on process modifications because add-on controls (*i.e.*, ACI) for dioxins/furans emissions were shown not to be cost effective at sinter plants at integrated iron and steel facilities in the ample margin of safety analysis. For details of this analysis, see the memorandum titled *Ample Margin of Safety Analysis for Point Sources in the Integrated Iron and Steel Industry* (Docket ID Item No. EPA-HQ-OAR-2002-0083-0952).

In terms of multiple pollutant control, for the purpose of this comment, because dioxins/furans are quite

different than other HAP, we typically would not add together the mass of other individual HAP together with dioxins/furans to generate a cost effectiveness value for the sum of HAP, such as in units of dollars per ton of total HAP or lbs per ton of total HAP. Nevertheless, in response to the comment, we estimated the cost effectiveness to control VOC, such as benzene, toluene, ethyl benzene, and xylene (BTEX), and carbonyl sulfide (COS) with ACI. Using the same annual costs for ACI described for control of dioxins/furans (see 84 FR 42725 (August 16, 2019) and also Docket ID Item No. EPA-HQ-OAR-2002-0083-0952), at \$1,849,781 per year, and assuming 85-percent control of BTEX and COS with ACI (average of vendor estimate of 80 to 90 percent),¹¹ the estimated cost effectiveness for BTEX and COS co-control is approximately \$14,000/ton, which is above the range that the EPA has typically considered cost effective for volatile HAP. Consequently, we continue to conclude that ACI is not cost effective for sinter plants, whether we consider ACI for only dioxins/furans controls or if we consider costs and cost effectiveness of the other HAP as well, and we are not promulgating any new or revised standards for sinter plants under the technology review pursuant to CAA section 112(d)(6).

We disagree with the comment that claims the EPA did not provide the underlying information the EPA relied on for its CAA section 112(d)(6) determination. The EPA provided all the relevant supporting information in the proposal preamble or technical memoranda, including the *Technology Review for the Integrated Iron and Steel NESHAP* (Docket ID Item No. EPA-HQ-OAR-2002-0083-0964) and *Ample Margin of Safety Analysis for Point Sources in the Integrated Iron and Steel Industry* (Docket ID Item No. EPA-HQ-OAR-2002-0083-0952). Regarding the title V permits, we made no reference to title V permits in this rule package or any of the supporting materials and technical memoranda; therefore, we cannot address the commenter's points on this issue.

Comment: One commenter stated the EPA cannot justify leaving other non-mercury emissions completely uncontrolled. Refusing to set limits on all uncontrolled pollutants that iron and steel sources emit is both unlawful and arbitrary. The commenter stated that the EPA's emission standards for iron and

¹¹ Telecommunication. Raymond, G., RTI International, Research Triangle Park, North Carolina, with C. Allen, Carbon Activated Corporation, Blasdell, New York. January 27, 2020.

steel plants lack any limits at all for certain HAP, such as hydrochloric acid (HCl), hydrogen cyanide (HCN), and COS, either direct or through a surrogate. Specifically, the iron and steel plants emit 12 tpy HCl, 4 tpy HCN, and 72 tpy COS. Although the EPA has set certain requirements that purport to be limits on VOC, it has not set any limit for iron and steel plants' emissions of COS. Indeed, when the EPA promulgated the Integrated Iron and Steel Manufacturing Facilities standards, it did not even recognize that they emit COS. Instead, the EPA claimed that iron and steel plants emit only "trace amounts of other organic HAP (such as polycyclic organic matter, benzene, and carbon disulfide)." Moreover, the EPA claimed that these "trace" emissions come entirely from oil used in the sintering process, and its only limit on them is to "establish limits on the amount of organic HAP precursor material (specifically oil and grease) that may be in the sinter feed . . ." The commenter stated because the EPA does not claim that COS emissions either come from organic HAP precursor material in sinter feed or can be reduced by limits on such material, its current standards do not limit emissions of COS. In addition, the extremely dangerous neurotoxicant HCN appears not to be currently restricted at all.

The commenter stated it is well-established that, under CAA section 112(d) of the CAA, the EPA's emission standards for a source category must include limits for each HAP that a source category emits. As the Court held in *National Lime Ass'n*, 233 F.3d 625, 634 (D.C. Cir. 2000), the Agency has a "clear statutory obligation to set emission standards for each listed HAP." In subsequent decisions, the Court has repeatedly confirmed that the EPA has this obligation, that it is unambiguous, and that the EPA's failure or refusal to set limits for each listed HAP that a category emits is flatly unlawful. See, e.g., *Sierra Club v. EPA*, 479 F.3d 875, 883 (D.C. Cir. 2007). Despite the plain language of the CAA and the Court precedent, the existing standards do not currently contain any limit at all on certain HAP.

The commenter stated that CAA section 112(d)(6) requires the EPA to review and revise "as necessary" the emission standards for integrated iron and steel facilities. This includes ensuring standards apply to all emitted HAPs and satisfying all currently applicable requirements. As part of its review rulemaking under CAA section 112(d)(6) of existing standards to determine whether it is "necessary" to revise the standards, EPA must ensure

that standards for Iron & Steel facilities meet the requirements of CAA section 112(d), consistent with its responsibility under the CAA and applicable case law.

The commenter stated while the EPA has been ignoring its statutory obligations to control these sources' toxic pollution, people in communities near these sources suffer as a result of their exposure to uncontrolled HAP emissions. The commenter stated as communities currently have no protection at all from these emitted HAP, it is both unlawful and arbitrary for the EPA not to set a limit in this rulemaking. If it fails to do so, it will fail to complete the review and revision rulemaking as CAA section 112(d)(6) requires, will violate the Court's Order in *California Communities Against Toxics v. Pruitt*, 241 F. Supp. 3d 199 (D.D.C. 2017), and will also issue a final rule that is unlawful and inadequate.

Response: Section 112(d)(6) of the CAA requires the EPA to review and revise, as necessary (taking into account developments in practices, processes, and control technologies), emission standards promulgated under this section. We do not agree with the commenter's assertion that the EPA must establish new standards for unregulated emission points or pollutants as part of a technology review of the existing standards.¹² The EPA reads CAA section 112(d)(6) as a limited provision requiring the Agency to, at least every 8 years, review the emission standards already promulgated in the NESHAP and to revise those standards as necessary taking into account developments in practices, processes, and control technologies. Nothing in CAA section 112(d)(6) directs the Agency, as part of or in conjunction with the mandatory 8-year technology review, to develop new emission standards to address HAP or emission points for which standards were not previously promulgated. As shown by the statutory text and the structure of CAA section 112, CAA section 112(d)(6) does not impose upon the Agency any obligation to promulgate emission standards for previously unregulated emissions. Establishing emissions standards for unregulated emission points or pollutants involves a different analytical approach from reviewing

emissions standards under CAA section 112(d)(6).

Though the EPA has discretion to develop standards under CAA section 112(d)(2) through (4) and CAA section 112(h) for previously unregulated pollutants at the same time as the Agency completes the CAA section 112(d)(6) review, any such action is not part of the CAA section 112(d)(6) review, and there is no obligation to undertake such actions at the same time as the CAA section 112(d)(6) review.¹² In the case of mercury, as described in sections III.C and IV.C of this preamble, the EPA has decided to promulgate new standards pursuant to CAA section 112(d)(2) and (3) to address an outstanding petition for reconsideration. However, the EPA is not establishing new standards for the other HAP described above (i.e., HCl, HCN, and COS) as part of this rulemaking, partly due to the fact that the EPA has insufficient time to gather the information to complete the necessary analyses and review in order to develop such additional standards before the court-ordered deadline of May 5, 2020. Nevertheless, the Agency may address these additional HAP in a future action.

4. What is the rationale for our final approach for the technology review?

Our technology review focused on the identification and evaluation of developments in practices, processes, and control technologies that have occurred since the MACT standards were promulgated. Where we identified such developments, we analyzed their technical feasibility, estimated costs, energy implications, and non-air environmental impacts. We also considered the emission reductions associated with applying each development. This analysis informed our decision of whether it is "necessary" to revise the emissions standards.

For the reasons explained in the proposed rule (84 FR 42704) and in this final rule preamble (section IV.B), we determined that there are no developments in practices, processes, or control technologies that warrant revisions to the standards. We evaluated all of the comments on the EPA's technology review and we determined no changes to the review are needed. Consequently, the EPA is not promulgating any new or revised standards in this action for the Integrated Iron and Steel NESHAP under CAA section 112 (d)(6) of the CAA.¹² More information concerning our technology review is in the memorandum titled *Technology Review for the Integrated Iron and Steel*

¹² On April 21, 2020, shortly before this rule was signed, the U.S. Court of Appeals for the D.C. Circuit issued an opinion in *LEAN v. EPA* (No. 17–1257) in which the court held that the EPA has an obligation to set standards for unregulated pollutants as part of technology reviews under CAA section 112(d)(6). At the time of signature, the mandate in that case had not been issued and the EPA is continuing to evaluate the decision.

NESHAP (Docket ID Item No. EPA-HQ-OAR-2002-0083-0964).

C. Mercury Emission Limits

1. What did we propose for mercury emissions for the Integrated Iron and Steel Manufacturing Facilities source category?

On August 16, 2019, the EPA proposed emissions standards for mercury for the Integrated Iron and Steel Manufacturing Facilities source category pursuant to CAA section 112(d)(3) in part to address a petition for reconsideration received by the EPA in 2004 from the Sierra Club. The proposed MACT floor limit was 0.00026 lbs of mercury per ton of scrap processed as an input-based limit for all existing BOPFs and related units at existing integrated iron and steel facilities. We proposed two options to demonstrate compliance with the input-based limit of 0.00026 lbs of mercury per ton of scrap processed for existing facilities. These options were: (1) Conduct an annual performance test at all BOPF-related units and convert the sum of the results to input-based units (*i.e.*, lbs of mercury per ton of scrap input) and document the results in a test report that can be submitted electronically to the delegated authority with the results (see section IV.E below); or (2) certify that the facility obtains all of their scrap from NVMSRP participants (or similar program as approved by the delegated authority), or establish that their scrap is not likely to contain mercury switches. We proposed that existing sources would be required to comply with these requirements within 1 year of promulgation of the final rule. We also proposed that for facilities demonstrating compliance with the mercury limits through performance testing, subsequent performance testing would be required annually. In addition, we proposed that facilities demonstrating compliance through the scrap selection options, would be required to report their status with the appropriate required information in their semiannual compliance reports beginning 1 year after promulgation of final rule.

For new sources, we proposed a MACT limit of 0.00008 lbs of mercury per ton of scrap processed as an input-based limit for any new BOPF and related units, and new integrated iron and steel facility, pursuant to the CAA section 112(d)(3) requirements for new sources that the standard for new sources shall not be less stringent than the emission control that is achieved in practice by the best controlled similar source. With regard to compliance, the

EPA proposed that new sources would have the same options to demonstrate compliance as the existing sources. A new BOPF and new integrated iron and steel facility was defined, with respect to the mercury standard, to be any BOPF or facility constructed or reconstructed on or after August 16, 2019.

2. How did the mercury emissions standards change for the Integrated Iron and Steel Manufacturing Facilities source category?

For the final rule, in response to comments, we changed the mercury testing frequency after the initial performance test to twice per permit cycle, *i.e.*, every 2.5 years in a 5-year title V permit cycle or every 2.5 years for facilities without a permit (where the initial performance test is performed within 1 year from the effective date of the rule); changed definitions for motor vehicle scrap; changed 40 CFR 63.7825 Equation 1 to reflect the correct calculation for mass emissions; and changed minor aspects of provisions that allow sources to demonstrate compliance through participation in the NVMSRP and other provisions related to compliance with the mercury limits. These changes are described in sections III.C, IV.C.4, and IV.C.5 of this preamble.

3. What key comments did we receive on the mercury emissions standards, and what are our responses?

This section provides a summary of key comments and responses regarding the mercury standard. A summary of all other public comments on the proposal and the EPA's responses to those comments is available in the *Summary of Public Comments and Responses for the Risk and Technology Review for Integrated Iron and Steel Manufacturing Facilities* (Docket ID No. EPA-HQ-OAR-2002-0083).

Comment: One commenter stated the EPA has appropriately proposed a measure to reduce mercury emissions, which the emission standards currently do not control, by (proposing to) set standards for the first time pursuant to CAA sections 112(d)(2) and (3). (84 FR 42730). The commenter urged the EPA to finalize this measure, but also asserted that it does not satisfy CAA section 112(d)(6). The commenter added, as the EPA acknowledges, the EPA also has a pending petition for reconsideration asking the EPA to set mercury limits. (*Id.* at 42,731). The EPA granted the petition on the issue of the mercury limits. The commenter opined that the EPA should not have waited 15 years to propose measures to reduce iron and steel plants' mercury

emissions, and its current proposal falls short of the CAA's requirements. (*Id.*).

The commenter stated the EPA's proposed practices for the removal of mercury switches from the scrap metal used by iron and steel plants are not numeric emission limits. At best, the commenter stated, they constitute a work practice requirement the EPA has not even claimed, let alone shown, as it must under CAA section 112(h), that the statutory preconditions for setting work practice requirements instead of numeric emission limits have been satisfied. For this reason alone, the commenter asserted that the EPA's proposed mercury requirements are unlawful and arbitrary.

The commenter asserted that the limits fail to satisfy the stringency requirements under CAA sections 112(d)(2) and (3). Specifically, the commenter argues that the EPA has not demonstrated with substantial evidence, as it must, that these requirements reflect the mercury emissions levels actually achieved by the plants that are best-performing with respect to mercury and contravene CAA section 112(d)(3). Further, the commenter stated that the EPA has neither claimed nor demonstrated that its mercury requirements require the "maximum" degree of reduction in mercury emissions that is "achievable" through the full range of reduction measures enumerated in CAA section 112(d)(2) and, therefore, this violates CAA section 112(d)(2).

The commenter affirmed that the mercury switch requirements the EPA has proposed should be included in the Agency's final mercury emission limits. The commenter acknowledged that the EPA has the authority to set limits for mercury that reflect, among other things, the application of operational measures, such as the proposed mercury switch requirements. However, they questioned whether such measures are sufficient and asserted that, if not, the EPA must set numeric limits for mercury that satisfy the stringency requirements in CAA sections 112(d)(2) and (3).

The commenter stated that the proposed limits for mercury are unlawfully and arbitrarily weak, because they simply codify what the majority of sources are already doing—instead of ensuring the "maximum achievable degree of emission reduction." (42 U.S.C. 7412(d)(2) and (3); see 84 FR 42730–32, August 16, 2019). The commenter stated that the EPA does not claim that this satisfies CAA sections 112(d)(2) and (3), or determine that numerical emission limits are not feasible.

Response: We acknowledge the support for our proposal to set mercury standards. This is the first time the EPA is promulgating a mercury emissions standard for this source category. Therefore, CAA section 112(d)(6) does not apply. Section 112(d)(6) of the CAA only applies to existing standards and requires that the EPA review existing standards within 8 years, and revise them as necessary, taking into account developments in practices, processes, or technologies.¹²

Pursuant to CAA sections 112(d)(2) and (3), and based on data from all facilities, we proposed MACT floor limits for new and existing sources in terms of lbs of mercury per ton of scrap processed as an input-based limit for all BOPFs and related units (HMTDS and ladles) at integrated iron and steel facilities. These limits, which are in units of mass of mercury emissions from all BOPFs and related units at each facility (hereafter called the “BOPF Group”¹³) per mass of scrap processed by each facility in their BOPFs, were derived using performance test data and data on amount of metal scrap processed obtained through an ICR sent to the industry in 2011, and are based in part on the assumption that the mass of mercury emitted from all BOPFs and related units is equivalent to the mass of mercury in the scrap input. Mercury is neither created nor destroyed in the BOPF and, based on our understanding of the steelmaking process, the primary source of mercury emissions is mercury contained in the scrap feedstock. Thus, the EPA determined it was reasonable to set a standard that limits the amount of mercury that may be emitted per ton of scrap processed.

Because we collected test data from BOPF Groups at all facilities in the industry, we necessarily collected test data from the best performing sources. We then used the test data to develop mercury-to-scrap input ratios for the facilities’ BOPF Groups and used the best performing five facilities out of all 11 integrated iron and steel facilities in the source category to develop the data set to derive the input-based MACT floor for existing sources for mercury, pursuant to CAA section 112(d)(3). For new sources, we established a standard no less stringent than the emission control achieved in practice by the best

controlled source, as determined by the Administrator, pursuant to CAA section 112(d)(3).

Once we established the MACT floor data set, we then determined an upper prediction limit (UPL)¹⁴ to develop the mercury MACT standard that incorporates the potential variability in future measurements. The EPA’s MACT analyses use the UPL approach to identify the average emission limitation achieved by the best performing sources to determine the MACT level of performance, or MACT emission limit, as described in the EPA memorandum titled *Mercury Emissions, Controls, and Costs at Integrated Iron and Steel Facilities* (Docket ID Item No. EPA–HQ–OAR–2002–0083–0958). The EPA uses this approach because it incorporates the average performance of the best performing sources as well as the variability of the performance during testing conditions. The UPL estimates what the upper bound of future values will be based upon present or past background data. The UPL approach encompasses all the data point-to-data point variability in the collected data, as derived from the dataset to which it is applied. We then took the mercury mass-to-scrap input ratio from the lowest-emitting facility in regard to mercury and used this value to establish the new source standard, after applying the same UPL procedure. Details of this procedure also are described in the technical memorandum cited above.

After calculating the MACT floor, the EPA evaluated and considered a beyond-the-floor option pursuant to CAA section 112(d)(2) based on ACI. However, for the reasons explained in the proposal preamble, including the relatively high capital and annualized cost of ACI with baghouses, and poor cost effectiveness, the EPA did not propose a beyond-the-floor option and instead proposed the MACT floor emission limits for new and existing sources as described above in this preamble. Additional details of the development of the proposed mercury emission limits and beyond-the-floor analyses are available in the proposed rule preamble and technical document titled *Mercury Emissions, Controls, and Costs at Integrated Iron and Steel Facilities* (Docket ID Item No. EPA–HQ–OAR–2002–0083–0958).

With regard to compliance with the proposed mercury emission limits, we

proposed that facilities would have two options to demonstrate compliance with the proposed input-based MACT emission limit: (1) Conduct a performance test annually at all BOPF-related units and convert the sum of the results to input-based units (*i.e.*, lbs of mercury per ton of scrap input) and document the results in a test report that can be submitted electronically to the delegated authority with the results; or (2) certify that the facility obtains all of their scrap from NVMSRP participants (or similar program as approved by the delegated authority), or establish that the facility’s scrap is not likely to contain mercury switches.

In the proposal preamble (84 FR 42704), we explained that although we did not know exactly what type of scrap was used when the integrated iron and steel facilities performed the ICR testing for mercury, we assumed the scrap was either NVMSRP scrap or scrap with higher amounts of mercury per ton of scrap than NVMSRP scrap. In response to the proposal, industry (AISI and one facility, U.S. Steel) submitted comments¹⁵ stating that the performance tests conducted to establish the MACT floor limits and, thus, the MACT for mercury in the proposal were based on facilities participating in the NVMSRP. We expect NVMSRP scrap in the future will contain similar levels of mercury or, more likely, less mercury than the scrap used to develop the MACT floor limits because the amount of mercury in scrap is declining overall due to the ban on the use of mercury in switches in U.S. automobiles after 2002, the expected continual retirement of older vehicles, and success of the NVMSRP. Based on the EPA’s understanding of the NVMSRP and the commitments made by the parties in the memoranda of understanding, the NVMSRP scrap constitutes some of the cleanest, if not the cleanest, scrap available in terms of mercury content. Therefore, if a facility chooses to comply with the mercury emission limit by certifying that all their scrap is from NVMSRP participants (or a similarly-approved program) or establishes that their scrap does not contain mercury switches, it is also reasonable to conclude that the amount of mercury left in the scrap due to the removal of mercury switches by the

¹³ Basic oxygen process furnace group is defined to be the collection of BOPF shop steelmaking operating units including the BOPF primary units (BOPF emissions from oxygen blow for iron refining); BOPF secondary units (secondary fugitive emissions in the shop from iron charging, steel tapping, and auxiliary processes not elsewhere controlled); ladle metallurgy units; and HMTDS and slag skimming units that are operating at the time of each mercury test sequence.

¹⁴ Westlin, P., and R. Merrill. *Data and procedure for handling below detection level data in analyzing various pollutant emissions databases for MACT and RTR emissions limits*. U.S. EPA, Research Triangle Park, North Carolina. December 13, 2011 (revised April 5, 2012) (Docket ID Item No. EPA–HQ–OAR–2002–0083–0857).

¹⁵ “Comments of the American Iron and Steel Institute and United States Steel Corporation on Proposed National Emission Standards for Hazardous Air Pollutants: Integrated Iron and Steel Manufacturing Facilities Residual Risk and Technology Review 84 FR 42,704 (Aug. 16, 2019) and Notice of Comment Period Reopening 84 FR 53,662 (Oct. 8, 2019).” Docket ID No. EPA–HQ–OAR–2002–0083. Submitted November 7, 2019.

NVMSRP achieves at least the same level of mercury reduction or likely better reduction compared to the numeric MACT floor limits.

By finalizing this emissions standard for mercury and two options to demonstrate compliance, the EPA has fulfilled its legal obligations under CAA sections 112 (d)(2) and (d)(3).

Comment: One commenter supported the EPA's proposal to continue to rely on the NVMSRP as an effective and efficient means of reducing mercury emissions in the steel industry. The commenter stated mercury is not an ingredient in steel, nor is it intentionally added in the steelmaking process; however, mercury is a contaminant sometimes present in scrap metal feedstock. The commenter acknowledges that the EPA correctly stated in the proposal that the primary source of mercury contamination in scrap metal is mercury-containing convenience switches that were used in automobiles until their use was phased out in model year 2002.

The commenter stated the NVMSRP has been a component of the NESHAP for Area Source Electric Arc Furnaces (EAF) Steelmaking Facilities in 40 CFR part 63, subpart YYYYY ("subpart YYYYY") for over a decade. As evidenced by the EPA's own data, the commenter noted that the program has been highly effective in removing mercury from scrap feedstock and reducing mercury emissions from EAF mills. The commenter stated as EAF steel production uses a feedstock of nearly 100-percent steel scrap, Steel Manufacturers Association and its members have gone to great lengths to prevent mercury switches and other sources of mercury contamination from entering the scrap metal recycling stream. Foremost among those efforts, the commenter stated, is the development of the NVMSRP in 2006. Since that time, the commenter noted that the NVMSRP and its participants have removed and safely diverted from the scrap supply and environment over seven million mercury convenience light switches containing nearly 7.8 tons of mercury. By removing these switches from scrap feedstock, the commenter stated, the steel industry prevented that mercury from being charged into its furnaces and released into the atmosphere.

The commenter agreed with the EPA that the amount of mercury emitted from steel manufacturers using scrap metal as feedstock has declined significantly due to the elimination of mercury-containing switches in cars in 2002 and the steel industry's efforts through the NVMSRP to ensure that

those remaining mercury switches are not charged into steelmaking furnaces. Critically, the commenter stated, the removal of mercury from convenience switches in cars is only one part—albeit, an important part—of a larger trend toward removing mercury from products. The commenter stated that all available data show the downward trend in mercury emissions is continuing and will continue until there are so few remaining pre-2003 vehicles reaching the end of their useful lives that mercury emissions will cease to be an issue for the steel manufacturing industry.

The commenter stated that the facilities in the Integrated Iron and Steel Manufacturing Facilities source category that use automotive shredded scrap inputs obtain automotive shredded scrap solely from suppliers participating in the NVMSRP.¹⁵ Furthermore, the commenter stated, the performance tests conducted to establish the MACT floor limits and, thus, the MACT limits for mercury in this rule were based on these very facilities participating in the program. The commenter stated the NVMSRP seeks to ensure that mercury switches are removed from scrap used in integrated iron and steel and other industries' production processes; this approach allows for responsible recycling of vehicles while minimizing the likelihood of mercury emissions from companies using this scrap to make new products. Based on this, the commenter asserted the EPA has appropriately proposed to account for the NVMSRP.

Response: We agree with the commenter that mercury is not intentionally added to the steelmaking process, that the NVMSRP works to remove mercury from the scrap supply, and that the level of mercury in steel scrap should continue to decline in the future because, based on available information and our analyses, the overwhelming majority of the mercury originates from mercury-containing convenience switches that were used in automobiles until their use was banned in the U.S. after model year 2002.

Comment: One commenter stated that because mercury emissions from scrap consuming facilities are caused by contamination in the scrap feedstock, mercury emissions are necessarily random and episodic. The commenter stated the intermittence of these emissions—and the widespread reduction in sources of mercury contamination—strongly weigh against the imposition of specific numerical limits. The commenter recognized that the EPA believes the Agency is legally compelled to promulgate numerical

mercury limits, and the commenter takes no position on whether the Agency is compelled to do so in this rulemaking. The commenter viewed these limits as inappropriate given the nature of mercury emissions in scrap-consuming facilities. The commenter asserted the NVMSRP remains a highly protective and effective surrogate for numerical limits and recommended that the EPA continue to rely on it as such.

Response: As explained above, the EPA has decided to promulgate a mercury emission limit for the BOPF and related processes pursuant to section 112(d) of the CAA in part, to address a 2004 petition for reconsideration. The steel-making units, although by definition a batch process, operate on a cycle where one batch starts as soon as the previous one ends so that the furnace remains operating almost all the time (except for occasional maintenance or repair activities) to prevent cooling and the need to reheat. Three test runs are required for a performance test. The steelmaking process cycle, although a batch process, is sufficiently long enough to allow at least one test run in each cycle. Because the scrap content and amount of mercury in each batch may change from batch to batch, using an average of three runs to develop the standard that the facilities will use to determine compliance (or for any other testing purpose) contributes to the accuracy of the data and, therefore, is to the benefit of both steel facilities as well as the EPA. The final three-run test average, then, is considered representative of typical operations and not just one "batch." Therefore, the EPA determined it was feasible and reasonable to develop a numerical emission limit based on the data we had. However, as explained above, the EPA is including two options to demonstrate compliance: (1) Conduct performance testing; or (2) certify scrap is obtained from suppliers who participate in the NVMSRP or similar program, or is free of mercury switches. With this final rule, the EPA has fulfilled its legal obligations under CAA sections 112(d)(2) and (3) to set emission standards for mercury.

Comment: The commenter stated that the use of a 99-percent UPL to develop the MACT floor for mercury is appropriate and consistent with the EPA's approach in other rulemakings. The commenter stated the ability of the UPL, however, to properly account for variability here is in question, given that 80 percent of the sampling results included at least one mass fraction below the detection limit (non-detect), and 8 percent of total runs included all

non-detect values. In sum, the commenter stated only 12 percent of runs included all detected results, severely limiting the above-detection-limit dataset on which the UPL calculation was based.

Response: In the procedure the EPA uses to develop the MACT standards, the calculated UPL is compared to three times the HAP and method-specific “representative detection level” (RDL) developed by the EPA, and the higher value of the two (UPL v. 3xRDL) is used as the MACT standard. This step ensures that the final MACT floor values will be a measurable above-detection-limit value. (See Westlin and Merrill,

2011¹⁴). When multiplying RDL by a factor of 3, the measurement imprecision is decreased to around 10 to 15 percent. Using the larger value for the MACT standard ensures that measurement variability is adequately addressed.

In regard to the number of below detection limit (BDL) values, see the procedure from the EPA memorandum titled *Determination of “Non-Detect” from EPA Method 29 (Multi-Metals) and EPA Method 23 (Dioxin/Furan) Test Data When Evaluating the Setting of MACT Floors Versus Establishing Work Practice Standards* (S. Johnson, U.S. EPA, June 5, 2014) located in the docket

to this final rule. In the memorandum (page 8, item 3), there is a discussion of a procedure for data classification for mercury and nonmercury metals obtained via EPA Method 29. According to the procedure: “Where test results for any single analyte are detection level limited (DLL) or above detection limit (ADL), we assume detection (*i.e.*, ADL) for that test run data for that specific analyte.” Therefore, the integrated iron and steel mercury data classified as DLL, at 80 percent, are considered ADL and consequently, the number of runs considered ADL is 92 percent, a clear majority of the data set. See summary table of the MACT floor run data below.

TABLE 4—INTEGRATED IRON AND STEEL SOURCE MERCURY MACT FLOOR RUN DATA CLASSIFICATIONS

Source	Data	Number of runs				Percentage of total runs		
		BDL	DLL	ADL	Total	BDL	DLL	ADL
BOPF Group	Before reclassification ¹	7	73	11	91	8	80	12
	After reclassification ²	7	0	84	91	8	0	92

¹ From the memorandum titled *Mercury Emissions, Controls, and Costs at Integrated Iron and Steel Facilities* (Docket ID Item No. EPA-HQ-OAR-2002-0083-0958).

² As per the procedures described in the memorandum titled *Determination of “Non-Detect” from EPA Method 29 (Multi-Metals) and EPA Method 23 (Dioxin/Furan) Test Data When Evaluating the Setting of MACT Floors Versus Establishing Work Practice Standards*. S. Johnson, U.S. EPA, Research Triangle Park, North Carolina. June 5, 2014.

Comment: A commenter stated the EPA’s equating of hourly mercury test results with annual mercury rates and use of annual scrap usage to determine lbs of mercury per ton of scrap value is problematic for several reasons. The commenter stated that hourly mercury tests only account for the amount of mercury in the scrap at the time of the test and are not normalized for fluctuations in the short-term scrap usage rates, short-term scrap/iron ratios, or scrap and lime mercury concentration. The commenter asserted the differences in the mercury emissions rates between facilities and their respective operations are not appropriately accounted for in the EPA’s calculations, based on the amount of scrap and mercury concentration in the scrap during the time of the test, which could add variability not properly factored into the EPA’s calculations. The commenter stated it is inappropriate to assume that the type of scrap, scrap usage, and scrap-to-molten iron ratio at the time of the test were indicative of the long-term averages. Thus, the commenter stated, this critical element of the proposal’s analysis is unjustified and cannot support standard-setting. In addition, the commenter stated that although the proposed standards in 40 CFR part 63, subpart FFFFF, Table 1 are intended to be set at the CAA section 112(d) floor level, they fail to account for the degree

of variability present in steelmaking inputs and, thus, go beyond the floor without proper justification.

The commenter also stated the EPA’s annualized approach (lbs/yr mercury + ton scrap/yr) resulted in the skewness and kurtosis data analyses being represented as a lognormal distribution, whereas the output-based steel production approach (that accounts for short-term production rates) is skewed non-normal distribution, according to the prescribed MACT floor methodology. The commenter stated that since the mercury emissions data sets are the same between the two input- and output-based approaches, one could properly conclude that the annualized approach is not adequately accounting for the short-term production rate variability and, thus, it may be comparatively less representative of actual variability in mercury emissions during operations.

The commenter stated the EPA’s analysis appears not to have accounted properly for the scrap mercury content variability and, thus, does not adequately apply the UPL concept of ensuring that sources controlled to the level of the best performing five sources would achieve the limit 99 percent of the time. The commenter stated that, as proposed, the UPL calculation does account for some degree of variability. However, the commenter stated the EPA needs to revisit the associated MACT

floor calculations to better represent the variability among individual loads of scrap in terms of the variability in mercury content and the associated long-term emission performance in assessing the emission limit that is achieved by the top five performing sources or UPL.

The commenter asserted that the EPA should calculate the variability using all viable mercury emissions stack testing results in the UPL analysis and then apply that variability factor to the five best performing sources. Particularly when there is a small dataset for which the raw material content is indicative of emissions, the commenter asserted that the EPA needs to determine the variability that can reasonably be expected from the top performers. Given that the facilities in question were all accepting scrap from suppliers in the NVMSRP, the commenter said the variability in scrap obtained from such suppliers is reflected in all of the test results, not just the top five performers.

The commenter noted that in the NESHAP for the EAF source, which used similar scrap inputs as the Integrated Iron and Steel Manufacturing Facilities source category but at much greater volumes and proportions, the EPA recognized that an additional scrap variability factor would be needed to account for variation in mercury emissions if an emission limit was to be developed. Therefore, the commenter

stated, although the EPA did not ultimately establish a numeric mercury emission limit, working documents from development of the EAF rule show a “scrap (mercury) variability” factor was applied in an attempt to develop a mercury limit. The commenter stated that the EPA cited the variability of mercury in scrap metal as the reason why performance test averages varied by over 2 orders of magnitude at a single EAF plant. (72 FR 53817). The commenter stated that if the EPA decides to proceed, it needs to seek additional data regarding scrap mercury content and variability similar to the approach the EPA considered with the EAF NESHAP so that the UPL can account for that variability using standard and accepted methods.

The commenter stated rather than the approach the EPA took in the proposal of calculating the mercury per ton of scrap values by using a source’s annual total scrap input tonnage, the EPA should refine its approach by comparing the scrap tonnage used in the individual heats when the ICR stack test results were obtained. Moreover, the commenter stated the EPA should look not only at the total scrap used for those heats, but also to the extent possible based on available records, the proportion of automotive shredded scrap used in those heats. The commenter stated this approach would be far more accurate than the one reflected in the proposal, which fails to account for any relation between the stack test data and the scrap used at the time those results were obtained. The commenter stated that failure to take this critical factor into account renders the standard not rationally related to the performance of the top performing sources and, thus, arbitrary and capricious.

Response: Because scrap varied from unit to unit and facility to facility, the variability in the scrap was already accounted for in the data used to develop the MACT floor. We used data for the mercury content of scrap from all units in the BOPF Group¹³ at the top five best performing facilities from five locations in three states that stretched from Chicago, Illinois, to Pittsburgh, Pennsylvania. Over 100 runs of data were used to develop the facility lbs mercury/ton steel scrap values used to calculate the UPL. The variability in the scrap in the over 100 runs was almost certainly captured by the UPL calculation for the MACT floor.

In addition, the procedure the EPA uses to develop the MACT standards allows for variability in future emission measurements. To determine the MACT standard, an initially calculated UPL is

compared to 3 times the HAP- and method-specific representative detection level (RDL) developed by the EPA, and the higher value is used as the MACT standard. This step ensures that the final MACT floor values will be measurable ADL values. (See Westlin and Merrill, 2011.¹⁴)

As explained at the following website, a lognormal distribution is a type of skewed distribution (see <https://www.statisticshowto.com/lognormal-distribution/>; <https://www.investopedia.com/terms/s/skewness.asp>). A lognormal distribution leans toward the right because all values are above zero, by definition of a log. “Skew” refers to distortion or asymmetry as compared to a symmetrical bell curve, or normal distribution, in a set of data. If the curve leans towards the left or to the right, it is said to be skewed. Skewness can be quantified as a representation of the extent to which a given distribution varies from a normal distribution. A normal distribution has a skew of zero, while a lognormal distribution has some degree of right-skew. Both the input- and output-based approaches to calculate a mercury MACT limit are skewed because they are both lognormally distributed.

With regard to the mercury MACT calculations, when data from the same facilities were compared, the variability of the lbs mercury/ton scrap input dataset had more variability than the lbs mercury/ton steel output variability. Consequently, more variability is incorporated into the UPL calculation for the input-based standard than for an output-based.

Not every facility reported run-by-run scrap tonnage values to the EPA in the ICR, whereas every facility reported an annual scrap tonnage value. In addition, almost all facilities did not report percent automotive scrap use during testing or annually. Most facilities left this ICR answer field blank, said it was confidential, or was unknown. Therefore, the annual approach was the only option available to the EPA based on the data provided to the EPA by the integrated iron and steel facilities.

Comment: One commenter stated although the EPA’s MACT floor calculation includes a mass concentration value for mercury content in lime, as is discussed in an attached engineering report providing independent evaluation by Barr Engineering Co. commissioned by AISI/ U.S. Steel, the MACT floor calculation fails to account for potential mercury variability in lime inputs as the EPA has appropriately done in other contexts.

The commenter stated this approach fails to account for variability in a manner that is appropriate for the source category.

Response: We agree with the commenter’s Barr evaluation that some mercury emissions can be attributed to the other inputs to the BOPF, which include lime. However, the stack performance test data the EPA collected through the 2011 ICR would account for the lime portion of the mercury emissions and include some of the variability in emissions as well. Variability is accounted for both by the number and length of the source test runs and the fact that multiple sources were tested. Our MACT floor calculation relied on this data and, thus, accounted for variability in lime inputs. At this time, we do not have additional data regarding variability in lime inputs. The Barr evaluation cites the Portland Cement UPL calculation as an example of the EPA accounting for mercury variability in lime inputs in the UPL MACT floor calculation. The commenter pointed to the “Intra-quarry Variability Estimate for Mercury” memorandum for the Portland Cement NESHAP (40 CFR part 63, subpart LLL) memorandum (Docket ID item No. EPA-HQ-OAR-2002-0051-3323), and stated that, in that rulemaking, the EPA had 30 daily mercury concentrations, parts per million (ppm) in limestone by quarry values for three kilns that were in the MACT floor pool or used the same quarry as MACT floor pool kilns. The commenter also stated that those values were used to calculate temporal correlation between the quarries and calculate intra-quarry variability. That information, the commenter asserts, was then incorporated into the Portland Cement UPL MACT floor calculation. The commenter is correct that the EPA does not have direct data regarding mercury content of the lime used at the integrated iron and steel industry. For the integrated iron and steel ICR, facilities had to report the amount of lime used annually, but not the mercury content of that lime.

As shown in the memorandum titled *Mercury Emissions, Controls, and Costs at Integrated Iron and Steel Facilities* (Docket ID Item No. EPA-HQ-OAR-2002-0083-0958), Table 4, the mercury from lime was estimated to comprise less than 15 percent of the total mercury inputs to the BOPF, on average. The value for mercury content of lime, at 0.03035 ppm, was developed from the average of data from two reference sources. One reference source was the information (Limestone Mercury Concentrations (ppb) with Revised Data from Buzzi. July 21, 2009) gathered for

the Portland Cement NESHAP (40 CFR part 63, subpart LLL; Docket ID Item No. EPA-HQ-OAR-2002-0051-3400) and the other source was from a Portland Cement Association research report (Hills and Stevenson, 2006; Docket ID Item No. EPA-HQ-OAR-2002-0083-0872).

The EPA estimated that mercury in the scrap accounts for over 85 percent of the total mercury inputs to the BOPF and constitutes the vast majority of mercury content; therefore, regulating the scrap input is sufficiently correlated to the numeric emission limitation for mercury to enable setting a standard for mercury from scrap. And, as noted above, as a result of the robustness of the mercury emission data used and the calculations performed to develop the MACT standard (UPL, etc.), we have accounted for the variability of mercury in both the scrap and lime. The mercury emission limitations are based on the best data available to the Agency and satisfies our obligation under CAA section 112(d) to establish a standard for mercury emissions from the BOPF. For information on the data used to develop the MACT floor, see the memorandum titled *Mercury Emissions, Controls, and Costs at Integrated Iron and Steel Facilities* (Docket ID Item No. EPA-HQ-OAR-2002-0083-0958).

Comment: One commenter stated that with a small source category, and, thus, small number of sources setting the floor, a proper UPL analysis is essential to a technically defensible standard that is consistent with the statute. The commenter stated the EPA's technical memorandum regarding its mercury floor calculations acknowledges, however, that its dataset including just five data points is small and, in fact, below the minimum of seven data points that the EPA considers the threshold for a "limited dataset." The commenter stated that this limited dataset is the result of calculating a mercury emissions per ton of steel scrap value for only the top five sources in the source category and then running the UPL calculation based only on those five sources.

Response: The BOPF Group existing source MACT floor pool dataset (five data points) is based on fewer than seven data points. Therefore, the EPA used the protocol for developing MACT floors for small datasets. (See technical memorandum titled *Mercury Emissions, Controls, and Costs at Integrated Iron and Steel Facilities* (Docket ID Item No. EPA-HQ-OAR-2002-0083-0958)). For limited datasets, the EPA can further evaluate each individual dataset in order to ensure that the uncertainty associated with a limited dataset does

not cause the calculated emission limit to be so high that it does not reflect the average performance of the units upon which the limit is based after accounting for variability in the emissions of those units. The EPA evaluated this specific integrated iron and steel mercury dataset to determine whether it is appropriate to make any modifications to the approach used to calculate MACT floors for each of these datasets. The EPA ensured that the selected data distribution best represents each dataset; ensured that the correct equation for the distribution was then applied to the data; and compared individual components of each limited dataset to determine if the standards based on limited datasets reasonably represent the performance of the units included in the dataset. Based on an evaluation of the limited datasets, the EPA determined that no changes to the standard floor calculation procedure were warranted.

For new sources, in the EPA's experience from the past, limited datasets warranted close scrutiny because sources with the lowest average emissions, but with a relatively high variance, could be identified mistakenly as the best performing source. In the mercury emission limit for new integrated iron and steel sources, the best performing source identified had 28 data points in the MACT floor pool, so it is not a limited dataset, nor does it have relatively high variance. Therefore, we conclude that further inspection of the existing emissions datasets is not warranted.

Comment: One commenter stated given the need to finalize this RTR in March 2020 and given that any data collection and analysis needed to generate a sound mercury emission limit would take at least a year, the EPA should not finalize the mercury emission limit at this time but instead should withdraw it and defer action to a later date to allow the EPA to address the flaws in the proposed standard. The commenter stated the proposed mercury emission limit should be withdrawn and, if the Agency ultimately determines a standard must be set, the EPA should issue a new, separate proposal because the changes necessary to both the dataset and the floor setting methodologies are sufficiently great that interested persons will need an opportunity to comment on the EPA's efforts to address them. In short, the commenter stated any mercury gap-filling should proceed on an independent track from the RTR, and it would be arbitrary and capricious for the EPA to finalize a mercury emission limit in reliance on the limited data it

has and particularly using the flawed methodologies reflected in the proposal.

The commenter stated the EPA can and should determine that it currently lacks adequate data to establish a mercury emission limit, in light of the limited timeframe allowed under the judicial deadline to complete this rulemaking. The commenter stated such a decision would be afforded an "extreme degree of deference" by the Court on review. The commenter stated the EPA's obligation under the court order is to complete the RTR. The commenter stated filling a perceived gap in the original standard is not mandated under CAA section 112 generally and certainly is not compelled to be part of the RTR. Accordingly, the commenter stated the EPA need not finalize the mercury proposal by the March 2020 RTR deadline. The commenter stated if the EPA promulgates now, the standard will necessarily lack adequate data and a record to support it and, thus, would not only be ill-advised, but also arbitrary and capricious.

Response: The EPA opted to promulgate these mercury emission limits at the same time we conducted the RTR in part to address an outstanding petition for reconsideration asking the Agency to set a mercury emissions standard. The data used for the mercury emission limit were stack test data obtained using typical mercury testing methodology and the procedures we followed to develop the MACT limits were typical MACT standard development procedures. The mercury data are not flawed, as explained elsewhere in this preamble in responses to commenters' specific allegations. All alleged flaws have been addressed above in responses to comments received, and we have shown that the allegations were unfounded and/or lacking scientific basis and that the EPA data and data handling procedures were performed correctly to develop the numeric emission limitation. Thus, we did not make any changes to the mercury emission limit in response to comments received. The mercury emission limitation promulgated in this rule is based on the best data available to the Agency and satisfies our obligation under CAA section 112(d) to establish a standard for mercury emissions from the BOPF.

Comment: One commenter stated if the EPA proceeds with a mercury emission limit, the proposal to allow facilities to satisfy the mercury requirements by certifying that their scrap is "not likely to contain motor vehicle scrap" in the proposed rule, e.g., proposed 40 CFR 63.7791(b) (final 40 CFR 63.7791(d)), is reasonable but needs

to be revised to better match the requirements in 40 CFR 63.10685(b) in 40 CFR part 63, subpart YYYYY. For example, the commenter stated the EPA needs to clarify that the option applies to “scrap not likely to contain automotive shredded scrap,” rather than all “motor vehicle scrap” as it is currently proposed; regulatory language changes should be made to reflect this clarification. This is because mercury switches, the commenter stated, the driver of mercury emissions, are not present in all motor vehicle scrap; rather, mercury switches are typically only present in *shredded* automotive scrap. The commenter stated facilities should, thus, be able to comply by certifying that scrap inputs are not likely to contain automotive shredded scrap. The commenter recommended the EPA modify proposed 40 CFR 63.7791(a)(1), 63.7791(a)(2), 63.7791(b)(1), 63.7791(b)(2), 63.7791(c), 63.7840(f)(1), and 63.7852 (final 40 CFR 63.7791(c)(1), 63.7791(c)(2), 63.7791(d)(1) through (d)(3), 63.7791(e), 63.7840(f)(1), and 63.7852, respectively) definitions for motor vehicle scrap, scrap provider, and steel scrap accordingly.

Response: The EPA acknowledges the clarification requested by the commenter and has incorporated these suggestions as much as appropriate into the final rule. We agree with the commenter that given today’s automobile fleet, where motor vehicles from 2003 production and earlier still contain mercury switches, the scrap containing mercury switches is typically shredded automotive scrap. We have revised the proposed option that would have allowed facilities to comply by certifying that the facility’s scrap is “not likely to contain motor vehicle scrap.” As finalized, this option has been changed to allow facilities to comply by certifying that the facility’s scrap “does not contain mercury switches.” This approach allows facilities to establish the absence of mercury switches in their scrap, as appropriate for their facility, *i.e.*, their scrap is recovered for its specialty alloy content, their scrap does not contain motor vehicle scrap, or their scrap does not contain shredded motor vehicle scrap.

Comment: One commenter stated facilities that use small amounts of automotive shredded scrap relative to other inputs per ton of steel produced, even from non-NVMSRP suppliers, would not be expected to emit mercury at levels exceeding the emission limitations reflected in the proposed rule. As the proposal acknowledges, the commenter stated that the mercury content associated with mercury

switches in older, end-of-life vehicles is the basis for the mercury emission limit. The commenter stated mercury switches are not present in all scrap, and not even in all automotive scrap; rather, mercury switches are only potentially present in shredded automotive scrap. Because of this, the commenter stated, facilities using small amounts of automotive shredded scrap would not be expected to have mercury emissions in excess of the proposed standard. Thus, the commenter stated, sources using minimal amounts of automotive shredded scrap should not be burdened with the costs of testing or documenting participation in the switch recovery programs, particularly given the low risk modeled for the source category.

The commenter stated the EPA should modify the proposed 40 CFR 63.7791(b) to allow facilities to instead certify that they use only minimal amounts of automotive shredded scrap inputs, such as 10-percent automotive shredded scrap per ton of steel produced. So long as a facility does not use more automotive shredded scrap than the threshold, the commenter stated that certification should constitute its compliance demonstration; this would enable facilities that use very minimal amounts of automotive shredded scrap or that use automotive shredded scrap only occasionally based on the scrap supply market, and are, thus, unlikely to exceed the mercury emission limit, to be deemed compliant, as well.

The commenter added the EPA should acknowledge that when the NVMSRP ends this event will, in essence, establish compliance with the proposed mercury emission limit because it will signal achievement of substantial elimination of mercury switches from automotive scrap. Consistent with the compliance option for the proposed mercury requirements of allowing purchase of scrap from NVMSRP participants, the commenter stated the EPA should include in any final rule a provision that when the NVMSRP ends, sources would be deemed compliant with the mercury emission limit (because the commenter stated the EPA would have deemed that the NVMSRP is no longer needed to reduce mercury switches from automotive scrap).

The commenter stated the EPA should revise proposed 40 CFR 63.7791(c) or add a new 40 CFR 63.7791(d) to allow sources to otherwise show that their shredded motor vehicle scrap is unlikely to contain mercury. For example, the commenter stated, if the NVMSRP has ended with a finding that the mercury switches remaining in vehicles on the road are minimal, the

fact that there is no need for such a program establishes the diminished presence of mercury. Or, the commenter stated, if a scrap dealer uses only recycled post-2003 vehicles, the use of this automotive scrap should not contain any appreciable mercury. In other words, the commenter stated, at some point the number of recycled vehicles containing mercury switches will diminish to the extent that mercury in automotive scrap is no longer a concern. At this point, the commenter stated, facilities should be able to rely on some provision in 40 CFR 63.7791 to conclude that their scrap is unlikely to contain mercury switches. The commenter stated such an approach is reasonable because the standard is driven by the use of automotive shredded scrap at BOPF shops and the mercury content in that scrap, and the NVMSRP is aimed at removing mercury switches from automotive shredded scrap. The commenter stated meeting the NVMSRP’s program goals, which should be the rationale for ending the program, will occur when mercury switches are sufficiently removed from automotive scrap. When that has occurred, the commenter stated, it will mean that the remaining automotive scrap inputs available to integrated iron and steel facilities will in effect satisfy the NVMSRP criteria, and facilities should be considered to be in compliance with the mercury emissions standard. In that case, the commenter stated, it would not add value to require further compliance with the administrative burdens associated with complying with the standard, since the source will have been effectively eliminated.

Response: The commenter appears to be asking the EPA to create an exemption from the requirements for certain sources and to not regulate the mercury emissions from those sources. In other words, the commenter is asking the EPA to read a *de minimis* exemption into the requirement that the EPA regulate all HAP emitted by major sources. The court, however, has previously upheld the EPA’s rejection of this argument on the grounds that the statute does not provide for *de minimis* exemptions where a MACT floor exists. *See Nat’l Lime Assn. v. EPA*, 233 F.3d 625, 640 (D.C. Cir. 2000). For this reason, the EPA is not making any changes to the proposed rule to create an exemption for *de minimis* mercury emissions as per this comment.

However, in the final rule, the compliance option in 40 CFR 63.7791(d) “*Use of scrap that does not contain mercury switches*” can be used by a source if the facility can establish that

their scrap does not include mercury switches. This option is available regardless of whether or not the NVMSRP is in operation. If the NVMSRP were to be discontinued, however, the fact that the program had been discontinued would not establish the mercury level, or lack thereof, in the scrap. Thus, the potential scenario of NVMSRP discontinuation could not be relied upon to demonstrate compliance with the mercury emission limit.

Comment: One commenter stated the proposed standards for the integrated iron and steel source category are very similar to the requirements for facilities in the EAF area source standards to obtain scrap from participants in the NVMSRP and therefore the EPA should reconcile this rule with the EAF rule. The commenter stated the rule language should be revised to maintain consistency with the existing EAF NVMSRP regulatory language.

As background, the commenter explained that some companies with facilities subject to the subpart FFFFF standards for integrated iron and steel sources also operate EAF facilities subject to the subpart YYYYY standards, and they purchase and manage scrap that is charged both into BOPF vessels and the EAF at a corporate level, using the same policies and management methods to obtain scrap for both source categories. Since these companies have area source EAF facilities that must comply with the mercury switch program requirements in subpart YYYYY, the commenter stated their entire scrap management system is already compliant with the motor vehicle scrap management requirements in those standards. The commenter stated the language differences between subpart YYYYY and the proposed subpart FFFFF motor vehicle scrap management requirements could cause issues in managing these companies' scrap supply chains and ensuring compliance with both regulations. The commenter stated the proposal does not explain why these differently worded requirements are being imposed on integrated iron and steel facilities, particularly given that EAF sources use a greater proportion of scrap inputs than integrated iron and steel BOPF sources and that doing so would impose burdens on facilities, including the need to modify contracts and additional administrative costs. Because of the identical supply chain for BOPF shops and EAFs, the commenter stated there should be no differentiation in the requirements. The commenter suggested revisions to the proposed language 40 CFR 63.7791(b) (final 40 CFR 63.7791(d)) and to add

allowance for specialty metal scrap from motor vehicles.

Response: The EPA agrees with the rationale for the suggested changes and we have made revisions to the rule to make this rule more similar to 40 CFR part 63, subpart YYYYY, as described below in section IV.C.5. In terms of NVMSRP participation, the proposed rule was identical to subpart YYYYY except for the scrap plan requirement; we have removed the scrap plan requirement in the final rule. As discussed above in a previous comment, in the final rule, we have revised the proposed option that allowed sources to comply by certifying that the facility's scrap is "not likely to contain motor vehicle scrap." As finalized, the facility can establish compliance with the mercury emission limit by certifying the absence of mercury switches in their scrap, as appropriate for their facility: By either certifying that their scrap is recovered for its specialty alloy content, or their scrap does not contain motor vehicle scrap, or their scrap does not contain shredded motor vehicle scrap.

Comment: One commenter stated the proposed annual testing for sources opting to comply under subpart FFFFF Table 1 should be revised to once per five-year title V permit term, which is consistent with frequencies for other title V testing requirements for the sources, such as for secondary BOPF baghouses. The commenter stated more frequent testing is unnecessary given that emissions are steadily declining among the source category in conjunction with the depletion of mercury switches in automotive scrap. If the EPA believes that more frequent than once-per-term testing is needed, the commenter stated EPA then should adopt a twice per five-year permit term, similar to the testing frequency for primary BOPF controls, given the high cost of testing. The commenter stated requiring annual testing would be excessive, costly, without basis, and inconsistent with any other requirements in the subpart FFFFF standards. In the event that EPA retains the annual testing requirement, the commenter stated revisions to the proposed language regarding time between performance tests should be made to clarify the point at which facilities should begin to calculate these dates.

Response: The EPA agrees with a reduction in testing frequency to coincide with tests for PM already promulgated in the rule (40 CFR 63.7821(b)) for units equipped with control devices other than a baghouse (which includes all of the primary BOPF control devices), which will reduce the

testing burden on the industry. The change is as follows (for testing compliance option, only): Change from annual testing to twice per permit cycle (initial/final and mid-term) for facilities with title V permits, and every 2.5 years for facilities without a title V permit, to match the PM testing frequency in 40 CFR 63.7821. Testing would then take place after the initial performance test at the next specified point in the permit cycle, either at initial, final, or mid-term of the permit (for facilities with permits), whichever comes first after the initial performance test, which is one year after the effective date of the rule, or within 2.5 years after promulgation (for facilities without permits).

Comment: One commenter stated in any final rule, and consistent with the approach the EPA took in the ICR testing, the EPA should explicitly provide for similar units at a source to rely on the testing of one of those units for subpart FFFFF Table 1 compliance demonstration purposes, where the units are exhausted to the same type of control device, processed the same types of materials, were similar size and design, and have similar operating conditions.

Response: We understand the economic benefit associated with reducing the testing burden where possible. The EPA allows testing of representative units on a case-by-case basis as described in the 2009 EPA guidance document, *Clean Air Act National Stack Test Guidance*,¹⁶ pursuant to the EPA's authority cited in the General Provisions to part 63 at 40 CFR 63.7(h). Similar to the requirements to establish similarity that was used in the integrated iron and steel ICR for this RTR, the stack test guidance requires submission of design and operating parameters to establish the case of identical units, as described further in the guidance, with the final decision to be determined by the Administrator or delegated authority. The EPA thus provides options for reducing testing burden and no addition to or modification of the rule is needed to provide this testing option.

Comment: One commenter stated the proposed 40 CFR 63.7825(a)(2) provision requires either a single compliance test with all affected units in operation or separate compliance tests on each emission unit in the BOPF Group. The commenter stated most facilities have multiple stacks that

¹⁶ *Clean Air Act National Stack Test Guidance*. U.S. Environmental Protection Agency, Washington, DC. April 27, 2009. (Docket ID Item No. EPA-HQ-OAR-2002-0061). https://www.epa.gov/sites/production/files/2013-09/documents/stacktesting_1.pdf.

would need to be tested under the current Proposed Rule; simultaneously testing all stacks during a single compliance testing event would be difficult or impossible. The commenter stated this leaves the option of performing separate compliance testing on each emission unit. The commenter stated proposed 40 CFR 63.7825(a)(2) requires that when units are tested separately, they must be tested “as soon as is practicable,” which is not defined. The commenter stated the EPA should allow a three-month period for all stacks to be tested. To implement this, the commenter stated the EPA should create a new subparagraph, e.g., 63.7825(a)(3), as follows: “Testing of related BOPF Group units shall be conducted within a 3-month period.”

The commenter stated since the BOPF Group mercury limit applies to all BOPF shop steelmaking operation units, the compliance demonstration for performance testing requires mercury emissions from all BOPF Group stacks to be added up to demonstrate compliance. The commenter stated this calculation cannot be made until all BOPF Group sources have been tested. Under proposed 40 CFR 63.7840(e)(2), the commenter stated facilities are required to submit a notification of compliance status within 60 days of completion of the performance test. The commenter requested that EPA allow for one notification of compliance status to be submitted 60 days after the final performance test. The commenter also stated that in the proposal, facilities are required to provide a 60-day notification of intent to conduct performance testing. Therefore, the commenter requested that the rule also provide that the 60-day notice be submitted at least 60 days prior to the first BOPF Group unit control device test; then the initial testing notification can be required to include a schedule of when testing of other BOPF Group unit control devices will be tested, rather than require additional notification for subsequently tested sources.

Response: The EPA has decided that it is not appropriate to allow a three-month window for testing because this time period likely would include very different batches of scrap and possibly wide variation in levels of mercury. However, we discuss in the previous comment and response that EPA provides for facilities to be able to apply for a waiver of testing in the case of multiple and identical units via stack test guidance¹⁶ pursuant to EPA’s authority in 40 CFR 63.7(h). For the final rule, the EPA changed the requirement for a 60-day notification of the start of “mercury compliance

testing” to “notification of the first compliance test in the BOPF Group with a schedule of all subsequent tests in the BOPF Group.” The final rule also differs from the proposed rule in that it states that “for the purposes of submitting the notification of compliance status, the performance test shall be considered complete when the final BOPF Group unit control device is tested.” These changes eliminate multiple start notices for testing of the BOPF Group and clarify that only one notice of compliance status is needed to show compliance with the mercury emission limit. Because all units in the BOPF Group must be tested before the mercury emissions can be calculated and compared to the emission limit in the rule, it is logical to require one notice of compliance status after the last BOPF Group unit is tested. See section IV.C.5 below for details of the rule changes.

Comment: One commenter stated mercury testing samples were collected during the ICR process following sampling procedures in 40 CFR 63.7822(f), (g), and (h), which dictate when sampling begins and ends during specific process BOPF operations for PM testing. The commenter stated the same procedures should apply to mercury testing and should be incorporated by reference in the mercury testing requirements. Accordingly, the commenter stated proposed 40 CFR 63.7825 should be modified to include the procedures in 40 CFR 63.7822(f), (g), and (h) as applicable.

Response: The EPA agrees that mercury testing samples were collected during the ICR process following sampling procedures in 40 CFR 63.7822(f), (g), and (h). Therefore, we have added these procedures to the final rule. See section IV.C.5 for details of the rule changes.

Comment: One commenter stated the 40 CFR 63.7825(b)(2) provision requires a minimum sample volume of 60 dscf of gas during each mercury test run. The commenter stated it is inappropriate to collect 60 dscf when using EPA Method 30B because the method itself contains guidelines for selecting proper sampling rates. The commenter stated the collection of 60 dscf should be clarified to only apply to EPA Method 29 or other isokinetic sampling methods.

Response: We agree with the commenter that EPA Method 30B has a method-specific volume requirement tied to the detection limit of the method, so we do not need to identify a minimum volume for EPA Method 30B in the rule. However, a sample volume of 60 dscf is appropriate for EPA

Method 29. The rule text has been revised to specify that the 60 dscf minimum sample volume applies to Method 29 only. See section IV.C.5 for details of the rule changes.

Comment: One commenter stated the EPA should also include EPA Method 101A, *Determination of Particulate and Gaseous Mercury Emissions From Sewage Sludge Incinerators*, which is a viable alternative to both EPA Methods 29 and 30B.

Response: The EPA does not consider EPA Method 101A to be equivalent to EPA Method 29 for mercury measurement for all purposes. However, the EPA is willing to consider EPA Method 101A as an alternative test method under the General Provisions to 40 CFR part 63 (40 CFR 63.7(f)) on a case-by-case basis, provided the petitioner can provide adequate information demonstrating that this candidate method is equivalent to the standards (i.e., EPA Methods 29 and/or 30B). The proposed rule text has been revised to elaborate on EPA’s ability to allow alternative test methods to be considered on a case-by-case basis. See section IV.C.5 for details of the rule changes.

Comment: One commenter stated in order to use the NVMSRP or equivalent program option, the EPA lists in proposed 40 CFR 63.7791(a) and (c) a host of requirements that companies will need to meet. The commenter stated a key purpose of the NVMSRP was to have suppliers register and participate so that companies could rely on that participation to prevent mercury from entering their feedstocks in the form of automotive shredded scrap. The commenter stated since its initiation, the NVMSRP has proven to be a success. As recognition of that success, in 2017, the commenter stated that the EPA, along with the original parties to the 2006 agreement, came together to extend the program through 2021. The commenter stated unfortunately, the proposed language fails to recognize that the industry has substantially invested to make the program a success and instead would put individual companies in the role of policing the program. The commenter stated companies need to be able to rely on the program and that its suppliers are participants therein. The commenter stated nothing more should be required.

The commenter said specifically that the EPA should delete 40 CFR 63.7791(a)(3)–(5) and (c)(3)–(5). The commenter stated these provisions are inconsistent with the requirements that apply to the NVMSRP as it is considered an “approved mercury program” in 40 CFR 63.10685 in 40 CFR part 63,

subpart YYYYY. The commenter stated companies are not in a position to renegotiate supplier contracts to allow them to enter and inspect suppliers. Moreover, the commenter stated the EPA is unclear about what “other corroboration” even means in the context of the program; the participation of the suppliers in the program should be sufficient. Finally, the commenter stated any broker contracts would provide that the scrap needs to be from NVMSRP-participating suppliers and it is entirely unclear how the EPA expects companies to ensure that suppliers are “implementing appropriate steps to minimize the presence of mercury in scrap from end-of-life vehicles.” The commenter stated that this assurance is implicitly made by contracting for scrap from suppliers participating in the program.

The commenter stated while the EPA correctly states that companies are already participating in the NVMSRP, the requirements in the proposed rule take the verification process to a more burdensome level, which will impose significant additional costs. The commenter stated creating the plans required in the proposed rule is likely to far exceed the proposed approximate \$1,000 estimate, given the labor and supervision required, not to mention ongoing plan updates. Moreover, the commenter stated the proposed cost estimate entirely excludes consideration of the massive costs that would be required to satisfy the due diligence obligations the proposed regulatory language would create. For example, according to the commenter, the proposed requirement to “conduct periodic inspections or provide other means of corroboration to ensure that scrap providers and brokers are aware of the need for and are implementing appropriate steps to minimize the presence of mercury in scrap from end-of-life vehicles” would impose an obligation on integrated iron and steel facilities that would be both onerous and expensive. The commenter stated it also would be potentially impossible to satisfy because existing contracts are in place that do not provide authority for the purchaser to inspect suppliers or otherwise ensure *their* “appropriate” implementation of mercury removal practices. If the plan is not removed, and a mercury emission limit is issued, the commenter said the EPA should revise the cost-effectiveness analysis to better account for the costs of the NVMSRP (or equivalent) program. Specifically, the commenter stated the proposal needs to better account for the cost of the NVMSRP option, which is

estimated at \$1,058 per facility and \$11,638 across the industry, with similar costs assumed for certifying compliance not likely to contain automotive scrap.

The commenter stated instead of these requirements, as explained above, the EPA should simply require that the company to purchase from suppliers that state they are participating in the NVMSRP (which may be reflected on invoices or in contracts). The commenter stated additional obligations need not be imposed because the EPA’s record for this rulemaking establishes that the NVMSRP is an effective program for removing mercury switches from shredded automobile scrap. The commenter stated the EPA can reasonably rely on that record.

The commenter stated similarly, just as the NVMSRP is an EPA approved program, any alternative “approved mercury program” contemplated in the proposal would have the same level of approval as the NVMSRP, and integrated iron and steel facilities should be able to rely on the stipulation in contracts with their scrap suppliers that any shredded automotive scrap received is from NVMSRP or similar EPA-approved program participants and is compliant with the program’s standards.

Response: The EPA has considered the commenter’s request and rationale, and has eliminated the proposed plan requirement in the final rule and instead is requiring facilities to both identify their scrap dealers or brokers and certify that these dealers and brokers participate in the NVMSRP or other EPA-approved program. See section IV.C.5 of this preamble for details of the rule changes.

Comment: One commenter stated the EPA proposes to require compliance with the proposed mercury emission limits within 1 year of publication of the final rule, and that all other amendments to the 40 CFR part 63, subpart FFFFF standards will become effective 180 days after publication of the final rule. The commenter stated these proposed compliance dates are inadequate to allow facilities to undertake all the necessary planning and operational adjustments needed to ensure compliance with the Proposed Rule. The commenter stated the EPA should not proceed to finalize the proposed mercury provisions with this RTR rulemaking, however, if the Agency proceeds to do so nonetheless, the EPA must provide a 3-year compliance period to allow facilities to comply. The commenter stated because the proposed mercury requirement constitutes new standard setting under CAA sections

112(d)(2) and (3), more time is needed for facilities to ensure compliance. The commenter stated the remaining proposed amendments to the 40 CFR part 63, subpart FFFFF standards will likewise require additional time for facilities to conform their existing practices. The commenter stated the EPA should, thus, extend the proposed effective date of 180 days after promulgation of the final rule to 1 year after that date.

Response: It is our understanding that all facilities are already participating in the NVMSRP and facilities have the option of complying with the mercury emission limit by certifying that all their scrap is from NVMSRP participants (or a similarly-approved program). Further, we determined 1 year after promulgation is sufficient for facilities to familiarize themselves with the new reporting requirements in the amended rule for this compliance option. For these reasons, we have concluded that it is reasonable to require existing sources to comply with the mercury requirements within 1 year. Existing sources will be given 180 days to comply with the changes to the SSM provisions in 40 CFR part 63, subpart FFFFF and all other new or revised requirements in this final rule, except the requirements for mercury. We have determined that there are no other compliance requirements as a result of this rule that require more than 180 days except for those for complying with the mercury emission limit and potentially for electronic reporting. Regarding the electronic reporting requirement, because we are revising the spreadsheet template for integrated iron and steel facilities as a result of comments discussed in section IV.E of this preamble, we are allowing the beginning of electronic reporting of compliance reports to begin 180 days after the new template is available in CEDRI if later than 180 days after promulgation of the final rule.

4. What is the rationale for our final approach for the mercury emission limits?

The mercury MACT limit for existing sources (*i.e.*, 0.00026 lbs of mercury per ton of scrap processed, as an input-based limit) was derived using data obtained from source tests performed to fulfill an EPA ICR to determine the mass of mercury emissions from the BOPF Groups¹³ at each facility per mass of scrap used in their BOPFs. The format of this standard is based, in part, on the assumption that the mass of mercury emitted from all BOPFs and related units was substantially equivalent to the mass of mercury in the input materials

because mercury is neither created nor destroyed in the BOPF. Furthermore, based on available data and information, we conclude that the primary source of mercury in the input materials are mercury switches. Therefore, we used mercury-to-scrap input ratios from the best performing five facilities out of all 11 integrated iron and steel facilities in the Integrated Iron and Steel Manufacturing Facilities source category to develop an input-based MACT floor limit for mercury. To establish the limit, we calculated a UPL that incorporates the potential variability in future measurements. Because there are fewer than 30 sources in the Integrated Iron and Steel Manufacturing Facilities source category, as described below, we evaluated the best performing five sources in the category to establish a standard for existing sources, pursuant to CAA section 112(d)(3)(B).

The EPA's MACT analyses used the UPL approach to identify the average emission limitation achieved by the best performing five sources. The EPA uses this approach because it incorporates the average performance of the best performing sources as well as the variability of the performance during testing conditions. The UPL represents the value which one can expect the mean of a specified number of future observations (*e.g.*, three-run average) to fall below for the specified level of confidence (99 percent), based upon the results from the same population. In other words, the UPL estimates what the upper bound of future values will be based upon present or past background data. The UPL approach encompasses all the data point-to-data point variability in the collected data, as derived from the dataset to which it is applied. For more details regarding how this limit was derived, see the technical memorandum on the mercury emission limits, referenced above.

The steel industry submitted comments¹⁵ on the proposed rule indicating that the scrap currently used by all facilities is NVMSRP scrap. Furthermore, industry stated¹⁵ that the performance tests conducted to establish the MACT floor limits and, thus, the MACT for mercury in the proposal were based on facilities participating in the NVMSRP. Because of the projected decline in the number of mercury switches in the automobile fleet over time due to the ban of such switches after 2002, and with the continuing implementation of the NVMSRP, it is reasonable for the EPA to conclude that NVMSRP scrap in the future will contain similar mercury, or more likely less mercury, than the scrap used to develop the MACT floor limits.

This rule relies, in part, on that conclusion. Therefore, if a facility chooses to comply with the emission limit by certifying that all their scrap is from NVMSRP participants (or a similarly-approved program) or certify that their scrap does not contain mercury switches, it is also reasonable to conclude that such certification achieves the same level of mercury reduction or more reduction as the numeric MACT floor limits.

The mercury emission limit for new sources in the final rule, at 0.000081 lbs of mercury per ton of scrap processed, was derived using ICR test data of the mass of mercury emissions from all BOPF and related units (HMTDS and ladles) per mass of scrap used by the lowest-emitting facility, pursuant to CAA section 112(d)(3). For the final rule, we are correcting the mercury limit from proposal to include two significant figures, from 0.00008 to 0.000081 lbs of mercury per ton of scrap processed, as in the standard for existing sources and as typically done in EPA regulations.

Following the same reasoning discussed above in connection with the existing source standard, we assumed and industry confirmed¹⁵ that the scrap used by the best performing source was either NVMSRP scrap or scrap with higher amounts of mercury per ton of scrap than NVMSRP scrap. Furthermore, industry stated¹⁵ that the performance tests conducted to establish the MACT floor limits and, thus, the MACT for mercury in the proposal were based on facilities participating in the NVMSRP.

As described above, we expect mercury levels in scrap to continue to decline over time due to the switch ban and success of the NVMSRP. Therefore, it is reasonable for the EPA to conclude that scrap subject to the NVMSRP or other approved scrap program in the future will contain similar levels of mercury or, more likely, less mercury than the scrap used to develop the new source limit. Because mercury levels in scrap in the NVMSRP have decreased since 2011 and continue to decrease, it is reasonable to assume that mercury emissions from sources that obtain their metal scrap from participants of that program (or similar program) will be equal to, or more likely lower than, the MACT floor limits for both new and existing sources.

Similar to existing sources above, for new BOPFs and new facilities, we are finalizing provisions in the NESHAP that allow two options to demonstrate compliance with the input-based limit of 0.000081 lbs of mercury per ton of scrap processed, as follows: (1) Conduct performance test twice per permit cycle,

i.e., mid-term and at initial or end term for facilities with permits or every 2.5 years for facilities without permits, after the initial performance testing, which is required to be performed within 180 days of July 13, 2020 or within 180 days of initial startup of the new BOPF or new facility, whichever is later, convert the sum of the results to input-based units (*i.e.*, lbs of mercury per ton of scrap input) and document the results in a test report created using the ERT and submitted electronically to the delegated authority through CEDRI (see section IV.E below); or (2) certify in their semiannual compliance reports, with the first semiannual compliance report required after July 13, 2021 or after initial startup of your BOPF Group, whichever is later, that the facility obtains all of their scrap from NVMSRP participants (or similar program as approved by the delegated authority) or certify that their scrap does not contain mercury switches. However, based on consideration of comments, in this final rule the EPA has eliminated the proposed requirement to develop and maintain onsite a scrap plan demonstrating the manner through which facilities are participating in the NVMSRP or similar approved program. Facilities complying via the performance testing option and facilities complying via the NVMSRP or similarly-approved program, or facilities that use scrap that does not contain mercury switches will have 1 year to comply. New facilities must be in compliance with the rule upon startup.

5. What rule changes did we make to the final rule for the mercury emissions standards from proposal?

In response to comments submitted in regard to the proposed mercury emissions standards, we made the following changes for the final rule:

- Added 40 CFR 63.7783(f) to establish the deadline for existing and new affected sources to comply with the emission limitations for mercury;
- Revised proposed 40 CFR 63.7791 title to "How do I comply with the requirements for the control of mercury?";
- Revised proposed 40 CFR 63.7791 opening paragraph to start with the letter (a); renamed "Compliance deadlines"; created new subsections 40 CFR 63.7791(a)(1), 63.7791(a)(2), 63.7791(b)(1) through (3); re-lettered the subsections that followed: 63.7791(c)(1) through (4); 63.7791(d)(1) through (3); and 63.7791(e)(1) through (4); and updated citations throughout the remaining rule text to reflect new organization;

- Revised 40 CFR 63.7791(c)(2) (proposed as (a)(2)) to specify the notification of compliance requirement to identify all scrap providers in semiannual compliance report;
- Revised 40 CFR 63.7791(c)(3) (proposed as (a)(3)) to specify the requirement to identify all scrap providers used by all scrap brokers in semiannual compliance report;
- Removed proposed 40 CFR 63.7791(a)(4) scrap plan requirement to develop and maintain onsite plan demonstrating the manner through which facilities are participating in the NVMSRP (or other EPA-approved program);
- Revised 40 CFR 63.7791(d) (proposed as (b)(1)) to delete the scrap plan features to obtain information from scrap suppliers or other entities with established knowledge of scrap content that the steel scrap used is not likely to contain motor vehicle scrap and maintain records of this information, and reassigning proposed 40 CFR 63.7791(b)(2) as new, revised 40 CFR 63.7791(d);
- Added 40 CFR 63.7791(d)(1) through (3) regarding compliance by certification of the use of scrap that does not contain mercury switches or is recovered for the specialty alloy content;
- Removed proposed 40 CFR 63.7791(c)(1)(i) through (iii), limitations on future approved programs;
- Revised 40 CFR 63.7791(e)(2) (proposed as (c)(2)) to specify the notification of compliance requirement to identify all scrap providers in semiannual compliance report;
- Revised 40 CFR 63.7791(e)(3) (proposed as (c)(3)) to specify the requirement to identify all scrap providers used by all scrap brokers in semiannual compliance report;
- Removed proposed 40 CFR 63.7791(c)(4) scrap plan requirement to prevent limitations on future approved plan, and reassigned proposed 40 CFR 63.7791(c)(5) as new, revised 40 CFR 63.7791(e)(4);
- Added 40 CFR 63.7820(e)(1) through (4) to establish the deadlines for conducting initial performance tests to demonstrate compliance with the mercury emission limitations;
- Added and revised 40 CFR 63.7821(e) to require performance tests to be conducted twice per permit cycle for sources with title V operating permits and every 2.5 years for sources without a title V operating permit;
- Added 40 CFR 63.7825 for test methods and other procedures to demonstrate initial compliance with the emission limit for mercury;
- Revised 40 CFR 63.7825(a) to clarify that initial compliance tests must be

conducted by the deadlines in 40 CFR 63.7820;

- Revised 40 CFR 63.7825(b)(1)(v) to clarify that the minimum sample volume of 1.7 dry standard cubic meters (dscm) (60 dry standard cubic feet (dscf)) is for EPA Method 29 only and to clarify alternative test methods can be considered on a case-by-case basis per 40 CFR 63.7(f);
- Revised 40 CFR 63.7825(b)(2) to remove requirement of minimum sample volume of 1.7 dscm (60 dscf);
- Added to 40 CFR 63.7825(b)(3), (b)(4)(i), (b)(4)(ii), and (b)(5) to make sampling procedures consistent with 40 CFR 63.7822(f), (g), and (h) in regard to when sampling should start and stop for BOPF operations;
- Revised 40 CFR 63.7825(c) Equation 1 to correctly calculate the mass emissions and revised units to those typically used in the measurement of metals;
- Revised 40 CFR 63.7833(h) to clarify requirements for demonstrating compliance with the mercury emission limits in Table 1 through mercury performance testing;
- Revised 40 CFR 63.7833(i) to clarify requirement for demonstrating compliance with the mercury emission limits in Table 1 by certifying participation in the NVMSRP or another EPA-approved mercury program, or by using scrap that does not contain mercury switches;
- Revised 40 CFR 63.7840(e) requirement for notification of mercury compliance testing for BOPF Group units to include notification of the first mercury compliance test in the BOPF Group along with a schedule of all subsequent tests in the BOPF Group, and that testing is considered complete when the final unit or control device in the BOPF Group is tested;
- Revised 40 CFR 63.7840(f) to include citation to 40 CFR 63.7791(c), (d), and (e) (proposed as (a), (b), and (c));
- Revised 40 CFR 63.7840(f)(1) to remove requirements regarding preparing a plan per proposed 40 CFR 63.7791 (a)(4) or (c)(4);
- Added 40 CFR 63.7841(b)(11) to clarify the reporting statements required per 40 CFR 63.7791(c), (d) or (e);
- Revised 40 CFR 63.7852 to add or change definitions for “basic oxygen process furnace group,” “mercury switch,” “motor vehicle,” “motor vehicle scrap,” “opening,” “post-consumer steel scrap,” “pre-consumer steel scrap,” “steel scrap,” “scrap provider,” “shredded motor vehicle scrap,” and “specialty metal scrap;” and
- Revised the mercury emission limits in Tables 1, 2, and 3 from 0.00008 to 0.000081 lbs of mercury per ton of

scrap processed to include two significant figures.

D. Changes to SSM Provisions

1. What did we propose for SSM?

On August 16, 2019, we proposed to eliminate the SSM exemption in this rule which appears at 40 CFR 63.7810(a). We also proposed to revise the references in Table 4 (the General Provisions table) of 40 CFR part 63, subpart FFFFF, including the references to 40 CFR 63.6(f)(1) and (h)(1), which were vacated by the Court in *Sierra Club v. EPA*, 551 F. 3d 1019 (D.C. Cir. 2008). Consistent with *Sierra Club v. EPA*, we proposed that the standards in this rule would apply at all times. We also proposed several additional revisions to Table 4 of 40 CFR part 63, subpart FFFFF. For example, we proposed to eliminate the incorporation of the General Provisions’ requirement that the source develop an SSM plan. We also proposed to eliminate or revise certain recordkeeping and reporting requirements related to the SSM exemption. We aimed to ensure that the provisions we proposed to eliminate were inappropriate, unnecessary, or redundant in the absence of the SSM exemption.

2. How did the SSM provisions change for the Integrated Iron and Steel Manufacturing Facilities source category?

We did not make any major changes to the proposed SSM provisions for the Integrated Iron and Steel Manufacturing Facilities source category. We made minor edits to the proposed SSM provisions in response to comments that are shown in section IV.D.5, below.

3. What key comments did we receive on SSM, and what are our responses?

This section provides a summary of key comments and responses regarding SSM. A summary of all other public comments on the proposal and the EPA’s responses to those comments is available in the *Summary of Public Comments and Responses for the Risk and Technology Review for Integrated Iron and Steel Manufacturing Facilities* (Docket ID No. EPA-HQ-OAR-2002-0083).

Comment: One commenter stated certain aspects of the Proposed Rule, including the proposed elimination of the SSM exemption, are not based on the EPA’s authority to conduct RTR rulemakings under CAA sections 112(f)(2) and (d)(6) but, instead, invoke the EPA’s discretion to exercise its other statutory authorities in the same rulemaking. The commenter stated the

proposed elimination of the SSM exemption would bring the 40 CFR part 63, subpart FFFFF standards in line with relevant Court decisions by the D.C. Circuit. The commenter stated in certain cases, the EPA's proposed language would create redundancies and pose problems for compliance that should be addressed.

The commenter stated the EPA should not finalize the additional recordkeeping and reporting requirements included in the proposal under 40 CFR 63.7835, 63.7841, and 63.7842 that would add regulatory burden without adding apparent value.

The commenter stated the preamble explains that the requirement would "ensure that there is adequate information to determine compliance, to allow the EPA to determine the severity of the failure to meet an applicable standard, and to provide data that may document how the source met the general duty to minimize emissions during a failure to meet an applicable standard." The commenter stated the preamble provides no information or examples of how or why the absence of this information has created any issues for the EPA or those subject to the regulation. As a practical matter, the commenter stated, it may not be possible to estimate the quantity of "each regulated pollutant" emitted over any emission limit.

The commenter stated the NESHAP provides for work practices and involves regulation of HAP emissions with the use of surrogates. Given that SSM or deviation reports may be due to a permitting authority in relatively short order, the commenter stated it could be very difficult to meet this requirement even where an estimate could be generated. The commenter stated minimizing regulatory burden and avoiding information "creep" that tends to institutionalize higher costs are important concerns for regulated entities; it is unclear why this information needs to be supplied on an ongoing basis, rather than providing it in response to an expected, infrequent request from a regulatory authority. Thus, the commenter stated the EPA should remove the proposed requirements to provide estimates quantifying emission limit exceedances or methods used to estimate those emissions in the proposed recordkeeping and reporting requirements in 40 CFR 63.7835, 63.7841, and 63.7842.

Response: The EPA disagrees that the additional reporting and recordkeeping requirements add burden without value. As stated in the proposed rule, recordkeeping and reporting of the

information specified in 40 CFR 63.7835, 63.7841, and 63.7842 ensure that there is adequate information to determine compliance, allow the EPA to determine the severity of the failure to meet an applicable standard, and to provide data that may document how the source met the general duty to minimize emissions during a failure to meet an applicable standard.

The procedure for estimating the quantity of pollutant emitted during the deviation is left open because we recognize that precise or direct measurement is not likely unless the failure to meet the applicable standard happens to occur during a performance test. The estimate of emissions is not for each HAP emitted, but for the regulated pollutant, which in the case of a surrogate such as PM, is the surrogate pollutant (PM) itself. A facility has the flexibility to employ any reasonable means to estimate the emissions from a deviation (e.g., mass balance calculations, measurements when available, or engineering judgment based on known process parameters or the effects of a work practice). The estimation of the quantity of pollutant emitted, as the product of the mass emission rate (determined from emissions concentration and gas flow) and the duration of the deviation, are direct indicators of the severity of an issue. Therefore, we maintain that it is appropriate and feasible for facilities to estimate the quantity of each regulated pollutant over the emission limit.

The SSM reports are no longer required by this rule with the removal of the SSM provisions, and the deviation reports are part of the semiannual compliance report, occurring on a known schedule, and have a fixed reporting deadline of 31 days after the end of the reporting period. This deadline provides sufficient time for reporting a deviation that may have occurred on the final day of the reporting period. The EPA is retaining the additional recordkeeping and reporting elements in the final rule, with the exception of the number of deviations, which is unnecessary in light of all deviations being reported.

We agree with the commenter that one of the proposed new SSM requirements, the inclusion of compliance procedures and emissions calculations in the Operations and Maintenance Plan, was not consistent with required content or use of an Operation and Maintenance Plan. To address this inconsistency, we removed certain SSM provisions, described below in section IV.D.5. In addition, see other related rule changes included

under electronic reporting, in section IV.E.5 of this preamble.

4. What is the rationale for our final approach for the SSM provisions?

In finalizing the SSM standards in this rule, the EPA has taken into account startup and shutdown periods and, for the reasons explained below, has not proposed alternate standards for those periods. The integrated iron and steel industry has not identified (and there are no data indicating) any specific problems with removing the SSM exemption. We solicited comment on whether any situations exist where separate standards, such as work practices, would be more appropriate during periods of startup and shutdown rather than the current standard. We did not receive any comments on this topic.

Periods of startup, normal operations, and shutdown are all predictable and routine aspects of a source's operations. Malfunctions, in contrast, are neither predictable nor routine. Instead they are, by definition, "sudden, infrequent, and not reasonably preventable failures of emissions control, process, or monitoring equipment." (40 CFR 63.2) (definition of malfunction).

The EPA interprets CAA section 112 as not requiring emissions that occur during periods of malfunction to be factored into development of CAA section 112 standards and this reading has been upheld as reasonable by the Court in *U.S. Sugar Corp. v. EPA*, 830 F.3d 579, 606–610 (2016). Under CAA section 112, emissions standards for new sources must be no less stringent than the level "achieved" by the best controlled similar source and for existing sources generally must be no less stringent than the average emission limitation "achieved" by the best performing 12 percent of sources in the category. There is nothing in CAA section 112 that directs the Agency to consider malfunctions in determining the level "achieved" by the best performing sources when setting emission standards. As the Court has recognized, the phrase "average emission limitation achieved by the best performing 12 percent of sources" says nothing about how the performance of the best units is to be calculated. *Nat'l Ass'n of Clean Water Agencies v. EPA*, 734 F.3d 1115, 1141 (D.C. Cir. 2013). While the EPA accounts for variability in setting emissions standards, nothing in CAA section 112 requires the Agency to consider malfunctions as part of that analysis. The EPA is not required to treat a malfunction in the same manner as the type of variation in performance that occurs during routine operations of a source. A malfunction is a failure of

the source to perform in a “normal or usual manner” and no statutory language compels the EPA to consider such events in setting CAA section 112 standards.

As the Court recognized in *U.S. Sugar Corp.*, accounting for malfunctions in setting standards would be difficult, if not impossible, given the myriad different types of malfunctions that can occur across all sources in the category and given the difficulties associated with predicting or accounting for the frequency, degree, and duration of various malfunctions that might occur. *Id.* at 608 (“the EPA would have to conceive of a standard that could apply equally to the wide range of possible boiler malfunctions, ranging from an explosion to minor mechanical defects. Any possible standard is likely to be hopelessly generic to govern such a wide array of circumstances.”). As such, the performance of units that are malfunctioning is not “reasonably” foreseeable. See, e.g., *Sierra Club v. EPA*, 167 F.3d 658, 662 (D.C. Cir. 1999) (“The EPA typically has wide latitude in determining the extent of data-gathering necessary to solve a problem. We generally defer to an Agency’s decision to proceed on the basis of imperfect scientific information, rather than to ‘invest the resources to conduct the perfect study.’”). See also, *Weyerhaeuser v. Costle*, 590 F.2d 1011, 1058 (D.C. Cir. 1978) (“In the nature of things, no general limit, individual permit, or even any upset provision can anticipate all upset situations. After a certain point, the transgression of regulatory limits caused by ‘uncontrollable acts of third parties’, such as strikes, sabotage, operator intoxication or insanity, and a variety of other eventualities, must be a matter for the administrative exercise of case-by-case enforcement discretion, not for specification in advance by regulation.”). In addition, emissions during a malfunction event can be significantly higher than emissions at any other time of source operation. For example, if an air pollution control device with 99-percent removal goes off-line as a result of a malfunction (as might happen if, for example, the bags in a baghouse catch fire) and the emission unit is a steady state type unit that would take days to shut down, the source would go from 99-percent control to zero control until the control device was repaired. The source’s emissions during the malfunction would be 100 times higher than during normal operations. As such, the emissions over a 4-day malfunction period would exceed the annual

emissions of the source during normal operations. As this example illustrates, accounting for malfunctions could lead to standards that are not reflective of (and significantly less stringent than) levels that are achieved by a well-performing non-malfunctioning source. It is reasonable to interpret CAA section 112 to avoid such a result. The EPA’s approach to malfunctions is consistent with CAA section 112 and is a reasonable interpretation of the statute.

Although no statutory language compels the EPA to set standards for malfunctions, the EPA has the discretion to do so where feasible. For example, when the EPA conducted the Petroleum Refinery Sector RTR, the EPA established a work practice standard for unique types of malfunctions that result in releases from pressure relief devices or emergency flaring events because the EPA had information to determine that such work practices reflected the level of control that applies to the best performers. 80 FR 75178, 75211–14 (December 1, 2015). The EPA will consider whether circumstances warrant setting standards for a particular type of malfunction and, if so, whether the EPA has sufficient information to identify the relevant best performing sources and establish a standard for such malfunctions. In the event that a source fails to comply with the applicable CAA section 112(d) standards as a result of a malfunction event, the EPA would determine an appropriate response based on, among other things, the good faith efforts of the source to minimize emissions during malfunction periods, including preventative and corrective actions, as well as root cause analyses to ascertain and rectify excess emissions. The EPA would also consider whether the source’s failure to comply with the CAA section 112(d) standard was, in fact, “sudden, infrequent, not reasonably preventable,” and was not caused (in any way) by poor maintenance or careless operation. 40 CFR 63.2 (definition of malfunction).

If the EPA determines in a particular case that an enforcement action against a source for violation of an emission standard is warranted, the source can raise any and all defenses in that enforcement action and the Federal district court will determine what, if any, relief is appropriate. The same is true for citizen enforcement actions. Similarly, the presiding officer in an administrative proceeding can consider any defense raised and determine whether administrative penalties are appropriate.

In summary, the EPA interpretation of the CAA and, in particular, CAA section 112 is reasonable and encourages

practices that will avoid malfunctions. Administrative and judicial procedures for addressing exceedances of the standards fully recognize that violations may occur despite good faith efforts to comply and can accommodate those situations. *U.S. Sugar Corp. v. EPA*, 830 F.3d 579, 606–610 (2016).

We are requiring compliance with the SSM changes for existing sources 180 days from publication of the final rule. This period of time will allow facilities to read and understand the amended rule requirements, to evaluate their operations to ensure that they can meet the standards during periods of startup and shutdown as defined in the rule and make any necessary adjustments, and to convert reporting mechanisms to install necessary hardware and software. The EPA considers a period of 180 days to be the most expeditious compliance period practicable for these source categories and, thus, all affected sources must comply with the revisions to the SSM provisions and electronic reporting requirements no later than 180 days from the effective date of the final rule, or upon startup, whichever is later.

5. What rule changes did we make for the final rule for the SSM Provisions?

In response to comments submitted in regard to the SSM provisions, we made the following changes for the final rule:

- Removed proposed 40 CFR 63.7800(b)(8), “The compliance procedures within the operation and maintenance plan shall not include any periods of startup or shutdown in emissions calculations.”

E. Electronic Reporting

1. What did we propose for electronic reporting for the Integrated Iron and Steel Manufacturing Facilities source category?

On August 16, 2019, the EPA proposed the requirement that owners and operators of integrated iron and steel facilities submit the required electronic copies of summaries of performance test and performance evaluation results and semiannual reports through the EPA’s CDX using the CEDRI. A description of the electronic data submission process is provided in the memorandum titled *Electronic Reporting Requirements for New Source Performance Standards (NSPS) and National Emission Standards for Hazardous Air Pollutants (NESHAP) Rules* (Docket ID Item No. EPA-HQ-OAR-2002-0083-0909). The proposed rule required performance test results to be collected using test methods that are supported by the EPA’s ERT, as listed on the ERT website

at the time of the test, be submitted in the format generated through the use of the ERT, and that other performance test results be submitted in PDF using the attachment module of the ERT. Similarly, performance evaluation results of continuous monitoring systems measuring relative accuracy test audit pollutants that are supported by the ERT at the time of the test would be submitted in the format generated through the use of the ERT and other performance evaluation results be submitted in PDF using the attachment module of the ERT.

For semiannual compliance reports, the proposed rule required owners and operators to use the appropriate spreadsheet template to submit information to CEDRI. A draft template for these reports was included in the docket for this rulemaking, and the final template will be available on the CEDRI homepage (<https://www.epa.gov/electronic-reporting-air-emissions/cedri>). Additionally, the EPA identified two broad circumstances in which electronic reporting extensions may be provided. In both circumstances, the decision to accept the claim of needing additional time to report would be within the discretion of the Administrator, and reporting should occur as soon as possible. The EPA is providing these potential extensions to protect owners and operators from noncompliance in cases where they cannot successfully submit a report by the reporting deadline for reasons outside of their control. The situation where an extension may be warranted due to outages of the EPA's CDX or CEDRI that preclude an owner or operator from accessing the system and submitting required reports is addressed in 40 CFR 63.7841(e). The situation where an extension may be warranted due to a force majeure event, which is defined as an event that would be or has been caused by circumstances beyond the control of the affected facility, its contractors, or any entity controlled by the affected facility that prevents an owner or operator from complying with the requirement to submit a report electronically as required by this rule is addressed in 40 CFR 63.7841(f). Examples of such events are acts of nature, acts of war or terrorism, or equipment failure or safety hazards beyond the control of the facility.

2. How did electronic reporting change for the Integrated Iron and Steel Manufacturing Facilities source category?

There were no major changes to the final rule for electronic reporting for the Integrated Iron and Steel Manufacturing

Facilities source category. Minor rule edits were made to the proposed requirements in response to comments and are shown in section IV.E.5 below.

3. What key comments did we receive on electronic reporting, and what are our responses?

This section provides a summary of key comments and responses regarding electronic reporting. A summary of all other public comments on the proposal and the EPA's responses to those comments is available in the Summary of Public Comments and Responses for the Risk and Technology Review for Integrated Iron and Steel Manufacturing Facilities (Docket ID No. EPA-HQ-OAR-2002-0083).

Comment: A commenter requested minor technical corrections to the compliance reporting template.

Response: The EPA acknowledges the thorough review of the template by the commenter. Updates to the Integrated Iron and Steel Manufacturing Facilities source category compliance template have been made accordingly to better reflect the provisions of the final rule and address industry comments. These corrections are shown in detail in the response to comment document with responses to specific elements of the comments.

4. What is the rationale for our final approach for electronic reporting?

The electronic submittal of the reports addressed in this rulemaking will increase the usefulness of the data contained in those reports, is in keeping with current trends in data availability and transparency, will further assist in the protection of public health and the environment, will improve compliance by facilitating the ability of regulated facilities to demonstrate compliance with requirements, and by facilitating the ability of delegated state, local, tribal, and territorial air agencies and the EPA to assess and determine compliance, and will ultimately reduce burden on regulated facilities, delegated air agencies, and the EPA. Electronic reporting also eliminates paper-based, manual processes, thereby saving time and resources, simplifying data entry, eliminating redundancies, minimizing data reporting errors, and providing data quickly and accurately to the affected facilities, air agencies, the EPA, and the public. Moreover, electronic reporting is consistent with the EPA's plan to implement Executive Order 13563 and is in keeping with the EPA's Agency-wide policy developed in response to the White House's Digital Government Strategy. For more information on the benefits of electronic reporting, see the

memorandum titled *Electronic Reporting Requirements for New Source Performance Standards (NSPS) and National Emission Standards for Hazardous Air Pollutants (NESHAP) Rules* (Docket ID Item No. EPA-HQ-OAR-2002-0083-0909).

5. What rule changes did we make for the final rule for electronic reporting?

In response to comments submitted in regard to electronic reporting, we made the following changes for the final rule:

- Revised 40 CFR 63.7835 to remove requirement to record number of failures to eliminate redundancy with the spreadsheet template that requires the inclusion of every failure;
- Revised 40 CFR 63.7841(b)(4) to remove requirement to report number of failures to eliminate redundancy with the spreadsheet template that requires the inclusion of every failure;
- Revised 40 CFR 63.7841(b)(7) to include citation to newly added 40 CFR 63.7841(b)(13);
- Revised 40 CFR 63.7841(b)(7)(i) to remove the requirement to report the "number" of deviations;
- Revised 40 CFR 63.7841(b)(8) to include citation to newly added 40 CFR 63.7841(b)(13);
- Revised 40 CFR 63.7841(b)(8)(ii) to add "and duration", as in (iii);
- Revised 40 CFR 63.7841(b)(9) to include citation to newly added 40 CFR 63.7841(b)(13);
- Added 40 CFR 63.7841(b)(13) to provide 180 days after publication in the **Federal Register** for all sources that failed to meet an applicable standard to include in the compliance report for each failure the start date, start time and duration of each failure and a list of the affected sources or equipment, an estimate of the quantity of each regulated pollutant emitted over any emission limit, and a description of the method used to estimate the emissions;
- Revised 40 CFR 63.7841(c) to specify the beginning of electronic reporting to begin either 180 days after promulgation of the final rule or 180 days after the template is available in CEDRI, whichever is later; and
- Removed proposed 40 CFR 63.7843(d) to eliminate redundancy with existing language in 40 CFR 63.10(b)(1).

F. Other Issues Regarding UFIP Sources of HAP Emissions

In this section we address other issues related to UFIP emissions sources that are not addressed above in section IV.A of this preamble.

1. How were other relevant issues regarding UFIP sources of HAP emissions addressed in the proposed rule for the Integrated Iron and Steel Manufacturing Facilities source category?

As described in Section IV.A of this preamble, in the August 16, 2019, proposal, we discussed seven UFIP HAP emission sources (84 FR at 42708) and requested comments on all aspects of the UFIP analyses. We did not propose any standards for these sources.

The UFIP emission sources described in the proposal included BF bleeder valve unplanned openings (also known as slips), BF bleeder valve planned openings, BF bell leaks, BF casthouse fugitives, BF iron beaching, BF slag handling and storage operations, and BOPF shop fugitives. These UFIP emission sources were identified by observation of visible plumes of fugitives and intermittent emissions being emitted from the seven UFIP sources during inspections by EPA Regional staff¹⁷ and discussed in the technical memorandum titled *Development of Emissions Estimates for Fugitive or Intermittent HAP Emission Sources for an Example Integrated Iron and Steel Facility for Input to the RTR Risk Assessment* (Docket ID Item No. EPA-HQ-OAR-2002-0083-0956). The NESHAP already contains opacity limits for two of these sources—BF casthouse fugitives and BOPF shop fugitives.

The emissions from these UFIP sources were included in the risk assessment in an example facility analysis to assess the potential risk contributed by UFIP and the effect that omission of these sources has on the estimated risks for the source category as a whole. (See section IV.A.1 and Table 2 of this preamble for the risk estimated for the source category).

As explained in section IV.A in regard to the UFIP and potential work practices, and consistent with our explanation in the proposed rule (see 84 FR 42704) that was based on consideration of all our analyses and related information including the risk analysis results, costs, and uncertainties, we determined in the proposal that the current NESHAP provides an ample margin of safety to protect public health and that no additional standards are required under CAA section 112(f). This decision was based largely on the substantial uncertainties in the estimates of the

baseline HAP emissions from UFIP emission sources, costs of the work practices, HAP risk reductions that would be achieved by the work practices, and uncertainties raised by industry in their comments regarding potential effects of the work practices on the facilities' operations, safety, and economics.

Furthermore, as described in section IV.B, for most of the same reasons discussed above in regard to ample margin of safety analysis for UFIP emissions, no new standards were proposed for the two regulated UFIP sources under the technology review pursuant to CAA section 112(d)(6).

2. How did the final rule change based on the comments received about UFIP sources?

We are not promulgating any new standards for UFIP emissions sources under the risk or technology reviews, as described in sections IV.A and IV.B. We also are not taking final action to establish additional emission standards for any of the UFIP emissions sources under any other CAA authority at this time. Although we received many comments on UFIP sources, both supporting and opposing additional standards, we did not receive any additional data on UFIP emissions or on the effectiveness of the work practices. We did receive some limited additional information on costs that suggested we may have underestimated the costs for some of the work practices discussed in the proposal, but no citations or documentation were provided to validate the new cost information. We also received comments that suggested we may have overestimated UFIP emissions and control-effectiveness of the work practices, but, again, without any citations of documentation for other emission estimates or control efficiencies of the work practices. For these reasons, and because we do not have adequate information to resolve the substantial uncertainty that remains for the UFIP emissions estimates, control efficiency of the work practices, costs, and other factors, we are not promulgating any new requirements for UFIP sources in this action.

3. What key comments did we receive about UFIP sources that were not already addressed under the risk review section of this preamble and what are our responses?

This section provides a summary of some of the key comments and responses regarding UFIP sources not addressed above in section IV.A.3. A summary of all other public comments on the proposal in regard to UFIP and

the EPA's responses to those comments are available in the document *Summary of Public Comments and Responses for the Risk and Technology Review for Integrated Iron and Steel Manufacturing Facilities*, located in the docket for this rule (Docket ID No. EPA-HQ-OAR-2002-0083).

Comment: One commenter recognized that the EPA identified the work practice information as uncertain, and in fact, too uncertain to be relied upon in this rulemaking. The commenter appreciated the EPA's recognition of these issues and supported the Agency's conclusions. The commenter is pleased that the EPA is not proposing to rely on unsupported conclusions as part of a final rule.

Another commenter stated the EPA created the "UFIP" designation to refer to emissions that facilities generally try to prevent from occurring in the first place. In other words, facilities are already naturally incentivized to prevent many UFIP emissions as they reflect nonoptimal operation. Thus, the commenter says, facilities operate to minimize these emissions without additional regulatory requirements; imposing a regulatory overlay would be problematic from an operational perspective and would not lead to reduced emissions. The commenter stated regulating these sources would dictate *how* facilities operate—effectively freezing approaches in time when they should be evolving as part of the continuous improvement process. Second, the commenter stated regulation would impose a one-size-fits-all approach for sources that make products in different ways and have different configurations. Third, the commenter stated regulation of UFIP would create a micro-managerial structure that would be costly—even if not from a capital investment perspective—because of the operational nature of many of the approaches the EPA considered. This micro-managerial structure, the commenter stated, would lead to only "paperwork" deviations, by imposing onerous recordkeeping requirements, which will mean that operators' and inspectors' attention will be taken away from critical aspects of plant operations, even when a plant is not causing increased emissions. Thus, the commenter concluded the emission reduction practices presented by the EPA for UFIP sources provide no risk reduction benefit despite the cost and effort they entail. Finally, the commenter stated that, given the intense competition in this industry, which stretches well beyond U.S. borders, these requirements would put U.S. facilities at a cost disadvantage—and

¹⁷ See the report, *EPA Region V Enforcement Summary—UFIP Opacity from Integrated Iron and Steel Facility Violation Reports—2007 through 2014*. (Docket ID Item No. EPA-HQ-OAR-2002-0083-0997.)

would do so without generating commensurate emissions and risk reductions.

The commenter stated the EPA appropriately acknowledges that there are significant uncertainties in costs, effectiveness, and feasibility of the work practice options on which it seeks comment. The commenter stated the estimates in the proposal drastically understate the costs and likewise overstate any emission reductions that would be achieved, since companies already work to prevent these emissions and are incentivized to do so to maintain their operations in the most efficient and safe manner. Although the EPA estimates the specific costs for each of the work practices discussed in the proposal preamble, the commenter stated the EPA fails to attribute potential HAP emissions reductions individually, and, thus, does not appropriately estimate cost effectiveness. The commenter stated that, even without these additional considerations, the EPA is right not to require them, and that with an accurate view of the costs and benefits of this regulatory overlay, the EPA decision is unquestionably correct.

The commenter stated given the risk modeling, the work practice options discussed are not necessary to provide an ample margin of safety. The commenter stated the various compliance and enforcement documents related to the so-called UFIP sources in the rulemaking docket are not to the contrary. Moreover, the commenter stated it would be unreasonable to require the potential work practices as doing so would codify practices that already occur voluntarily or pursuant to current federal or state requirements and drive up costs of compliance without resulting in any risk reduction. The commenter stated adding a substantial administrative burden to an important economic sector, particularly without clear benefit, is contrary to Congress' purpose under the CAA and with reasoned decision-making. The commenter stated the focus should be on maximizing environmentally beneficial results, not paperwork. The commenter stated codifying work practices that already take place on a case-by-case basis would result in a misdirection of resources not only from the steel industry to comply with added monitoring, recordkeeping, and reporting requirements, but also from the EPA by having to assure compliance with details that ultimately have little bearing on air quality and public health.

The commenter stated many of the work practices are practically infeasible as applied to particular plants or, generally, not cost effective and, in

some instances, could even be contrary to practices established to assure facility safety, such as what would result from reducing natural ventilation and other effects of closing the openings and air holes in the BF casthouse and BOP shop. These effects include cost to the facility to otherwise increase breathing space ventilation for workers; the wear and tear on control equipment due to higher-than-design air flowrates; the cost to document opening and closing of doors, windows, *etc.*, to accommodate large equipment and vehicle traffic into buildings; difficulty in accessing some openings that may be hundreds of feet off the ground, requiring significant precautions due to the height alone; and prevent the opening of pressure relief panels, which would badly damage building exteriors during high-pressure events, *etc.* Therefore, the commenter stated the EPA should, thus, finalize its proposal not to amend 40 CFR part 63, subpart FFFFF to require additional work practices for UFIP sources.

Response: The EPA acknowledges the support by the commenter for the proposed conclusions, which are being finalized in this document. The EPA also acknowledges, as the commenter points out, the complexities in controlling emissions from UFIP sources. The EPA also is pleased to know that the industry is already attempting to minimize these emissions.

We do not agree with the commenter that many of the work practices are "practically infeasible" at all plants, but we cannot adequately assess the effectiveness or impacts of the work practices without more specific descriptions of actual facility experience with, or analyses of, the impacts of the work practices, including potential changes in air flow into and out of the buildings beyond the extreme consequences hypothesized by the commenter, which mostly only concern BF casthouse and BOP shop operations. With the understanding that the work practices could be more difficult to implement at some facilities than others, we sought specific comments on the general feasibility of the work practices, with the hope that commenters could have described ways to improve or modify the work practice so as to be amenable to their use at all facilities. Unfortunately, we received very little information through the public comments to improve our understanding of which work practices would be generally feasible and appropriate across the industry.

In regard to calculating cost effectiveness, since the HAP being evaluated are all various PM HAP metals, we conclude that it would

neither be appropriate nor logical to apportion control costs of a work practice or control device to each metal HAP in this case, mainly because the intent of the control methods we analyzed is to minimize emissions of the mix of PM HAP metals. Nevertheless, as described elsewhere in this preamble, the EPA is not promulgating any new or revised standards for UFIP sources in this action.

Comment: One commenter stated, based on the record, it is unclear how or why the EPA ended its staff's consideration of the work practice standards for the proposal, or on what basis it did so. In addition, the commenter noted that the EPA contacted Michigan and Indiana and provided "draft work practice standards," as shown by email communications with these states in 2018. The commenter continued that there was some material in the bodies of the emails that the EPA has disclosed showing these would likely have been important and achieved significant emission reductions. It is clear to the commenter that the EPA staff long planned to propose significant emission reduction requirements, based on the evidence they have in the record, and that the state air quality inspectors and regulators also supported these requirements.

The commenter stated the EPA has failed to show how it can lawfully or rationally not follow what its own regulatory staff initially provided to stakeholders, what its enforcement staff apparently support (EPA Region V), and what state regulators in Michigan and Indiana have also supported as needed to reduce UFIP emissions and protect public health. The commenter stated the EPA's "about-face" from its staff's and state air regulators' recommendations, and its ultimate refusal to follow the evidence in the record illustrate that this proposal, if finalized, would be unlawful and arbitrary. The commenter stated it appears that the EPA Administrator has not acted with the requisite open mind to consider the relevant statutory requirements, record, or staff recommendations which would have led to a stronger proposal and a stronger final rule. The commenter stated the EPA will violate the CAA and engage in the ultimate in capricious decision making if it attempts to finalize this proposed rule which lacks the necessary statutory requirements as well as the required rational connection to the facts shown in the record.

Response: While the EPA agrees with the commenter that the UFIP HAP emissions issue and related information

available to the EPA were worthy of bringing forth to the public and asking for comment in the proposal, no additional technical information was received to improve our understanding or quantification of the UFIP emissions or our understanding of the effectiveness of using work practices to control UFIP emissions. We received some new cost information that suggests that we underestimated the costs of the work practices, but that new information was not documented or cited. We also received comments that we overestimated UFIP emissions and overestimated the effectiveness of the work practices, which combined with information suggesting we underestimated costs, if accurate, would make control of UFIP emissions substantially less cost-effective than the values we presented in the proposal preamble. In addition, although environmental groups submitted comments in general support of UFIP regulations, no comments were received from citizens or community groups living in the areas of the integrated iron and steel facilities supporting the UFIP emission regulations, or on the impact to local residents of not requiring work practices to reduce emissions from these sources, or any other claims as such. Therefore, because of the uncertainty in the UFIP emission estimates, cost estimates, and control efficiencies of the work practices; and the lack of complete information about the impact of UFIP emissions at all facilities (as described above in previous comments), the EPA is not promulgating any work practice standards for UFIP emissions at this time. See above section IV.A for a more detailed discussion of the estimated risk from UFIP emissions.

4. What is our rationale for our final approach for the UFIP sources?

The decision not to promulgate any new standards for UFIP sources at this time is based largely on the uncertainties in the UFIP assessment in terms of the emission estimates, costs of the work practices, how much emission reduction the work practices could achieve, and the potential negative effects of the work practices on the facilities' operations, safety, and economics. For five of the UFIP sources not currently regulated,¹⁸ we would need to promulgate standards for these sources pursuant to CAA section 112(d)(2) and (3), which would necessitate an analysis of the top

performers under CAA sections 112(d)(2) and (3). The lack of quantitative emissions data (and the time and techniques to obtain such data) for UFIP sources and/or the lack of other relevant information (such as reliable information regarding the effectiveness of each of the work practices), which is needed to establish the top performing facilities and the MACT floor level of control, prevents us from establishing appropriate emissions standards for the five UFIP sources at this time.

With regard to the other two UFIP sources currently regulated (*i.e.*, BF casthouse and BOPF shop), since we have concluded that risks due to emissions from the source category are acceptable, we would need to promulgate standards for these two UFIP sources pursuant to CAA section 112(d)(6) or under the ample margin of safety analysis phase of our section 112(f) review, both of which include considerations of costs and other factors. As explained previously in this preamble, the EPA has decided to not promulgate any of the work practices for these two UFIP sources at this time mainly because of the substantial uncertainties in the UFIP assessment in terms of baseline emissions, costs of the work practices, how much emission reduction the work practices could achieve; and, the potential negative effects of the work practices on the facilities' operations, safety, and economics.

G. Other Items

Other items in this final rule are IBR, compliance dates, and other rule changes not discussed elsewhere in this preamble. These issues are discussed below.

1. IBR Under 1 CFR Part 51

On August 16, 2019, the EPA proposed regulatory text that includes IBR. In accordance with requirements of 1 CFR 51.5, the EPA proposed to incorporate by reference the following documents and to amend 40 CFR 63.14 to identify the provisions for which these documents are IBR approved for this rule:

- ANSI/ASME PTC 19.10–1981, Flue and Exhaust Gas Analyses [Part 10, Instruments and Apparatus], issued August 31, 1981, IBR approved for 40 CFR 63.7822(b), 63.7824(e), and 63.7825(b). This method determines quantitatively the gaseous constituents of exhausts resulting from stationary combustion sources. The gases addressed in the method are oxygen, carbon dioxide, carbon monoxide, nitrogen, sulfur dioxide, sulfur trioxide, nitric oxide, nitrogen dioxide, hydrogen

sulfide, and hydrocarbons. The method is approved for this rule with caveats described in section VI.J of this preamble.

- EPA–454/R–98–015, Office of Air Quality Planning and Standards (OAQPS), Fabric Filter Bag Leak Detection Guidance, September 1997, IBR approved for 40 CFR 63.7831(f). This document provides guidance on the use of triboelectric monitors as fabric filter bag leak detectors. The document includes fabric filter and monitoring system descriptions; guidance on monitor selection, installation, setup, adjustment, and operation; and quality assurance procedures.

For the final rule, in response to comments, we have added the following voluntary consensus standard (VCS) approved as an alternate method to measure opacity under 40 CFR part 63, subpart FFFFF, with caveats described in section VI.J of this preamble; we will incorporate the method by reference in the amendments to 40 CFR 63.14:

- ASTM D7520–16, Standard Test Method for Determining the Opacity of a Plume in the Outdoor Ambient Atmosphere, approved April 1, 2016, IBR approved for 40 CFR 63.7823(c), 63.7823(d), 63.7823(e), and 63.7833(g). This method describes procedures to determine the opacity of a plume, using digital imagery and associated hardware and software, where opacity is caused by PM emitted from a stationary point source in the outdoor ambient environment. The opacity of emissions is determined by the application of a DCOT that consists of a digital still camera, analysis software, and the output function's content to obtain and interpret digital images to determine and report plume opacity. The method is approved for this rule with caveats described in section VI.J of this preamble.

The ANSI/ASME document is available from the American Society of Mechanical Engineers (ASME) at <http://www.asme.org>; by mail at Three Park Avenue, New York, NY 10016–5990; or by telephone at (800) 843–2763. The ASTM D7520–16 document is available from the American Society for Testing and Materials (ASTM) at <https://www.astm.org> or 1100 Barr Harbor Drive, West Conshohocken, PA 19428–2959, telephone number: (610) 832–9500, fax number: (610) 832–9555, or email: service@astm.org. The EPA has made, and will continue to make, the EPA document generally available electronically through <https://www.regulations.gov/> and at the EPA Docket Center (see the **ADDRESSES**

¹⁸The five currently unregulated UFIP sources are BF bleeder valve unplanned openings (also known as slips), BF bleeder valve planned openings, BF bell leaks, BF iron beaching, and BF slag handling and storage operations.

section of this preamble for more information).

2. Compliance Dates

On August 16, 2019, we proposed to provide existing sources with 180 days after the effective date of the final rule to comply with the changes to the SSM provisions in 40 CFR part 63, subpart FFFFF and all other new or revised requirements in this rule except for the mercury emission limits, for which we proposed to require compliance within 1 year. We proposed that new sources, defined as BOPFs, BOPF shops, or facilities constructed or reconstructed after August 16, 2019, would be required to comply with all requirements on the effective date of the final rule, or upon startup, whichever is later.

In the final rule, for the SSM provisions and all other new or revised requirements in this rule except for those related to the mercury standards, we are finalizing the compliance times as proposed (180 days) for existing sources, and new sources will need to comply upon the effective date of the final rule or upon startup, whichever is later. Regarding the mercury standards and associated requirements, we are providing for existing sources the same deadlines as proposed (*i.e.*, 1 year to comply). An additional year may be provided for compliance via the states as per 40 CFR part 63 General Provisions (40 CFR 63.6(i)) for facilities needing to make process changes or install control equipment. As proposed and consistent with the CAA, new sources must comply upon the effective date of the final rule or upon startup, whichever is later.

For electronic reporting, the final rule provides that facilities must comply with the electronic reporting requirements for semiannual compliance reports either 180 days after date of publication in the **Federal Register** of the final rule or 180 days after the electronic reporting template for Integrated Iron and Steel Manufacturing Facilities is available in CEDRI, whichever is later, to allow for EPA revisions to the template in response to comments.

3. What other rule changes did we make in the final rule?

In the final rule, we made the following technical and editorial corrections and clarifications:

- Revised 40 CFR 63.7810(a) to provide sources that commenced construction or reconstruction on or before August 16, 2019, 180 days after publication in the **Federal Register** for

all sources to comply with emission limitations during periods of SSM;

- Revised 40 CFR 63.7810(c) to remove the SSM plan requirement 180 days after publication in the **Federal Register** for sources that commenced construction or reconstruction on or before August 16, 2019 and to remove the SSM plan requirement upon publication in the **Federal Register** for all sources that commenced construction or reconstruction after August 16, 2019;

- Revised 40 CFR 63.7810(d) to provide sources that commenced construction or reconstruction on or before August 16, 2019 with 180 days to comply with the general duty requirement in 40 CFR 63.7810(d). Prior to the expiration of the 180 days, such sources must comply with the provisions in 40 CFR 63.6(e)(1)(i);

- Revised 40 CFR 63.7822(a) to provide 180 days after publication in the **Federal Register** for all sources that commenced construction or reconstruction on or before August 16, 2019 comply with the revised requirement to conduct each performance test under conditions representative of normal operations, excluding periods of startup and shutdown and malfunction. Prior to the expiration of 180 days, such sources must comply with the pre-existing requirement to conduct performance tests based on representative performance;

- Revised 40 CFR 63.7822 and 63.7823 to specify the conditions for conducting performance tests;
- Revised 40 CFR 63.7822(b)(1)(iii), 63.7824(e)(1)(iii), and 63.7825(b)(1)(iii) to IBR ANSI/ASME PTC 19.10-1981;
- Revised 40 CFR 63.7822, 63.7823, 63.7824, and 63.7833 to clarify the location in 40 CFR part 60 of applicable EPA test methods;

- Revised 40 CFR 63.7823(a) to specify initial compliance with the opacity limits should be based on representative performance which excludes periods of startup and shutdown and malfunction;

- Added to 40 CFR 63.7823(c)(1), (d)(1)(i), (d)(2)(i), (e)(1) and 63.7833(g)(3) to IBR the ASTM D7520-16 method as an alternative VCS to EPA Method 9 opacity observations; added "For Method 9" to 40 CFR 63.7823(e)(3) to clarify that using an observer is only for EPA Method 9;

- Revised 40 CFR 63.7831(a)(4) to clarify that sources that commenced construction or reconstruction on or before August 16, 2019, and, therefore, are not required to comply during periods of SSM until after 180 days after publication in the **Federal Register**, are

subject during that 180 day period to the requirements in 40 CFR 63.8(c)(1)(ii), (c)(3), (c)(4)(ii), (c)(7), and (c)(8);

- Revised 40 CFR 63.7831(a)(5) to clarify that sources that commenced construction or reconstruction on or before August 16, 2019, and, therefore, are not required to comply during periods of SSM until after 180 days after publication in the **Federal Register**, are subject during that 180 day period to the requirements related to SSM plans referenced in 40 CFR 63.8(d)(3);

- Revised 40 CFR 63.7831(a)(6) to provide sources constructed or reconstructed on or before August 16, 2019, and, therefore, are not required to comply during periods of SSM until after 180 days after publication in the **Federal Register**, are subject during that 180 day period to the requirements in § 63.10(c)(1) through (c)(14), and (e)(1) and (e)(2)(i);

- Revised 40 CFR 63.7831(f)(4) to IBR for EPA-454/R-98-015;

- Added 40 CFR 63.7835(d) to specify that for sources that commenced construction or reconstruction after August 16, 2019 the exemptions for deviations that occur during a period of startup, shutdown, or malfunction no longer apply 180 days after publication in the **Federal Register**, and for all other sources the exemptions no longer apply as of the date of publication of the final rule in the **Federal Register**;

- Revised 40 CFR 63.7835, 63.7841, and 63.7842 to include the requirements to record and report information on failures to meet the applicable standard;

- Added 40 CFR 63.7840 and 63.7841 electronic reporting requirements of required summaries of performance test results and semiannual reports;

- Revised 40 CFR 63.7841(b)(4) to specify that for sources that commenced construction or reconstruction after August 16, 2019 a SSM plan and the information in 40 CFR 63.10(d)(5)(i) are no longer required 180 days after publication in the **Federal Register**;

- Added 40 CFR 63.7841(b)(12) to specify that for sources that commenced construction or reconstruction after August 16, 2019 a SSM report is no longer required 180 days after publication in the **Federal Register**;

- Revised 40 CFR 63.7842(a)(2) to specify records related to SSM to be kept;

- Revised Table 1 of 40 CFR part 63, subpart FFFFF to add a mercury emission limit, revised Table 2 to add demonstration of initial compliance with the mercury emission limit, and revised Table 3 to add demonstration of continuous compliance with the mercury emission limit;

- Revised Tables 1 and 3 of 40 CFR part 63, subpart FFFFF to clarify that opacity observations be made at all openings to the BF casthouse;

- Revised Tables 1, 2, and 3 of 40 CFR part 63, subpart FFFFF to clarify that the affected source is each BOPF shop; and

- Eliminated the SSM exemption with revisions to Table 4 (the General Provisions table) of 40 CFR part 63, subpart FFFFF and updated citations throughout the remaining rule text.

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

A. What are the affected sources?

The affected sources are facilities in the Integrated Iron and Steel Manufacturing Facilities source category. This includes any facility engaged in producing steel from iron ore. Integrated iron and steel manufacturing includes the following processes: Sinter production, iron production, iron preparation (hot metal desulfurization), and steel production. The iron production process includes the production of iron in BF's by the reduction of iron-bearing materials with a hot gas. The steel production process includes BOPF. Based on the data we have, there are eleven integrated iron and steel manufacturing facilities subject to this NESHAP, but one of these facilities is idle.

B. What are the air quality impacts?

We are promulgating standards for mercury that may result in unquantified

reductions of mercury emissions and consequently improve air quality to some degree.

C. What are the cost impacts?

In this final rule, we require control of mercury emissions and allow sources to demonstrate compliance through performance testing or scrap selection requirements. We expect that facilities that choose scrap selection as their method of demonstrating compliance likely will not incur operational costs to comply with this requirement because we understand that most, if not all, facilities are already purchasing all their auto scrap from providers who participate in the NVMSRP. Therefore, we estimate a cost of \$1,058 per year per facility and \$11,639 per year for all 11 facilities in the industry, for recordkeeping and reporting of compliance with the standards.

D. What are the economic impacts?

Negligible economic impacts are expected to be incurred by integrated iron and steel facilities due to the mercury emission limit because the information available to the EPA indicates that most, if not all, facilities are already purchasing scrap from providers who participate in the NVMSRP.

E. What are the benefits?

These promulgated amendments may result in some unquantified reductions in emissions of mercury, depending on the extent of current limitation of mercury input or participation in the scrap selection program by integrated

iron and steel facilities. While the industry has reported to the EPA that most, or all, facilities are already meeting the proposed mercury emission limit, to the extent that additional reductions may be achieved, this rule may result in improved health in surrounding populations, especially protection of children from the negative health impacts of mercury exposure.

The requirements to submit reports and test results electronically will reduce paperwork and improve monitoring, compliance, and implementation of the rule.

F. What analysis of environmental justice did we conduct?

For this action, we examined the potential for any environmental justice issues that might be associated with the source category through a demographic analysis, which is an assessment of risks to individual demographic groups of the populations living within 5 kilometer (km) and within 50 km of the facilities. In the analysis, we evaluated the distribution of HAP-related cancer and noncancer risks from point sources in the Integrated Iron and Steel Manufacturing Facilities source category across different demographic groups within the populations living near facilities.

The results of the demographic analysis are summarized in Table 5 below. These results, for various demographic groups, are based on the estimated risk from actual emissions from point sources for the population living within 50 km of the facilities.

TABLE 5—INTEGRATED IRON AND STEEL MANUFACTURING FACILITIES DEMOGRAPHIC RISK ANALYSIS RESULTS

Item	Nationwide	Population with cancer risk at or above 1-in-1 million due to integrated iron and steel manufacturing facilities	Population with chronic HI at or above 1 due to integrated iron and steel manufacturing facilities
Total Population	317,746,049	64,158	0
White and Minority by Percent			
White	62%	63%	0%
Minority	38%	37%	0%
Minority by Percent			
African American	12%	29%	0%
Native American	0.8%	0.1%	0%
Hispanic or Latino (includes white and nonwhite)	18%	4%	0%
Other and Multiracial	7%	4%	0%
Income by Percent			
Below Poverty Level	14%	23%	0%
Above Poverty Level	86%	77%	0%
Education by Percent			
Over 25 and without High School Diploma	14%	12%	0%

TABLE 5—INTEGRATED IRON AND STEEL MANUFACTURING FACILITIES DEMOGRAPHIC RISK ANALYSIS RESULTS—
Continued

Item	Nationwide	Population with cancer risk at or above 1-in-1 million due to integrated iron and steel manufacturing facilities	Population with chronic HI at or above 1 due to integrated iron and steel manufacturing facilities
Over 25 and with a High School Diploma	86%	88%	0%
Linguistically Isolated by Percent			
Linguistically Isolated	6%	0.6%	0%

The results of the Integrated Iron and Steel Manufacturing Facilities source category demographic analysis indicate that point source emissions from the source category expose approximately 64,000 people to a cancer risk at or above 1-in-1 million and zero people to a chronic noncancer HI greater than or equal to 1. The percentages of the at-risk population in each demographic group (except for African American and Below Poverty Level) are similar to or lower than their respective nationwide percentages. The African American population with cancer risk at or above 1-in-1 million due to Integrated Iron and Steel Manufacturing Facilities source category emissions is more than 3 times the national average. Likewise, populations living “Below Poverty Level” exposed to cancer risk at or above 1-in-1 million is nearly twice the national average. However, the risks to all demographic groups is less than 100-in-1 million.

The methodology and the results of the demographic analysis are presented in a technical report, *Risk and Technology Review—Analysis of Demographic Factors for Populations Living Near Integrated Iron and Steel Manufacturing Facilities* (Docket ID Item No. EPA-HQ-OAR-2002-0083-1060).

VI. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at <https://www.epa.gov/laws-regulations/laws-and-executive-orders>.

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

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

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

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

C. Paperwork Reduction Act (PRA)

The information collection activities in this final rule have been submitted for approval to OMB under the PRA. The ICR document that the EPA prepared has been assigned EPA ICR number 2003.09. You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here. The information collection requirements are not enforceable until OMB approves them.

These amendments require electronic reporting; remove the SSM exemptions; and impose other revisions that affect reporting and recordkeeping for integrated iron and steel facilities. We are also promulgating standards for mercury that require facilities to certify the type of steel scrap they use or conduct a performance test. This information is collected to assure compliance with 40 CFR part 63, subpart FFFFF.

Respondents/affected entities: Integrated iron and steel manufacturing facilities.

Respondent’s obligation to respond: Mandatory (40 CFR part 63, subpart FFFFF).

Estimated number of respondents: 11 facilities.

Frequency of Response: One time.

Total estimated burden: The annual recordkeeping and reporting burden for facilities to comply with all of the requirements in the NESHAP is estimated to be 6,500 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: The annual recordkeeping and reporting cost for all facilities to comply with all of the requirements in the NESHAP is estimated to be \$800,000 (per year), of which \$20,000 (per year) is for this rule, and \$780,000 is for other costs related

to continued compliance with the NESHAP including \$50,300 for paperwork associated with operation and maintenance requirements. The total rule costs reflect a savings of \$210,000 (per year) from the previous ICR due to the transition to electronic reporting.

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

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities. No small entities are subject to the requirements of this rule.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of \$100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. While this action creates an enforceable duty on the private sector, the cost does not exceed \$100 million or more.

F. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175. It will not have substantial direct effects on tribal governments, 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. No tribal governments own facilities subject to the NESHAP. Thus, Executive Order 13175 does not apply to this action.

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

This action is not subject to Executive Order 13045 because the EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. This action's health and risk assessments are contained in sections III and IV of this preamble and further documented in the document titled *Residual Risk Assessment for the Integrated Iron and Steel Manufacturing Facilities Source Category in Support of the Risk and Technology Review 2020 Final Rule*, in the docket for this rule (Docket ID No. EPA-HQ-OAR-2002-0083).

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

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

J. National Technology Transfer and Advancement Act (NTTAA) and 1 CFR Part 51

This action involves technical standards. Therefore, the EPA conducted searches for the Iron and Steel Manufacturing Facilities NESHAP through the Enhanced National Standards Systems Network Database managed by the American National Standards Institute (ANSI). We also contacted VCS organizations and accessed and searched their databases. We conducted searches for EPA Methods 1, 2, 2F, 2G, 3, 3A, 3B, 4, 5, 5D, 9, 17, 25, 29, and 30B of 40 CFR part 60, appendix A and SW-846 Method 9071B Test Methods for Evaluating Solid Waste, Physical/Chemical Methods, EPA Publications SW-846 third edition. During the EPA's VCS search, if the title or abstract (if provided) of the VCS described technical sampling and analytical

procedures that are similar to the EPA's reference method, the EPA reviewed it as a potential equivalent method. We reviewed all potential standards to determine the practicality of the VCS for this rule. This review requires significant method validation data that meet the requirements of EPA Method 301 for accepting alternative methods or scientific, engineering and policy equivalence to procedures in the EPA reference methods. The EPA may reconsider determinations of impracticality when additional information is available for a particular VCS. No applicable VCS were identified for EPA Methods 1A, 2F, 2G, 5D, 30B, and SW-846 Method 9071B.

The EPA is incorporating by reference the VCS ANSI/ASME PTC 19.10-1981, "Flue and Exhaust Gas Analyses." We are revising 40 CFR 63.7822(b), 40 CFR 63.7824(e), and 40 CFR 63.7825(b) to provide that the manual procedures (but not instrumental procedures) of VCS ANSI/ASME PTC 19.10-1981—Part 10 may be used as an alternative to EPA Method 3B. The manual procedures (but not instrumental procedures) of VCS ANSI/ASME PTC 19.10-1981—Part 10 (incorporated by reference—see 40 CFR 63.14) may be used as an alternative to EPA Method 3B for measuring the oxygen or carbon dioxide content of the exhaust gas. This standard is acceptable as an alternative to EPA Method 3B and is available from ASME at <http://www.asme.org>; by mail at Three Park Avenue, New York, NY 10016-5990; or by telephone at (800) 843-2763. This method determines quantitatively the gaseous constituents of exhausts resulting from stationary combustion sources. The gases covered in ANSI/ASME PTC 19.10-1981 are oxygen, carbon dioxide, carbon monoxide, nitrogen, sulfur dioxide, sulfur trioxide, nitric oxide, nitrogen dioxide, hydrogen sulfide, and hydrocarbons, however the use in this rule is only applicable to oxygen and carbon dioxide.

In the final rule, the EPA is incorporating by reference the VCS ASTM D7520-16, Standard Test Method for Determining the Opacity of a Plume in the Outdoor Ambient Atmosphere, as an acceptable alternative to EPA Method 9 with the following caveats:

- During the DCOT certification procedure outlined in Section 9.2 of ASTM D7520-16, the facility or the DCOT vendor must present the plumes in front of various backgrounds of color and contrast representing conditions anticipated during field use such as blue sky, trees, and mixed backgrounds (clouds and/or a sparse tree stand).
- The facility must also have standard operating procedures in place including

daily or other frequency quality checks to ensure the equipment is within manufacturing specifications as outlined in Section 8.1 of ASTM D7520-16.

- The facility must follow the recordkeeping procedures outlined in 40 CFR 63.10(b)(1) for the DCOT certification, compliance report, data sheets, and all raw unaltered JPEGs used for opacity and certification determination.

- The facility or the DCOT vendor must have a minimum of four independent technology users apply the software to determine the visible opacity of the 300 certification plumes. For each set of 25 plumes, the user may not exceed 15-percent opacity of anyone reading and the average error must not exceed 7.5-percent opacity.

- This approval does not provide or imply a certification or validation of any vendor's hardware or software. The onus to maintain and verify the certification and/or training of the DCOT camera, software, and operator in accordance with ASTM D7520-16 is on the facility, DCOT operator, and DCOT vendor. This method describes procedures to determine the opacity of a plume, using digital imagery and associated hardware and software, where opacity is caused by PM emitted from a stationary point source in the outdoor ambient environment. The opacity of emissions is determined by the application of a DCOT that consists of a digital still camera, analysis software, and the output function's content to obtain and interpret digital images to determine and report plume opacity. The ASTM D7520-16 document is available from ASTM at <https://www.astm.org> or 1100 Barr Harbor Drive, West Conshohocken, PA 19428-2959, telephone number: (610) 832-9500, fax number: (610) 8329555 at service@astm.org.

The EPA is finalizing the use of the guidance document, *Fabric Filter Bag Leak Detection Guidance*, EPA-454/R-98-015, Office of Air Quality Planning and Standards (OAQPS), U.S. Environmental Protection Agency, Research Triangle Park, North Carolina, September 1997. This document provides guidance on the use of triboelectric monitors as fabric filter bag leak detectors. The document includes fabric filter and monitoring system descriptions; guidance on monitor selection, installation, setup, adjustment, and operation; and quality assurance procedures. The document is available at <https://nepis.epa.gov/Exe/ZyPDF.cgi?Dockey=2000D5T6.PDF>.

Additional information for the VCS search and determinations can be found

in the memorandum titled *Voluntary Consensus Standard Results for National Emission Standards for Hazardous Air Pollutants for Iron and Steel Manufacturing Facilities*, available in the docket for this final rule.

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

The EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations, and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994). The documentation for this decision is included in sections III.A and IV.A of this preamble and the technical report titled *Risk and Technology Review—Analysis of Socio-Economic Factors for Populations Living Near Integrated Iron and Steel Manufacturing Facilities*, available in the docket for this final rule.

We examined the potential for any environmental justice issues that might be associated with the source category by performing a demographic analysis of the population close to the facilities. In this analysis, we evaluated the distribution of HAP-related cancer and noncancer risks from the NESHAP source category across different social, demographic, and economic groups within the populations living near facilities identified as having the highest risks. The methodology and the results of the demographic analyses are included in a technical report titled *Risk and Technology Review—Analysis of Socio-Economic Factors for Populations Living Near Integrated Iron and Steel Manufacturing Facilities* (Docket ID No. EPA-HQ-OAR-2002-0083).

The results of the source category demographic analysis for the NESHAP (point sources only) indicate that emissions expose approximately 60 people to a cancer risk at or above 10-in-1 million and none exposed to a chronic noncancer TOSHI greater than or equal to 1. The specific demographic results indicate that the overall percentage of the population potentially impacted by emissions is less than its corresponding national percentage for the minority population (37 percent for the source category compared to 38-percent nationwide). However, the “African American” population (29 percent for the source category compared to 12-percent nationwide) and the population “Below the Poverty Level” are greater than their corresponding national percentages. The proximity results (irrespective of risk)

indicate that the population percentages for certain demographic categories within 5 km of source category emissions are greater than the corresponding national percentage for certain demographic groups including: “African American,” “Ages 0 to 17,” “Over age 25 without a high school diploma,” and “Below the poverty level.”

The risks due to HAP emissions from this source category are acceptable for all populations. Furthermore, we do not expect this rule to achieve significant reductions in HAP emissions. Therefore, we conclude that this final rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it does not affect the level of protection provided to human health or the environment. However, this final rule will provide additional benefits to these demographic groups by improving the compliance, monitoring, and implementation of the NESHAP.

L. Congressional Review Act (CRA)

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

List of Subjects in 40 CFR Part 63

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

Andrew Wheeler,
Administrator.

For the reasons set forth in the preamble, the EPA amends 40 CFR part 63 as follows:

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

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

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

Subpart A—General Provisions

■ 2. Section 63.14 is amended by revising paragraphs (e)(1), (h)(106), and (n)(3) to read as follows:

§ 63.14 Incorporations by reference.

* * * * *
(e) * * *

(1) ANSI/ASME PTC 19.10–1981, Flue and Exhaust Gas Analyses [Part 10,

Instruments and Apparatus], issued August 31, 1981, IBR approved for §§ 63.309(k), 63.457(k), 63.772(e) and (h), 63.865(b), 63.997(e), 63.1282(d) and (g), 63.1625(b), table 5 to subpart EEEE, 63.3166(a), 63.3360(e), 63.3545(a), 63.3555(a), 63.4166(a), 63.4362(a), 63.4766(a), 63.4965(a), 63.5160(d), table 4 to subpart UUUU, table3 to subpart YYYY, 63.7822(b), 63.7824(e), 63.7825(b), 63.9307(c), 63.9323(a), 63.11148(e), 63.11155(e), 63.11162(f), 63.11163(g), 63.11410(j), 63.11551(a), 63.11646(a), and 63.11945, table 5 to subpart DDDDD, table 4 to subpart JJJJJ, table 4 to subpart KKKKK, tables 4 and 5 of subpart UUUUU, table 1 to subpart ZZZZZ, and table 4 to subpart JJJJJJ.

* * * * *

(h) * * *

(106) ASTM D7520–16, Standard Test Method for Determining the Opacity of a Plume in the Outdoor Ambient Atmosphere, approved April 1, 2016, IBR approved for §§ 63.1625(b), table 3 to subpart LLLLL, 63.7823(c) through (e), and 63.7833(g).

* * * * *

(n) * * *

(3) EPA-454/R-98-015, Office of Air Quality Planning and Standards (OAQPS), Fabric Filter Bag Leak Detection Guidance, September 1997, <https://nepis.epa.gov/Exe/ZyPDF.cgi?Dockey=2000D5T6.pdf>, IBR approved for §§ 63.548(e), 63.864(e), 63.7525(j), 63.7831(f), 63.8450(e), 63.8600(e), and 63.11224(f).

* * * * *

Subpart FFFFF—[Amended]

■ 3. Section 63.7783 is amended by revising paragraphs (a) introductory text, (b), and (c) and adding paragraph (f) to read as follows:

§ 63.7783 When do I have to comply with this subpart?

(a) If you have an existing affected source, you must comply with each emission limitation, standard, and operation and maintenance requirement in this subpart that applies to you by the dates specified in paragraphs (a)(1) and (2) of this section. This paragraph does not apply to the emission limitations for mercury.

* * * * *

(b) If you have a new affected source and its initial startup date is on or before May 20, 2003, then you must comply with each emission limitation, standard, and operation and maintenance requirement in this subpart that applies to you by May 20, 2003. This paragraph does not apply to the emission limitations for mercury.

(c) If you have a new affected source and its initial startup date is after May 20, 2003, you must comply with each emission limitation, standard, and operation and maintenance requirement in this subpart that applies to you upon initial startup. This paragraph does not apply to the emission limitations for mercury.

* * * * *

(f) With regard to the mercury emission limitations, if you have a new or existing affected source, you must comply with each emission limitation for mercury that applies to you by the deadlines set forth in § 63.7791.

■ 4. The undesignated center heading before § 63.7790 is revised to read:

Emission Limitations and Standards

■ 5. Section 63.7791 is added before the undesignated center heading "Operation and Maintenance Requirements" to read as follows:

§ 63.7791 How do I comply with the requirements for the control of mercury?

(a) *Compliance deadlines.* (1) If you have an existing affected source or a new or reconstructed affected source for which construction or reconstruction commenced on or before August 16, 2019, each BOPF Group at your facility must be in compliance with the applicable mercury emission limit in Table 1 of this subpart through performance testing under §§ 63.7825 and 63.7833, or through procurement of steel scrap pursuant to the compliance options in § 63.7791(c), (d), or (e) beginning July 13, 2021.

(2) If you have a new or reconstructed affected source for which construction or reconstruction commenced after August 16, 2019, each BOPF Group at that source must be in compliance with the applicable mercury emission limit in Table 1 of this subpart beginning July 13, 2020 or upon initial startup of your affected source, whichever is later.

(b) *Alternative compliance demonstration.* (1) As an alternative to demonstrating compliance with the emission limits in Table 1 by conducting performance tests pursuant to §§ 63.7825 and 63.7833(h), you may demonstrate compliance with the emission limits in Table 1 by procuring scrap pursuant to the requirements in paragraph (c), (d), or (e) of this section for each scrap provider, contract, or shipment. It is not necessary to use the same BOPF scrap compliance provision for all scrap providers, contracts, or shipments. You may procure some scrap through providers, contracts, or shipments pursuant to one BOPF scrap compliance provision and other scrap

through providers, contracts, or shipments pursuant to other BOPF scrap compliance provisions.

(2) To utilize the alternative compliance options established in paragraph (b)(1) of this section, you must submit an initial certification of compliance and semiannual compliance reports consistent with the requirements of §§ 63.7840(f) and 63.7841(b)(9) through (11), and (13), and comply with the recordkeeping requirements in § 63.7842(e) and all other applicable provisions related to demonstrating compliance through participating in an approved mercury program or through the use of scrap that does not contain mercury switches.

(3) For any facility that initially elects to utilize the alternative compliance options established in paragraph (b)(1) of this section, but subsequently stops using scrap that meets the requirements of paragraph (c), (d), or (e) of this section for each scrap provider, contract, or shipment, within 180 days of the change you must, for that BOPF Group, demonstrate compliance through performance testing pursuant to the requirements of §§ 63.7825 and 63.7833(h), and submit a revised notice of compliance status in your next semiannual compliance report described in this section. You must also comply with the requirements for conducting subsequent performance tests in §§ 63.7821(e) and 63.7840(g), and all other applicable requirements related to demonstrating compliance with the emission limits through performance testing.

(c) *Participation in the NVMSRP.* (1) You must obtain all post-consumer scrap that contains motor vehicle scrap from scrap providers who participate in the NVMSRP. The NVMSRP is an EPA-approved program under this section unless and until the Administrator disapproves the program (in part or in whole);

(2) You must certify in your initial notification of compliance status required by § 63.7840(f) and semiannual compliance report required by § 63.7841(a) that you purchased post-consumer steel scrap containing motor vehicle scrap according to paragraph (c)(1) of this section, and identify all your scrap providers in your semiannual compliance report;

(3) If you purchase scrap from a broker, you must certify that all scrap received from that broker was obtained from other scrap providers who participate in the NVMSRP and identify all scrap providers used by all your scrap brokers in your semiannual compliance report; and

(4) You must conduct periodic inspections or provide other means of corroboration to ensure that scrap providers and brokers participate in the NVMSRP and, therefore, are aware of the need for and are implementing appropriate steps to minimize the presence of mercury in scrap from end-of-life vehicles.

(d) *Use of scrap that does not contain mercury switches.* For BOPF scrap not complying with the requirements in paragraph (c) or (e) of this section, you must certify in your initial notification of compliance report required by § 63.7840(f) and semiannual compliance report required by § 63.7841(a) and maintain records of documentation required by § 63.7842(e) establishing that the scrap does not contain mercury switches. You may satisfy this requirement by certifying and documenting that:

(1) The scrap does not contain motor vehicle scrap; or

(2) The scrap does not contain shredded motor vehicle scrap; or

(3) The only materials from motor vehicles in the scrap are materials recovered for their specialty alloy content (including, but not limited to, chromium, nickel, molybdenum, or other alloys); therefore, based on the type of the scrap and purchase specifications, the scrap does not contain mercury switches.

(e) *Use of an EPA-approved mercury removal program.* (1) You must obtain all post-consumer scrap containing motor vehicle scrap from scrap providers who participate in a program for the removal of mercury switches that has been approved by the Administrator;

(2) You must certify in your initial notification of compliance status required by § 63.7840(f) and semiannual compliance report required by § 63.7841(a) that you purchase post-consumer steel scrap containing motor vehicle scrap according to paragraph (e)(1) of this section and identify all your scrap providers in your semiannual compliance report;

(3) If you purchase scrap from a broker, you must certify that all scrap received from that broker was obtained from other scrap providers who participate in a program for the removal of mercury switches that has been approved by the Administrator and identify all scrap providers used by all your scrap brokers in your semiannual compliance report; and

(4) You must conduct periodic inspections or provide other means of corroboration to ensure that scrap providers and brokers are complying with the approved mercury removal

program and, therefore, are aware of the need for and are implementing appropriate steps to minimize the presence of mercury in scrap from end-of-life vehicles.

■ 6. Section 63.7800 is amended by revising paragraph (a) to read as follows:

§ 63.7800 What are my operation and maintenance requirements?

(a) You must always operate and maintain your affected source, including air pollution control and monitoring equipment, according to the requirements in § 63.7810(d).

* * * * *

■ 7. Section 63.7810 is amended by revising paragraphs (a) and (c) and adding paragraph (d) to read as follows:

§ 63.7810 What are my general requirements for complying with this subpart?

(a) On or before January 11, 2021, for each existing source, and for each new or reconstructed source for which construction or reconstruction commenced on or before August 16, 2019, you must be in compliance with the emission limitations, standards, and operation and maintenance requirements in this subpart at all times, except during periods of startup, shutdown, and malfunction. After January 11, 2021, for each such source you must be in compliance with the emission limitations in this subpart at all times. For new and reconstructed sources for which construction or reconstruction commenced after August 16, 2019, you must be in compliance with the emission limitations in this subpart at all times.

* * * * *

(c) On or before January 11, 2021, for each existing source, and for each new or reconstructed source for which construction or reconstruction commenced on or before August 16, 2019, you must develop a written startup, shutdown, and malfunction plan according to the provisions in § 63.6(e)(3). For each such source, a startup, shutdown, and malfunction plan is not required after January 11, 2021. No startup, shutdown, and malfunction plan is required for any new or reconstructed source for which construction or reconstruction commenced after August 16, 2019.

(d) On or before January 11, 2021, for each existing source, and for each new or reconstructed source for which construction or reconstruction commenced on or before August 16, 2019, you must always operate and maintain your affected source, including air pollution control and monitoring equipment, according to the provisions

in § 63.6(e)(1)(i). After January 11, 2021 for each such source, and after July 13, 2020 for new and reconstructed sources for which construction or reconstruction commenced after August 16, 2019, at all times, you must operate and maintain any affected source, including associated air pollution control equipment and monitoring equipment, in a manner consistent with safety and good air pollution control practices for minimizing emissions. The general duty to minimize emissions does not require you to make any further efforts to reduce emissions if levels required by the applicable standard have been achieved. Determination of whether a source is operating in compliance with operation and maintenance requirements will be based on information available to the Administrator which may include, but is not limited to, monitoring results, review of operation and maintenance procedures, review of operation and maintenance records, and inspection of the source.

■ 8. Section 63.7820 is amended by adding paragraph (e) to read as follows:

§ 63.7820 By what date must I conduct performance tests or other initial compliance demonstrations?

* * * * *

(e) Notwithstanding the deadlines in this section, existing and new affected sources must comply with the deadlines for making the initial compliance demonstrations for the mercury emission limit set forth in (e)(1) through (4) in this section.

(1) If you have an existing affected BOPF Group or a new or reconstructed affected source for which construction or reconstruction commenced on or before August 16, 2019, and you are demonstrating compliance with the emission limit in Table 1 through performance testing, you must conduct the initial performance test at your BOPF Group to demonstrate compliance with the mercury emission limit in Table 1 no later than July 13, 2021.

(2) If you have a new or reconstructed affected BOPF Group for which construction or reconstruction commenced after August 16, 2019, and you are demonstrating compliance with the emission limit in Table 1 through performance testing, you must conduct the initial performance test at your BOPF Group to demonstrate compliance with the mercury emission limit in Table 1 within 180 days of July 13, 2020 or within 180 days of initial startup of your affected source, whichever is later.

(3) If you have an existing affected BOPF Group or a new or reconstructed affected source for which construction

or reconstruction commenced on or before August 16, 2019, and you are demonstrating compliance with the mercury emission limit in Table 1 through the requirements in § 63.7791(c) through (e), you must certify compliance in accordance with § 63.7840(f) in your notification of compliance and in accordance with § 63.7841(b)(11) in your first semiannual compliance report after July 13, 2021.

(4) If you have a new affected BOPF Group or a new or reconstructed affected source for which construction or reconstruction commenced after August 16, 2019, and you are demonstrating compliance with the mercury emission limit in Table 1 through the requirements in § 63.7791(b) through (d), you must certify compliance in accordance with § 63.7840(f) in your initial notification of compliance and in accordance with § 63.7841(b)(11) in your first semiannual compliance report after July 13, 2021 or after initial startup of your BOPF Group, whichever is later.

■ 9. Section 63.7821 is amended by revising paragraph (a) and adding paragraph (e) to read as follows:

§ 63.7821 When must I conduct subsequent performance tests?

(a) You must conduct subsequent performance tests to demonstrate compliance with all applicable emission and opacity limits in Table 1 to this subpart at the frequencies specified in paragraphs (b) through (e) of this section.

* * * * *

(e) For each BOPF Group, if demonstrating compliance with the mercury emission limit in Table 1 to this subpart through performance testing under §§ 63.7825 and 63.7833, you must conduct subsequent performance tests twice per permit cycle (*i.e.*, mid-term and initial/final) for sources with title V operating permits, and every 2.5 years for sources without a title V operating permit, at the outlet of the control devices for the BOPF Group.

■ 10. Section 63.7822 is amended by revising paragraphs (a) and (b)(1) to read as follows:

§ 63.7822 What test methods and other procedures must I use to demonstrate initial compliance with the emission limits for particulate matter?

(a) On or before January 11, 2021, for each existing source, and for each new or reconstructed source for which construction or reconstruction commenced on or before August 16, 2019, you must conduct each performance test that applies to your

affected source based on representative performance (*i.e.*, performance based on normal operating conditions) of the affected source for the period being tested, according to the conditions detailed in paragraphs (b) through (i) of this section. After January 11, 2021 for each such source, and after July 13, 2020 for new and reconstructed sources for which construction or reconstruction commenced after August 16, 2019, you must conduct each performance test under conditions representative of normal operations. The owner or operator must record the process information that is necessary to document operating conditions during the test and include in such record an explanation to support that such conditions represent normal operation. Upon request, the owner or operator shall make available to the Administrator such records as may be necessary to determine the conditions of performance tests. Representative conditions exclude periods of startup and shutdown. You shall not conduct performance tests during periods of malfunction. You must record the process information that is necessary to document operating conditions during the test and include in such record an explanation to support that such conditions represent normal operation. Upon request, you shall make available to the Administrator such records as may be necessary to determine the conditions of performance tests.

(b) * * *

(1) Determine the concentration of particulate matter according to the following test methods:

(i) EPA Method 1 in appendix A–1 to part 60 of this chapter to select sampling port locations and the number of traverse points. Sampling ports must be located at the outlet of the control device and prior to any releases to the atmosphere.

(ii) EPA Method 2 or 2F in appendix A–1 to part 60 of this chapter or EPA Method 2G in appendix A–2 to part 60 of this chapter to determine the volumetric flow rate of the stack gas.

(iii) EPA Method 3, 3A, or 3B in appendix A–2 to part 60 of this chapter to determine the dry molecular weight of the stack gas. The manual procedures (but not instrumental procedures) of voluntary consensus standard ANSI/ASME PTC 19.10–1981—Part 10 (incorporated by reference—see § 63.14) may be used as an alternative to EPA Method 3B.

(iv) EPA Method 4 in appendix A–3 to part 60 of this chapter to determine the moisture content of the stack gas.

(v) EPA Method 5 or 5D in appendix A–3 to part 60 of this chapter or EPA

Method 17 in appendix A–6 to part 60 of this chapter, as applicable, to determine the concentration of particulate matter (front half filterable catch only).

* * * * *

■ 11. Section 63.7823 is amended by revising paragraphs (a), (c)(1), (d)(1)(i), (d)(2)(i), and (e)(1) and (3) to read as follows:

§ 63.7823 What test methods and other procedures must I use to demonstrate initial compliance with the opacity limits?

(a) You must conduct each performance test that applies to your affected source based on representative performance (*i.e.*, performance based on normal operating conditions) of the affected source for the period being tested, according to the conditions detailed in paragraphs (b) through (d) of this section. Representative conditions exclude periods of startup and shutdown. You shall not conduct performance tests during periods of malfunction. You must record the process information that is necessary to document operating conditions during the test and include in such record an explanation to support that such conditions represent normal operation. Upon request, you shall make available to the Administrator such records as may be necessary to determine the conditions of performance tests.

* * * * *

(c) * * *

(1) Using a certified observer, determine the opacity of emissions according to EPA Method 9 in appendix A–4 to part 60 of this chapter. Alternatively, ASTM D7520–16, (incorporated by reference, see § 63.14) may be used with the following conditions:

(i) During the digital camera opacity technique (DCOT) certification procedure outlined in Section 9.2 of ASTM D7520–16 (incorporated by reference, see § 63.14), the owner or operator or the DCOT vendor must present the plumes in front of various backgrounds of color and contrast representing conditions anticipated during field use such as blue sky, trees, and mixed backgrounds (clouds and/or a sparse tree stand).

(ii) The owner or operator must also have standard operating procedures in place including daily or other frequency quality checks to ensure the equipment is within manufacturing specifications as outlined in Section 8.1 of ASTM D7520–16 (incorporated by reference, see § 63.14).

(iii) The owner or operator must follow the recordkeeping procedures

outlined in § 63.10(b)(1) for the DCOT certification, compliance report, data sheets, and all raw unaltered JPEGs used for opacity and certification determination.

(iv) The owner or operator or the DCOT vendor must have a minimum of four independent technology users apply the software to determine the visible opacity of the 300 certification plumes. For each set of 25 plumes, the user may not exceed 15-percent opacity of anyone reading and the average error must not exceed 7.5-percent opacity.

(v) Use of this approved alternative does not provide or imply a certification or validation of any vendor's hardware or software. The onus to maintain and verify the certification and/or training of the DCOT camera, software, and operator in accordance with ASTM D7520–16 (incorporated by reference, see § 63.14) and these requirements is on the facility, DCOT operator, and DCOT vendor.

* * * * *

(d) * * *

(1) * * *

(i) Using a certified observer, determine the opacity of emissions according to EPA Method 9 in appendix A–4 to part 60 of this chapter except as specified in paragraphs (d)(1)(ii) and (iii) of this section. Alternatively, ASTM D7520–16 (incorporated by reference, see § 63.14) may be used with the following conditions:

(A) During the DCOT certification procedure outlined in Section 9.2 of ASTM D7520–16 (incorporated by reference, see § 63.14), the owner or operator or the DCOT vendor must present the plumes in front of various backgrounds of color and contrast representing conditions anticipated during field use such as blue sky, trees, and mixed backgrounds (clouds and/or a sparse tree stand).

(B) The owner or operator must also have standard operating procedures in place including daily or other frequency quality checks to ensure the equipment is within manufacturing specifications as outlined in Section 8.1 of ASTM D7520–16 (incorporated by reference, see § 63.14).

(C) The owner or operator must follow the recordkeeping procedures outlined in § 63.10(b)(1) for the DCOT certification, compliance report, data sheets, and all raw unaltered JPEGs used for opacity and certification determination.

(D) The owner or operator or the DCOT vendor must have a minimum of four independent technology users apply the software to determine the visible opacity of the 300 certification

plumes. For each set of 25 plumes, the user may not exceed 15-percent opacity of anyone reading and the average error must not exceed 7.5-percent opacity.

(E) Use of this approved alternative does not provide or imply a certification or validation of any vendor's hardware or software. The onus to maintain and verify the certification and/or training of the DCOT camera, software, and operator in accordance with ASTM D7520-16 (incorporated by reference, see § 63.14) and these requirements is on the facility, DCOT operator, and DCOT vendor.

* * * * *

(2) * * *

(i) Using a certified observer, determine the opacity of emissions according to EPA Method 9 in appendix A-4 to part 60 of this chapter. Alternatively, ASTM D7520-16 (incorporated by reference, see § 63.14) may be used with the following conditions:

(A) During the DCOT certification procedure outlined in Section 9.2 of ASTM D7520-16 (incorporated by reference, see § 63.14), the owner or operator or the DCOT vendor must present the plumes in front of various backgrounds of color and contrast representing conditions anticipated during field use such as blue sky, trees, and mixed backgrounds (clouds and/or a sparse tree stand).

(B) The owner or operator must also have standard operating procedures in place including daily or other frequency quality checks to ensure the equipment is within manufacturing specifications as outlined in Section 8.1 of ASTM D7520-16 (incorporated by reference, see § 63.14).

(C) The owner or operator must follow the recordkeeping procedures outlined in § 63.10(b)(1) for the DCOT certification, compliance report, data sheets, and all raw unaltered JPEGs used for opacity and certification determination.

(D) The owner or operator or the DCOT vendor must have a minimum of four independent technology users apply the software to determine the visible opacity of the 300 certification plumes. For each set of 25 plumes, the user may not exceed 15-percent opacity of anyone reading and the average error must not exceed 7.5-percent opacity.

(E) Use of this approved alternative does not provide or imply a certification or validation of any vendor's hardware or software. The onus to maintain and verify the certification and/or training of the DCOT camera, software, and operator in accordance with ASTM D7520-16 (incorporated by reference,

see § 63.14) and these requirements is on the facility, DCOT operator, and DCOT vendor.

* * * * *

(e) * * *

(1) Using a certified observer, determine the opacity of emissions according to EPA Method 9 in appendix A-4 to part 60 of this chapter. Alternatively, ASTM D7520-16 (incorporated by reference, see § 63.14) may be used with the following conditions:

(i) During the DCOT certification procedure outlined in Section 9.2 of ASTM D7520-16 (incorporated by reference, see § 63.14), the owner or operator or the DCOT vendor must present the plumes in front of various backgrounds of color and contrast representing conditions anticipated during field use such as blue sky, trees, and mixed backgrounds (clouds and/or a sparse tree stand).

(ii) The owner or operator must also have standard operating procedures in place including daily or other frequency quality checks to ensure the equipment is within manufacturing specifications as outlined in Section 8.1 of ASTM D7520-16 (incorporated by reference, see § 63.14).

(iii) The owner or operator must follow the recordkeeping procedures outlined in § 63.10(b)(1) for the DCOT certification, compliance report, data sheets, and all raw unaltered JPEGs used for opacity and certification determination.

(iv) The owner or operator or the DCOT vendor must have a minimum of four independent technology users apply the software to determine the visible opacity of the 300 certification plumes. For each set of 25 plumes, the user may not exceed 15-percent opacity of anyone reading and the average error must not exceed 7.5-percent opacity.

(v) Use of this approved alternative does not provide or imply a certification or validation of any vendor's hardware or software. The onus to maintain and verify the certification and/or training of the DCOT camera, software, and operator in accordance with ASTM D7520-16 (incorporated by reference, see § 63.14) and these requirements is on the facility, DCOT operator, and DCOT vendor.

* * * * *

(3) Make visible emission observations of uncovered portions of sinter plant coolers with the line of sight generally in the direction of the center of the cooler.

■ 12. Section 63.7824 is amended by revising paragraphs (e) introductory text and (e)(1) and (2) and the defined term

“M_c” in Equation 1 in paragraph (e)(3) to read as follows:

§ 63.7824 What test methods and other procedures must I use to establish and demonstrate initial compliance with operating limits?

* * * * *

(e) To demonstrate initial compliance with the alternative operating limit for volatile organic compound emissions from the sinter plant windbox exhaust stream in § 63.7790(d)(2), follow the test methods and procedures in paragraphs (e)(1) through (5) of this section. You must conduct each performance test that applies to your affected source based on representative performance (*i.e.*, performance based on normal operating conditions) of the affected source for the period being tested. Representative conditions exclude periods of startup and shutdown. You shall not conduct performance tests during periods of malfunction. You must record the process information that is necessary to document operating conditions during the test and include in such record an explanation to support that such conditions represent normal operation. Upon request, you shall make available to the Administrator such records as may be necessary to determine the conditions of performance tests.

(1) Determine the volatile organic compound emissions according to the following test methods:

(i) EPA Method 1 in appendix A-1 to part 60 of this chapter to select sampling port locations and the number of traverse points. Sampling ports must be located at the outlet of the control device and prior to any releases to the atmosphere.

(ii) EPA Method 2 or 2F in appendix A-1 to part 60 of this chapter or EPA Method 2G in appendix A-2 to part 60 of this chapter to determine the volumetric flow rate of the stack gas.

(iii) EPA Method 3, 3A, or 3B in appendix A-2 to part 60 of this chapter to determine the dry molecular weight of the stack gas. The manual procedures (but not instrumental procedures) of voluntary consensus standard ANSI/ASME PTC 19.10-1981-Part 10 (incorporated by reference—see § 63.14) may be used as an alternative to EPA Method 3B.

(iv) EPA Method 4 in appendix A-3 to part 60 of this chapter to determine the moisture content of the stack gas.

(v) EPA Method 25 in appendix A-7 to part 60 of this chapter to determine the mass concentration of volatile organic compound emissions (total gaseous nonmethane organics as carbon) from the sinter plant windbox exhaust stream stack.

(2) Determine volatile organic compound (VOC) emissions every 24 hours (from at least three samples taken at 8-hour intervals) using EPA Method 25 in appendix A-7 to part 60 of this chapter. Record the sampling date and time, sampling results, and sinter produced (tons/day).

(3) * * *

M_c = Average concentration of total gaseous nonmethane organics as carbon by EPA Method 25 in appendix A-7 to part 60 of this chapter, milligrams per dry standard cubic meters (mg/dscm) for each cubic

* * * * *

§§ 63.7825 and 63.7826 [Redesignated as §§ 63.7826 and 63.7827]

■ 13. Sections 63.7825 and 63.7826 are redesignated as §§ 63.7826 and 63.7827, respectively, and a new § 63.7825 is added to read as follows:

§ 63.7825 What test methods and other procedures must I use to demonstrate initial compliance with the emission limit for mercury?

(a) If demonstrating compliance with the mercury emission limits for each BOPF Group in Table 1 to this subpart through performance testing, you must conduct a performance test to demonstrate initial compliance with the emission limit. If demonstrating compliance with the emission limit through performance testing, you must conduct each performance test that applies to your affected source based on representative performance (*i.e.*, performance based on normal operating conditions) of the affected source for the period being tested, according to the conditions detailed in paragraphs (b) through (f) of this section. Representative conditions exclude periods of startup and shutdown. You shall not conduct performance tests during periods of malfunction. Initial compliance tests must be conducted by the deadlines in § 63.7820(e).

(1) You must record the process information that is necessary to document operating conditions during the test and include in such record an explanation to support that such conditions represent normal operation. Upon request, you shall make available to the Administrator such records as may be necessary to determine the conditions of performance tests.

(2) For sources with multiple emission units ducted to a common control device and stack, compliance testing must be performed either by conducting a single compliance test with all affected emissions units in operation or by conducting a separate

compliance test on each emissions unit. Alternatively, the owner or operator may request approval from the permit authority for an alternative testing approach. If the units are tested separately, any emissions unit that is not tested initially must be tested as soon as is practicable.

(b) To demonstrate compliance with the emission limit for mercury in Table 1 to this subpart through performance testing, follow the test methods and procedures in paragraphs (b)(1) and (2) of this section.

(1) Determine the concentration of mercury according to the following test methods:

(i) EPA Method 1 in appendix A-1 to part 60 of this chapter to select sampling port locations and the number of traverse points. Sampling ports must be located at the outlet of the control device and prior to any releases to the atmosphere.

(ii) EPA Method 2 or 2F in appendix A-1 to part 60 of this chapter or EPA Method 2G in appendix A-2 to part 60 of this chapter to determine the volumetric flow rate of the stack gas.

(iii) EPA Method 3, 3A, or 3B in appendix A-2 to part 60 of this chapter to determine the dry molecular weight of the stack gas. The manual procedures (but not instrumental procedures) of voluntary consensus standard ANSI/ASME PTC 19.10-1981—Part 10 (incorporated by reference—see § 63.14) may be used as an alternative to EPA Method 3B.

(iv) EPA Method 4 in appendix A-3 to part 60 of this chapter to determine the moisture content of the stack gas.

(v) EPA Method 29 or 30B in appendix A-8 to part 60 of this chapter to determine the concentration of mercury from each unit of the BOPF Group exhaust stream stack. If performing measurements using EPA Method 29, you must collect a minimum sample volume of 1.7 dscm (60 dscf). Alternative test methods may be considered on a case-by-case basis per § 63.7(f).

(2) Three valid test runs are needed to comprise a performance test of each BOPF Group unit. If the performance testing results for any of the emission points yields a non-detect value, then the minimum detection limit (MDL) must be used to calculate the mass emissions (lb) for that emission unit and, in turn, for calculating the sum of the emissions (in units of pounds of mercury per ton of steel scrap) for all BOPF Group units subject to the emission standard for determining compliance. If the resulting mercury emissions are greater than the MACT emission standard, the owner or

operator may use procedures that produce lower MDL results and repeat the mercury performance testing one additional time for any emission point for which the measured result was below the MDL. If this additional testing is performed, the results from that testing must be used to determine compliance (*i.e.*, there are no additional opportunities allowed to lower the MDL).

(3) For a primary emission control device applied to emissions from a BOPF with a closed hood system, sample only during the primary oxygen blow and do not sample during any subsequent reblows. Continue sampling for each run for an integral number of primary oxygen blows.

(4) For a primary emission control system applied to emissions from a BOPF with an open hood system and for a control device applied solely to secondary emissions from a BOPF, you must complete the requirements of paragraphs (b)(4)(i) and (ii) of this section:

(i) Sample only during the steel production cycle. Conduct sampling under conditions that are representative of normal operation. Record the start and end time of each steel production cycle and each period of abnormal operation; and

(ii) Sample for an integral number of steel production cycles. The steel production cycle begins when the scrap is charged to the furnace and ends 3 minutes after the slag is emptied from the vessel into the slag pot.

(5) For a control device applied to emissions from BOPF shop ancillary operations (hot metal transfer, skimming, desulfurization, or ladle metallurgy), sample only when the operation(s) is being conducted.

(c) Calculate the mercury mass emissions, based on the average of three test run values, for each BOPF Group unit (or combination of units that are ducted to a common stack and are tested when all affected sources are operating pursuant to paragraph (a) of this section) using Equation 1 of this section as follows:

$$E = \frac{C_s \times Q \times t}{454,000 \times 35.31} \quad (\text{Eq. 1})$$

Where:

E = Mass emissions of mercury, pounds (lb);

C_s = Concentration of mercury in stack gas, mg/dscm;

454,000 = Conversion factor (mg/lb);

Q = Volumetric flow rate of stack gas, dscf/min;

35.31 = Conversion factor (dscf/dscm); and

t = Duration of test, minutes.

(d) You must install, calibrate, maintain, and operate an appropriate

weight measurement device, to measure the tons of steel scrap input to the BOPF cycle simultaneous with each BOPF Group unit's stack test.

(e) You must maintain the systems for measuring weight within ±5 percent accuracy. You must describe the specific equipment used to make measurements at your facility and how that equipment is periodically calibrated. You must also explain, document, and maintain written procedures for determining the accuracy of the measurements and make these written procedures available to your permitting authority upon request. You must determine, record, and maintain a record of the accuracy of the measuring systems before the beginning of your initial compliance test and during each subsequent quarter of affected source operation.

(f) Calculate the emissions from each new and existing affected source in pounds of mercury per ton of steel scrap to determine initial compliance with the mercury emission limit in Table 1. Sum the mercury mass emissions (in pounds) from all BOPF Group units calculated using Equation 1 of this section. Divide that sum by the sum of the total amount of steel scrap charged to the BOPFs (in tons).

■ 14. Section 63.7831 is amended by revising paragraphs (a)(4) through (6) and (f)(4) to read as follows:

§ 63.7831 What are the installation, operation, and maintenance requirements for my monitors?

(a) * * *

(4) On or before January 11, 2021, for each existing source, and for each new or reconstructed source for which construction or reconstruction commenced on or before August 16, 2019, ongoing operation and maintenance procedures in accordance with the general requirements of § 63.8(c)(1)(ii), (c)(3), (c)(4)(ii), and (c)(7) and (8). After January 11, 2021 for each such source, and after July 13, 2020 for new and reconstructed sources for which construction or reconstruction commenced after August 16, ongoing operation and maintenance procedures in accordance with the general requirements of § 63.8(c)(1)(ii), (c)(3), (c)(4)(ii), and (c)(7) and (8);

(5) On or before January 11, 2021, for each existing source, and for each new or reconstructed source for which construction or reconstruction commenced on or before August 16, 2019, ongoing data quality assurance procedures in accordance with the general requirements of § 63.8(d). After January 11, 2021 for each such source, and after July 13, 2020 for new and

reconstructed sources for which construction or reconstruction commenced after August 16, 2019, ongoing data quality assurance procedures in accordance with the general requirements of § 63.8(d) except for the requirements related to startup, shutdown, and malfunction plans referenced in § 63.8(d)(3). The owner or operator shall keep these written procedures on record for the life of the affected source or until the affected source is no longer subject to the provisions of this part, to be made available for inspection, upon request, by the Administrator. If the performance evaluation plan is revised, the owner or operator shall keep previous (*i.e.*, superseded) versions of the performance evaluation plan on record to be made available for inspection, upon request, by the Administrator, for a period of 5 years after each revision to the plan. The program of corrective action should be included in the plan required under § 63.8(d)(2);

(6) On or before January 11, 2021, for each existing source, and for each new or reconstructed source for which construction or reconstruction commenced on or before August 16, 2019, ongoing recordkeeping and reporting procedures in accordance with the general requirements of § 63.10(c)(1) through (14), (e)(1), and (e)(2)(i). After January 11, 2021 for each such source, and after July 13, 2020 for new and reconstructed sources for which construction or reconstruction commenced after August 16, 2019, ongoing recordkeeping and reporting procedures in accordance with the general requirements of § 63.10(c)(1) through (14), (e)(1), and (e)(2)(i);

* * * * *

(f) * * *

(4) Each system that works based on the triboelectric effect must be installed, operated, and maintained in a manner consistent with the guidance document, "Fabric Filter Bag Leak Detection Guidance," EPA-454/R-98-015 (incorporated by reference, see § 63.14). You may install, operate, and maintain other types of bag leak detection systems in a manner consistent with the manufacturer's written specifications and recommendations.

* * * * *

■ 15. Section 63.7833 is amended by revising paragraph (g)(3) and adding paragraphs (h) and (i) to read as follows:

§ 63.7833 How do I demonstrate continuous compliance with the emission limitations that apply to me?

* * * * *

(g) * * *

(3) For purposes of paragraphs (g)(1) and (2) of this section, in the case of an exceedance of the hourly average opacity operating limit for an electrostatic precipitator, measurements of the hourly average opacity based on visible emission observations in accordance with EPA Method 9 (in appendix A-4 to part 60) may be taken to evaluate the effectiveness of corrective action. ASTM D7520-16 (incorporated by reference, see § 63.14) may be used with the following conditions:

(i) During the DCOT certification procedure outlined in Section 9.2 of ASTM D7520-16 (incorporated by reference, see § 63.14), the owner or operator or the DCOT vendor must present the plumes in front of various backgrounds of color and contrast representing conditions anticipated during field use such as blue sky, trees, and mixed backgrounds (clouds and/or a sparse tree stand).

(ii) The owner or operator must also have standard operating procedures in place including daily or other frequency quality checks to ensure the equipment is within manufacturing specifications as outlined in Section 8.1 of ASTM D7520-16 (incorporated by reference, see § 63.14).

(iii) The owner or operator must follow the recordkeeping procedures outlined in § 63.10(b)(1) for the DCOT certification, compliance report, data sheets, and all raw unaltered JPEGs used for opacity and certification determination.

(iv) The owner or operator or the DCOT vendor must have a minimum of four independent technology users apply the software to determine the visible opacity of the 300 certification plumes. For each set of 25 plumes, the user may not exceed 15-percent opacity of anyone reading and the average error must not exceed 7.5-percent opacity.

(v) Use of this approved alternative does not provide or imply a certification or validation of any vendor's hardware or software. The onus to maintain and verify the certification and/or training of the DCOT camera, software, and operator in accordance with ASTM D7520-16 (incorporated by reference, see § 63.14) and these requirements is on the facility, DCOT operator, and DCOT vendor.

* * * * *

(h) If you are demonstrating compliance with the mercury emission limits in Table 1 of this section for your BOPF Groups through performance testing, you must conduct mercury performance tests in accordance with §§ 63.7821(e) and 63.7825 and calculate

the emissions from each new and existing affected source in pounds of mercury per ton of steel scrap to determine compliance with the mercury emission limits in Table 1. Sum the mercury mass emissions (in pounds) from all BOPF Group units calculated using Equation 1 of § 63.7825. Divide that sum by the sum of the total amount of steel scrap charged to the BOPFs (in tons).

(i) If you are demonstrating compliance with the mercury emission limits in Table 1 of this section for your BOPF Groups by certifying participation in the NVMSRP or another EPA-approved mercury program, or by using scrap that does not contain mercury switches, you must obtain and certify your use of steel scrap per § 63.7791(c), (d), or (e), as applicable, and § 63.7841(b)(11) to demonstrate continuous compliance with the standard.

■ 16. Section 63.7835 is revised to read as follows:

§ 63.7835 What other requirements must I meet to demonstrate continuous compliance?

Except as provided in § 63.7833(g), you must report each instance in which you did not meet each emission limitation in § 63.7790 that applies to you. This includes periods of startup, shutdown, and malfunction. You also must report each instance in which you did not meet each operation and maintenance requirement in § 63.7800 that applies to you. These instances are deviations from the emission limitations and operation and maintenance requirements in this subpart. These deviations must be reported according to the requirements in § 63.7841.

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

(b) For each failure to meet an applicable standard, record and retain a list of the affected sources or equipment, an estimate of the quantity of each regulated pollutant emitted over any emission limit and a description of the method used to estimate the emissions.

(c) Record actions taken to minimize emissions in accordance with § 63.7810(d), and any corrective actions taken to return the affected unit to its normal or usual manner of operation.

(d) For existing sources and for new or reconstructed sources which commenced construction or reconstruction on or before August 16, 2019, before January 11, 2021, consistent with §§ 63.6(e) and 63.7(e)(1), deviations that occur during a period of startup, shutdown, or malfunction are

not violations if you demonstrate to the Administrator's satisfaction that you were operating in accordance with § 63.6(e)(1). The Administrator will determine whether deviations that occur during a period of startup, shutdown, or malfunction are violations, according to the provisions in § 63.6(e). After January 11, 2021 for such sources, and after July 13, 2020 for new and reconstructed sources which commence construction or reconstruction after August 16, 2019, the exemptions for periods of startup, shutdown, and malfunction in § 63.6(e) no longer apply.

■ 17. Section 63.7840 is amended by revising paragraphs (d), (e) introductory text, and (e)(2) and adding paragraphs (f) through (h) to read as follows:

§ 63.7840 What notifications must I submit and when?

* * * * *

(d) If you are required to conduct a performance test, you must submit a notification of intent to conduct a performance test at least 60 calendar days before the performance test is scheduled to begin as required in § 63.7(b)(1). For the first mercury compliance test in the BOPF Group for anyone sequence of tests, you must include a schedule of all subsequent tests in the BOPF Group in the test series.

(e) If you are required to conduct a performance test, opacity observation, or other initial compliance demonstration, you must submit a notification of compliance according to § 63.9(h)(2)(ii), except that for the purposes of submitting the notification of compliance status for BOPF Group mercury testing, the performance test shall be considered complete when the final unit or control device in the BOPF Group in the sequence is tested.

* * * * *

(2) For each initial compliance demonstration that includes a performance test, you must submit the notification of compliance status, including the summary of performance test results, before the close of business on the 60th calendar day following the completion of the performance test according to § 63.10(d)(2).

(f) The notification of compliance status required by §§ 63.9(b) and (h) and 63.7826(c) must include each applicable certification of compliance, signed by a responsible official, in paragraphs (f)(1) and (2) of this section, regarding the mercury requirements, as applicable, in § 63.7791(c) through (e).

(1) "This facility participates in and purchases scrap only from scrap providers who participate in a program for removal of mercury switches that

has been approved by the EPA Administrator, in accordance with § 63.7791(c) or (e)"; or

(2) "This facility complies with the requirements for scrap that does not contain mercury switches, in accordance with § 63.7791(d)."

(g) Within 60 calendar days after the date of completing each performance test required by this subpart, you must submit the results of the performance test following the procedures specified in paragraphs (g)(1) through (3) of this section. Where applicable, you may assert a claim of EPA system outage, in accordance with § 63.7841(e), or force majeure, in accordance with § 63.7841(f), for failure to timely comply with this requirement.

(1) Data collected using test methods supported by EPA's Electronic Reporting Tool (ERT) as listed on EPA's ERT website (<https://www.epa.gov/electronic-reporting-air-emissions/electronic-reporting-tool-ert>) at the time of the test. Submit the results of the performance test to the EPA via the Compliance and Emissions Data Reporting Interface (CEDRI), which can be accessed through EPA's Central Data Exchange (CDX) (<https://cdx.epa.gov/>). The data must be submitted in a file format generated through the use of EPA's ERT. Alternatively, you may submit an electronic file consistent with the extensible markup language (XML) schema listed on EPA's ERT website.

(2) Data collected using test methods that are not supported by EPA's ERT as listed on EPA's ERT website at the time of the test. The results of the performance test must be included as an attachment in the ERT or an alternate electronic file consistent with the XML schema listed on EPA's ERT website. Submit the ERT generated package or alternative file to the EPA via CEDRI.

(3) Confidential business information (CBI). If you claim some of the information submitted under paragraph (g) of this section is CBI, you must submit a complete file, including information claimed to be CBI, to the EPA. The file must be generated through the use of EPA's ERT or an alternate electronic file consistent with the XML schema listed on EPA's ERT website. Submit the file on a compact disc, flash drive, or other commonly used electronic storage medium and clearly mark the medium as CBI. Mail the electronic medium to U.S. EPA/OAQPS/CORE CBI Office, Attention: Group Leader, Measurement Policy Group, MD C404-02, 4930 Old Page Rd., Durham, NC 27703. The same file with the CBI omitted must be submitted to the EPA via EPA's CDX as described in paragraph (g) of this section.

(h) Within 60 calendar days after the date of completing each continuous monitoring system (CMS) performance evaluation (as defined in § 63.2), you must submit the results of the performance evaluation following the procedures specified in paragraphs (h)(1) through (3) of this section. Where applicable, you may assert a claim of EPA system outage, in accordance with § 63.7841(e), or force majeure, in accordance with § 63.7841(f), for failure to timely comply with this requirement.

(1) Performance evaluations of CMS measuring relative accuracy test audit (RATA) pollutants that are supported by EPA's ERT as listed on EPA's ERT website at the time of the evaluation. Submit the results of the performance evaluation to the EPA via CEDRI, which can be accessed through EPA's CDX. The data must be submitted in a file format generated through the use of EPA's ERT. Alternatively, you may submit an electronic file consistent with the XML schema listed on EPA's ERT website.

(2) Performance evaluations of CMS measuring RATA pollutants that are not supported by EPA's ERT as listed on EPA's ERT website at the time of the evaluation. The results of the performance evaluation must be included as an attachment in the ERT or an alternate electronic file consistent with the XML schema listed on EPA's ERT website. Submit the ERT generated package or alternative file to the EPA via CEDRI.

(3) Confidential business information (CBI). If you claim some of the information submitted under this paragraph (h) is CBI, you must submit a complete file, including information claimed to be CBI, to the EPA. The file must be generated through the use of EPA's ERT or an alternate electronic file consistent with the XML schema listed on EPA's ERT website. Submit the file on a compact disc, flash drive, or other commonly used electronic storage medium and clearly mark the medium as CBI. Mail the electronic medium to U.S. EPA/OAQPS/CORE CBI Office, Attention: Group Leader, Measurement Policy Group, MD C404-02, 4930 Old Page Rd., Durham, NC 27703. The same file with the CBI omitted must be submitted to the EPA via EPA's CDX as described in this paragraph (h).

■ 18. Section 63.7841 is amended by:

■ a. Revising paragraphs (b) introductory text, (b)(4), (b)(7) introductory text, (b)(7)(ii), (b)(8) introductory text, and (b)(8)(ii), (iv), and (vi);

■ b. Adding paragraphs (b)(9) through (13);

- c. Revising paragraph (c);
- d. Redesignating paragraph (d) as paragraph (g) and revising it; and
- e. Adding new paragraph (d) and paragraphs (e) and (f).

The revisions and additions read as follows:

§ 63.7841 What reports must I submit and when?

* * * * *

(b) *Compliance report contents.* Each compliance report must include the information in paragraphs (b)(1) through (3) of this section and, as applicable, paragraphs (b)(4) through (13) of this section.

* * * * *

(4) For existing sources and for new or reconstructed sources for which construction or reconstruction commenced on or before August 16, 2019, before January 11, 2021, if you had a startup, shutdown, or malfunction during the reporting period and you took actions consistent with your startup, shutdown, and malfunction plan, the compliance report must include the information in § 63.10(d)(5)(i). A startup, shutdown, and malfunction plan and the information in § 63.10(d)(5)(i) is not required after January 11, 2021.

* * * * *

(7) For each deviation from an emission limitation in § 63.7790 that occurs at an affected source where you are not using a continuous monitoring system (including a CPMS, COMS, or CEMS) to comply with an emission limitation in this subpart, the compliance report must contain the information in paragraphs (b)(1) through (4) of this section, the information in paragraphs (b)(7)(i) and (ii) of this section, and the information in (b)(13) of this section. This includes periods of startup, shutdown, and malfunction.

* * * * *

(ii) Information on the duration and cause of deviations (including unknown cause, if applicable) as applicable and the corrective action taken.

* * * * *

(8) For each deviation from an emission limitation occurring at an affected source where you are using a continuous monitoring system (including a CPMS or COMS) to comply with the emission limitation in this subpart, you must include the information in paragraphs (b)(1) through (4) of this section, the information in paragraphs (b)(8)(i) through (xi) of this section, and the information in (b)(13) of this section. This includes periods of malfunction.

* * * * *

(ii) The date, time, and duration that each continuous monitoring was inoperative, except for zero (low-level) and high-level checks.

* * * * *

(iv) The date and time that each deviation started and stopped, and whether each deviation occurred during a malfunction or during another period.

* * * * *

(vi) A breakdown of the total duration of the deviations during the reporting period including those that are due to control equipment problems, process problems, other known causes, and other unknown causes.

* * * * *

(9) Any deviation from the requirements in § 63.7791 and the corrective action taken. For each deviation, you must include the information in (b)(13) of this section.

(10) If there were no deviations from the requirements in § 63.7791, a statement that there were no deviations from the requirements during the reporting period.

(11) If the facility demonstrates compliance with the mercury emission limits in Table 1 through the compliance options in § 63.7791(c), (d), or (e), the report must contain the applicable statement in paragraphs (b)(11)(i) and (ii) of this section, as applicable.

(i) "This facility participates in and purchases scrap only from scrap providers who participate in a program for removal of mercury switches that has been approved by the EPA Administrator, in accordance with § 63.7791(c) or (e)"; or

(ii) "This facility complies with the requirements for scrap that does not contain mercury switches, in accordance with § 63.7791(d)."

(12) For existing sources and for new or reconstructed sources which commenced construction or reconstruction on or before August 16, 2019, before January 11, 2021, for each startup, shutdown, or malfunction during the reporting period that is not consistent with your startup, shutdown, and malfunction plan you must submit an immediate startup, shutdown and malfunction report. Unless the Administrator has approved a different schedule for submission of reports under § 63.10(a), you must submit each report according to paragraphs (f)(1) and (2) of this section. An immediate startup, shutdown, and malfunction report is not required after January 11, 2021.

(13) Beginning on January 11, 2021 if you failed to meet an applicable standard, the compliance report must

include the start date, start time, and duration of each failure. For each failure, the compliance report must include a list of the affected sources or equipment, an estimate of the quantity of each regulated pollutant emitted over any emission limit, and a description of the method used to estimate the emissions.

(c) *Use of CEDRI template.* Beginning on January 11, 2021 or 180 days after the date the reporting template becomes available in CEDRI, whichever is later, submit all subsequent reports following the procedure specified in paragraph (d) of this section.

(d) *CEDRI submission.* If you are required to submit reports following the procedure specified in this paragraph, you must submit reports to the EPA via CEDRI, which can be accessed through EPA's CDX (<https://cdx.epa.gov/>). You must use the appropriate electronic report template on the CEDRI website (<https://www.epa.gov/electronic-reporting-air-emissions/compliance-and-emissions-data-reporting-interface-cedri>) for this subpart. The date report templates become available will be listed on the CEDRI website. The report must be submitted by the deadline specified in this subpart, regardless of the method in which the report is submitted. If you claim some of the information required to be submitted via CEDRI is CBI, submit a complete report, including information claimed to be CBI, to the EPA. The report must be generated using the appropriate form on the CEDRI website. Submit the file on a compact disc, flash drive, or other commonly used electronic storage medium and clearly mark the medium as CBI. Mail the electronic medium to U.S. EPA/OAQPS/CORE CBI Office, Attention: Group Leader, Measurement Policy Group, MD C404-02, 4930 Old Page Rd., Durham, NC 27703. The same file with the CBI omitted must be submitted to the EPA via EPA's CDX as described earlier in this paragraph.

(e) *CDX outage.* If you are required to electronically submit a report through CEDRI in EPA's CDX, you may assert a claim of EPA system outage for failure to timely comply with the reporting requirement. To assert a claim of EPA system outage, you must meet the requirements outlined in paragraphs (e)(1) through (7) of this section.

(1) You must have been or will be precluded from accessing CEDRI and submitting a required report within the time prescribed due to an outage of either EPA's CEDRI or CDX systems.

(2) The outage must have occurred within the period of time beginning five business days prior to the date that the submission is due.

(3) The outage may be planned or unplanned.

(4) You must submit notification to the Administrator in writing as soon as possible following the date you first knew, or through due diligence should have known, that the event may cause or has caused a delay in reporting.

(5) You must provide to the Administrator a written description identifying:

(i) The date(s) and time(s) when CDX or CEDRI was accessed and the system was unavailable;

(ii) A rationale for attributing the delay in reporting beyond the regulatory deadline to EPA system outage;

(iii) Measures taken or to be taken to minimize the delay in reporting; and

(iv) The date by which you propose to report, or if you have already met the reporting requirement at the time of the notification, the date you reported.

(6) The decision to accept the claim of EPA system outage and allow an extension to the reporting deadline is solely within the discretion of the Administrator.

(7) In any circumstance, the report must be submitted electronically as soon as possible after the outage is resolved.

(f) *Claim of force majeure.* If you are required to electronically submit a report through CEDRI in EPA's CDX, you may assert a claim of force majeure for failure to timely comply with the reporting requirement. To assert a claim of force majeure, you must meet the requirements outlined in paragraphs (f)(1) through (5) of this section.

(1) You may submit a claim if a force majeure event is about to occur, occurs, or has occurred or there are lingering effects from such an event within the period of time beginning five business days prior to the date the submission is due. For the purposes of this section, a force majeure event is defined as an event that will be or has been caused by circumstances beyond the control of the affected facility, its contractors, or any entity controlled by the affected facility that prevents you from complying with the requirement to submit a report electronically within the time period prescribed. Examples of such events are acts of nature (e.g., hurricanes, earthquakes, or floods), acts of war or terrorism, or equipment failure or safety hazard beyond the control of the affected facility (e.g., large scale power outage).

(2) You must submit notification to the Administrator in writing as soon as possible following the date you first knew, or through due diligence should have known, that the event may cause or has caused a delay in reporting.

(3) You must provide to the Administrator:

(i) A written description of the force majeure event;

(ii) A rationale for attributing the delay in reporting beyond the regulatory deadline to the force majeure event;

(iii) Measures taken or to be taken to minimize the delay in reporting; and

(iv) The date by which you propose to report, or if you have already met the reporting requirement at the time of the notification, the date you reported.

(4) The decision to accept the claim of force majeure and allow an extension to the reporting deadline is solely within the discretion of the Administrator.

(5) In any circumstance, the reporting must occur as soon as possible after the force majeure event occurs.

(g) *Part 70 monitoring report.* If you have obtained a title V operating permit for an affected source pursuant to part 70 or 71 of this chapter, you must report all deviations as defined in this subpart in the semiannual monitoring report required by § 70.6(a)(3)(iii)(A) or § 71.6(a)(3)(iii)(A) of this chapter. If you submit a compliance report for an affected source along with, or as part of, the semiannual monitoring report required by § 70.6(a)(3)(iii)(A) or § 71.6(a)(3)(iii)(A) of this chapter, and the compliance report includes all the required information concerning deviations from any emission limitation, standard, or operation and maintenance requirement in this subpart, submission of the compliance report satisfies any obligation to report the same deviations in the semiannual monitoring report. However, submission of a compliance report does not otherwise affect any obligation you may have to report deviations from permit requirements for an affected source to your permitting authority.

■ 19. Section 63.7842 is amended by:

■ a. Revising paragraph (a)(2);

■ b. Redesignating paragraph (a)(3) as paragraph (a)(5);

■ c. Adding new paragraph (a)(3) and paragraph (a)(4);

■ d. Revising paragraph (b)(3); and

■ e. Adding paragraph (e).

The revisions and additions read as follows:

§ 63.7842 What records must I keep?

(a) * * *

(2) For existing sources and for new or reconstructed sources which commenced construction or reconstruction on or before August 16, 2019, before January 11, 2021, the records in § 63.6(e)(3)(iii) through (v) related to startup, shutdown, and malfunction for a period of five years. A

startup, shutdown, and malfunction plan is not required after January 11, 2021.

(3) For each failure to meet an applicable standard, a list of the affected sources or equipment, an estimate of the quantity of each regulated pollutant emitted over any emission limit, and a description of the method used to estimate the emissions.

(4) Records of the actions taken to minimize emissions in accordance with § 63.7810(d), and any corrective actions taken to return the affected unit to its normal or usual manner of operation.

* * * * *

(b) * * *

(3) Previous (that is, superseded) versions of the performance evaluation plan required under § 63.8(d)(2), with the program of corrective action included in the plan.

* * * * *

(e) If you are demonstrating compliance with the mercury emission limit in Table 1 through § 63.7791(c), you must keep records to demonstrate compliance with the requirements for mercury in § 63.7791(c) as applicable. If you are demonstrating compliance with the mercury emission limit in Table 1 through § 63.7791(d), you must keep records documenting compliance with § 63.7791(d) for scrap that does not contain mercury switches. If you are demonstrating compliance with the mercury emission limit in Table 1 through § 63.7791(e), you must maintain records identifying each scrap provider and documenting the scrap provider's participation in an approved mercury switch removal program. If you purchase scrap from a broker, you must maintain records identifying each broker and documentation that all scrap provided by the broker was obtained from other scrap providers who participate in an approved mercury switch removal program.

■ 20. Section 63.7851 is amended by revising paragraph (c) introductory text and adding paragraph (c)(5) to read as follows:

§ 63.7851 Who implements and enforces this subpart?

* * * * *

(c) The authorities that will not be delegated to State, local, or tribal agencies are specified in paragraphs (c)(1) through (5) of this section.

* * * * *

(5) Approval of an alternative to any electronic reporting to the EPA required by this subpart.

■ 21. Section 63.7852 is amended by:

■ a. Adding in alphabetical order a definition for “basic oxygen process furnace group”;

■ b. Revising the definition of “deviation”; and

■ c. Adding in alphabetical order definitions for “mercury switch”, “motor vehicle”, “motor vehicle scrap”, “opening”, “post-consumer steel scrap”, “pre-consumer steel scrap”, “scrap provider”, “shredded motor vehicle scrap”, “specialty metal scrap”, and “steel scrap”.

The additions and revision read as follows:

§ 63.7852 What definitions apply to this subpart?

* * * * *

Basic oxygen process furnace group means the collection of BOPF shop steelmaking operating units and their control devices including the BOPF primary emission control system, BOPF secondary control system, ladle metallurgy units, and hot metal transfer, desulfurization and slag skimming units that are operating at the time of each mercury test sequence. In the case of duplicate units in the BOPF Group, the BOPF Group for purposes of this rule means only those units operating at the time of the test sequence. See related definitions in this section for “primary emissions,” “primary emission control system,” “secondary emissions,” and “secondary emission control system.”

* * * * *

Deviation means any instance in which an affected source subject to this subpart, or an owner or operator of such a source:

(1) Fails to meet any requirement or obligation established by this subpart, including but not limited to any emission limitation (including operating limits), standard, or operation and maintenance requirement;

(2) Fails to meet any term or condition that is adopted to implement an applicable requirement in this subpart and that is included in the operating permit for any affected source required to obtain such a permit; or

(3) Fails to meet any emission limitation in this subpart during startup, shutdown, or malfunction, regardless of whether or not such failure is permitted by this subpart.

* * * * *

Mercury switch means each mercury-containing capsule or switch assembly that is part of a convenience light switch mechanism installed in a motor vehicle.

Motor vehicle means an automotive vehicle not operated on rails and usually operated with rubber tires for use on roads and highways.

Motor vehicle scrap means post-consumer scrap from discarded automotive vehicles, in whole or in part, including automobile body hulks that have been processed through a shredder. Motor vehicle scrap does not include automobile manufacturing bundles or miscellaneous vehicle parts, such as wheels and bumpers, which do not contain mercury switches.

Opening means any roof monitor, vent, door, window, hole, crack or other conduit that allows gas to escape to the atmosphere from a blast furnace casthouse or BOPF shop.

Post-consumer steel scrap means steel scrap that is composed of materials made of steel that were purchased by households or by commercial, industrial, and institutional facilities in their role as end-users of the product and which can no longer be used for its intended purpose.

Pre-consumer steel scrap means steel scrap that is left over from industrial or manufacturing processes and which is subsequently recycled as scrap. Other terms used to describe this scrap are new, home, run-around, prompt-industrial, and return scrap.

* * * * *

Scrap provider means the company or person (including a broker) who contracts directly with an integrated iron and steel manufacturing facility to provide steel scrap. Scrap processors, such as shredder operators or vehicle dismantlers, who do not sell scrap directly to an integrated iron and steel manufacturing facility are not scrap providers.

* * * * *

Shredded motor vehicle scrap means post-consumer scrap from discarded automotive vehicles that has been processed through a shredder.

* * * * *

Specialty metal scrap means scrap where the only materials from motor vehicles in the scrap are materials (such as certain exhaust systems) recovered for their specialty alloy content (including, but not limited to, chromium, nickel, molybdenum, or other alloys), and, based on the nature of the scrap and purchase specifications, the scrap is not expected to contain mercury switches.

* * * * *

Steel scrap means pre-consumer and post-consumer discarded steel that is processed by scrap providers for resale (post-consumer) or used on-site (pre-consumer or run-around scrap from within a facility or company). Post-consumer steel scrap may or may not

contain motor vehicle scrap, depending on the type of scrap.

■ 22. Table 1 to Subpart FFFFF of Part 63 is revised to read as follows:

As required in § 63.7790(a), you must comply with each applicable emission and opacity limit in the following table:

TABLE 1 TO SUBPART FFFFF OF PART 63—EMISSION AND OPACITY LIMITS

For . . .	You must comply with each of the following . . .
1. Each windbox exhaust stream at an existing sinter plant.	You must not cause to be discharged to the atmosphere any gases that contain particulate matter in excess of 0.4 lb/ton of product sinter.
2. Each windbox exhaust stream at a new sinter plant.	You must not cause to be discharged to the atmosphere any gases that contain particulate matter in excess of 0.3 lb/ton of product sinter.
3. Each discharge end at an existing sinter plant.	a. You must not cause to be discharged to the atmosphere any gases that exit from one or more control devices that contain, on a flow-weighted basis, particulate matter in excess of 0.02 gr/dscf ^{1 2} ; and b. You must not cause to be discharged to the atmosphere any secondary emissions that exit any opening in the building or structure housing the discharge end that exhibit opacity greater than 20 percent (6-minute average).
4. Each discharge end at a new sinter plant.	a. You must not cause to be discharged to the atmosphere any gases that exit from one or more control devices that contain, on a flow weighted basis, particulate matter in excess of 0.01 gr/dscf; and b. You must not cause to be discharged to the atmosphere any secondary emissions that exit any opening in the building or structure housing the discharge end that exhibit opacity greater than 10 percent (6-minute average).
5. Each sinter cooler at an existing sinter plant.	You must not cause to be discharged to the atmosphere any emissions that exhibit opacity greater than 10 percent (6-minute average).
6. Each sinter cooler at a new sinter plant.	You must not cause to be discharged to the atmosphere any gases that contain particulate matter in excess of 0.01 gr/dscf.
7. Each casthouse at an existing blast furnace.	a. You must not cause to be discharged to the atmosphere any gases that exit from a control device that contain particulate matter in excess of 0.01 gr/dscf ² ; and b. You must not cause to be discharged to the atmosphere any secondary emissions that exit all openings in the casthouse or structure housing the blast furnace that exhibit opacity greater than 20 percent (6-minute average).
8. Each casthouse at a new blast furnace.	a. You must not cause to be discharged to the atmosphere any gases that exit from a control device that contain particulate matter in excess of 0.003 gr/dscf; and b. You must not cause to be discharged to the atmosphere any secondary emissions that exit all openings in the casthouse or structure housing the blast furnace that exhibit opacity greater than 15 percent (6-minute average).
9. Each BOPF at a new or existing shop.	a. You must not cause to be discharged to the atmosphere any gases that exit from a primary emission control system for a BOPF with a closed hood system at a new or existing BOPF shop that contain, on a flow-weighted basis, particulate matter in excess of 0.03 gr/dscf during the primary oxygen blow ^{2 3} ; and b. You must not cause to be discharged to the atmosphere any gases that exit from a primary emission control system for a BOPF with an open hood system that contain, on a flow-weighted basis, particulate matter in excess of 0.02 gr/dscf during the steel production cycle for an existing BOPF shop ^{2 3} or 0.01 gr/dscf during the steel production cycle for a new BOPF shop ³ ; and c. You must not cause to be discharged to the atmosphere any gases that exit from a control device used solely for the collection of secondary emissions from the BOPF that contain particulate matter in excess of 0.01 gr/dscf for an existing BOPF shop ² or 0.0052 gr/dscf for a new BOPF shop.
10. Each hot metal transfer, skimming, and desulfurization operation at a new or existing BOPF shop.	You must not cause to be discharged to the atmosphere any gases that exit from a control device that contain particulate matter in excess of 0.01 gr/dscf for an existing BOPF shop ² or 0.003 gr/dscf for a new BOPF shop.
11. Each ladle metallurgy operation at a new or existing BOPF shop.	You must not cause to be discharged to the atmosphere any gases that exit from a control device that contain particulate matter in excess of 0.01 gr/dscf for an existing BOPF shop ² or 0.004 gr/dscf for a new BOPF shop.
12. Each existing BOPF shop.	You must not cause to be discharged to the atmosphere any secondary emissions that exit any opening in the BOPF shop or any other building housing the BOPF or BOPF shop operation that exhibit opacity greater than 20 percent (3-minute average).
13. Each new BOPF shop . . .	a. You must not cause to be discharged to the atmosphere any secondary emissions that exit any opening in the BOPF shop or other building housing a bottom-blown BOPF or BOPF shop operations that exhibit opacity (for any set of 6-minute averages) greater than 10 percent, except that one 6-minute period not to exceed 20 percent may occur once per steel production cycle; or b. You must not cause to be discharged to the atmosphere any secondary emissions that exit any opening in the BOPF shop or other building housing a top-blown BOPF or BOPF shop operations that exhibit opacity (for any set of 3-minute averages) greater than 10 percent, except that one 3-minute period greater than 10 percent but less than 20 percent may occur once per steel production cycle.
14. Each BOPF Group at an existing BOPF shop.	You must not cause to be discharged to the atmosphere any gases that exit from the collection of BOPF Group control devices that contain mercury in excess of 0.00026 lb/ton of steel scrap input to the BOPF.
15. Each BOPF Group at a new BOPF shop.	You must not cause to be discharged to the atmosphere any gases that exit from the collection of BOPF Group control devices that contain mercury in excess of 0.00081 lb/ton of steel scrap input to the BOPF.

¹ This limit applies if the cooler is vented to the same control device as the discharge end.

² This concentration limit (gr/dscf) for a control device does not apply to discharges inside a building or structure housing the discharge end at an existing sinter plant, inside a casthouse at an existing blast furnace, or inside an existing BOPF shop if the control device was installed before August 30, 2005.

³ This limit applies to control devices operated in parallel for a single BOPF during the oxygen blow.

■ 23. Table 2 to Subpart FFFFF of Part 63 is revised to read as follows: As required in § 63.7826(a)(1), you must demonstrate initial compliance with the emission and opacity limits according to the following table:

TABLE 2 TO SUBPART FFFFF OF PART 63—INITIAL COMPLIANCE WITH EMISSION AND OPACITY LIMITS

For . . .	You have demonstrated initial compliance if . . .
1. Each windbox exhaust stream at an existing sinter plant.	The process-weighted mass rate of particulate matter from a windbox exhaust stream, measured according to the performance test procedures in § 63.7822(c), did not exceed 0.4 lb/ton of product sinter.
2. Each windbox exhaust stream at a new sinter plant.	The process-weighted mass rate of particulate matter from a windbox exhaust stream, measured according to the performance test procedures in § 63.7822(c), did not exceed 0.3 lb/ton of product sinter.
3. Each discharge end at an existing sinter plant.	a. The flow-weighted average concentration of particulate matter from one or more control devices applied to emissions from a discharge end, measured according to the performance test procedures in § 63.7822(d), did not exceed 0.02 gr/dscf; and b. The opacity of secondary emissions from each discharge end, determined according to the performance test procedures in § 63.7823(c), did not exceed 20 percent (6-minute average).
4. Each discharge end at a new sinter plant.	a. The flow-weighted average concentration of particulate matter from one or more control devices applied to emissions from a discharge end, measured according to the performance test procedures in § 63.7822(d), did not exceed 0.01 gr/dscf; and b. The opacity of secondary emissions from each discharge end, determined according to the performance test procedures in § 63.7823(c), did not exceed 10 percent (6-minute average).
5. Each sinter cooler at an existing sinter plant.	The opacity of emissions, determined according to the performance test procedures in § 63.7823(e), did not exceed 10 percent (6-minute average).
6. Each sinter cooler at a new sinter plant.	The average concentration of particulate matter, measured according to the performance test procedures in § 63.7822(b), did not exceed 0.01 gr/dscf.
7. Each casthouse at an existing blast furnace.	a. The average concentration of particulate matter from a control device applied to emissions from a casthouse, measured according to the performance test procedures in § 63.7822(e), did not exceed 0.01 gr/dscf; and b. The opacity of secondary emissions from each casthouse, determined according to the performance test procedures in § 63.7823(c), did not exceed 20 percent (6-minute average).
8. Each casthouse at a new blast furnace.	a. The average concentration of particulate matter from a control device applied to emissions from a casthouse, measured according to the performance test procedures in § 63.7822(e), did not exceed 0.003 gr/dscf; and b. The opacity of secondary emissions from each casthouse, determined according to the performance test procedures in § 63.7823(c), did not exceed 15 percent (6-minute average).
9. Each BOPF at a new or existing BOPF shop.	a. The average concentration of particulate matter from a primary emission control system applied to emissions from a BOPF with a closed hood system, measured according to the performance test procedures in § 63.7822(f), did not exceed 0.03 gr/dscf for a new or existing BOPF shop; b. The average concentration of particulate matter from a primary emission control system applied to emissions from a BOPF with an open hood system, measured according to the performance test procedures in § 63.7822(g), did not exceed 0.02 gr/dscf for an existing BOPF shop or 0.01 gr/dscf for a new BOPF shop; and c. The average concentration of particulate matter from a control device applied solely to secondary emissions from a BOPF, measured according to the performance test procedures in § 63.7822(g), did not exceed 0.01 gr/dscf for an existing BOPF shop or 0.0052 gr/dscf for a new BOPF shop.
10. Each hot metal transfer skimming, and desulfurization at a new or existing BOPF shop.	The average concentration of particulate matter from a control device applied to emissions from hot metal transfer, skimming, or desulfurization, measured according to the performance test procedures in § 63.7822(h), did not exceed 0.01 gr/dscf for an existing BOPF shop or 0.003 gr/dscf for a new BOPF shop.
11. Each ladle metallurgy operation at a new or existing BOPF shop.	The average concentration of particulate matter from a control device applied to emissions from a ladle metallurgy operation, measured according to the performance test procedures in § 63.7822(h), did not exceed 0.01 gr/dscf for an existing BOPF shop or 0.004 gr/dscf for a new BOPF shop.
12. Each existing BOPF shop.	The opacity of secondary emissions from each BOPF shop, determined according to the performance test procedures in § 63.7823(d), did not exceed 20 percent (3-minute average).
13. Each new BOPF shop ...	a. The opacity of the highest set of 6-minute averages from each BOPF shop housing a bottom-blown BOPF, determined according to the performance test procedures in § 63.7823(d), did not exceed 20 percent and the second highest set of 6-minute averages did not exceed 10 percent; or b. The opacity of the highest set of 3-minute averages from each BOPF shop housing a top-blown BOPF, determined according to the performance test procedures in § 63.7823(d), did not exceed 20 percent and the second highest set of 3-minute averages did not exceed 10 percent.
14. Each BOPF Group at an existing BOPF shop.	If demonstrating compliance through performance testing, the average emissions of mercury from the collection of BOPF Group control devices applied to the emissions from the BOPF Group, measured according to the performance test procedures in § 63.7825, did not exceed 0.00026 lb/ton steel scrap input to the BOPF.
15. Each BOPF Group at a new BOPF shop.	If demonstrating compliance through performance testing, the average emissions of mercury from the collection of BOPF Group control devices applied to the emissions from the BOPF Group, measured according to the performance test procedures in § 63.7825, did not exceed 0.000081 lb/ton steel scrap input to the BOPF.

■ 24. Table 3 to Subpart FFFFF of Part 63 is revised to read as follows: As required in § 63.7833(a), you must demonstrate continuous compliance with the emission and opacity limits according to the following table:

TABLE 3 TO SUBPART FFFFF OF PART 63—CONTINUOUS COMPLIANCE WITH EMISSION AND OPACITY LIMITS

For . . .	You must demonstrate continuous compliance by . . .
1. Each windbox exhaust stream at an existing sinter plant.	a. Maintaining emissions of particulate matter at or below 0.4 lb/ton of product sinter; and b. Conducting subsequent performance tests at the frequencies specified in § 63.7821.
2. Each windbox exhaust stream at a new sinter plant.	a. Maintaining emissions of particulate matter at or below 0.3 lb/ton of product sinter; and b. Conducting subsequent performance tests at the frequencies specified in § 63.7821.
3. Each discharge end at an existing sinter plant.	a. Maintaining emissions of particulate matter from one or more control devices at or below 0.02 gr/dscf; and b. Maintaining the opacity of secondary emissions that exit any opening in the building or structure housing the discharge end at or below 20 percent (6-minute average); and c. Conducting subsequent performance tests at the frequencies specified in § 63.7821.
4. Each discharge end at a new sinter plant.	a. Maintaining emissions of particulate matter from one or more control devices at or below 0.01 gr/dscf; and b. Maintaining the opacity of secondary emissions that exit any opening in the building or structure housing the discharge end at or below 10 percent (6-minute average); and c. Conducting subsequent performance tests at the frequencies specified in § 63.7821.
5. Each sinter cooler at an existing sinter plant.	a. Maintaining the opacity of emissions that exit any sinter cooler at or below 10 percent (6-minute average); and b. Conducting subsequent performance tests at the frequencies specified in § 63.7821.
6. Each sinter cooler at a new sinter plant.	a. Maintaining emissions of particulate matter at or below 0.1 gr/dscf; and b. Conducting subsequent performance tests at the frequencies specified in § 63.7821.
7. Each casthouse at an existing blast furnace.	a. Maintaining emissions of particulate matter from a control device at or below 0.01 gr/dscf; and b. Maintaining the opacity of secondary emissions that exit all openings in the casthouse or structure housing the casthouse at or below 20 percent (6-minute average); and c. Conducting subsequent performance tests at the frequencies specified in § 63.7821.
8. Each casthouse at a new blast furnace.	a. Maintaining emissions of particulate matter from a control device at or below 0.003 gr/dscf; and b. Maintaining the opacity of secondary emissions that exit all openings in the casthouse or structure housing the casthouse at or below 15 percent (6-minute average); and c. Conducting subsequent performance tests at the frequencies specified in § 63.7821.
9. Each BOPF at a new or existing BOPF shop.	a. Maintaining emissions of particulate matter from the primary control system for a BOPF with a closed hood system at or below 0.03 gr/dscf; and b. Maintaining emissions of particulate matter from the primary control system for a BOPF with an open hood system at or below 0.02 gr/dscf for an existing BOPF shop or 0.01 gr/dscf for a new BOPF shop; and c. Maintaining emissions of particulate matter from a control device applied solely to secondary emissions from a BOPF at or below 0.01 gr/dscf for an existing BOPF shop or 0.0052 gr/dscf for a new BOPF shop; and d. Conducting subsequent performance tests at the frequencies specified in § 63.7821.
10. Each hot metal transfer, skimming, and desulfurization operation at a new or existing BOPF shop.	a. Maintaining emissions of particulate matter from a control device at or below 0.01 gr/dscf at an existing BOPF or 0.003 gr/dscf for a new BOPF; and b. Conducting subsequent performance tests at the frequencies specified in § 63.7821.
11. Each ladle metallurgy operation at a new or existing BOPF shop.	a. Maintaining emissions of particulate matter from a control device at or below 0.01 gr/dscf at an existing BOPF shop or 0.004 gr/dscf for a new BOPF shop; and b. Conducting subsequent performance tests at the frequencies specified in § 63.7821.
12. Each existing BOPF shop.	a. Maintaining the opacity of secondary emissions that exit any opening in the BOPF shop or other building housing the BOPF shop or shop operation at or below 20 percent (3-minute average); and b. Conducting subsequent performance tests at the frequencies specified in § 63.7821.
13. Each new BOPF shop ...	a. Maintaining the opacity (for any set of 6-minute averages) of secondary emissions that exit any opening in the BOPF shop or other building housing a bottom-blown BOPF or shop operation at or below 10 percent, except that one 6-minute period greater than 10 percent but no more than 20 percent may occur once per steel production cycle; and b. Maintaining the opacity (for any set of 3-minute averages) of secondary emissions that exit any opening in the BOPF shop or other building housing a top-blown BOPF or shop operation at or below 10 percent, except that one 3-minute period greater than 10 percent but less than 20 percent may occur once per steel production cycle; and c. Conducting subsequent performance tests at the frequencies specified in § 63.7821.
14. Each BOPF Group at an existing BOPF shop.	a. Maintaining emissions of mercury from the collection of BOPF Group control devices at or below 0.00026 lb/ton steel scrap input to the BOPF; and b. If demonstrating compliance through performance testing, conducting subsequent performance tests at the frequencies specified in § 63.7821; and c. If demonstrating compliance through § 63.7791(c), (d), or (e), maintaining records pursuant to § 63.7842(e).
15. Each BOPF Group at a new BOPF shop.	a. Maintaining emissions of mercury from the collection of BOPF Group control devices at or below 0.000081 lb/ton steel scrap input to the BOPF; and b. If demonstrating compliance through performance testing, conducting subsequent performance tests at the frequencies specified in § 63.7821; and

TABLE 3 TO SUBPART FFFFF OF PART 63—CONTINUOUS COMPLIANCE WITH EMISSION AND OPACITY LIMITS—Continued

For . . .	You must demonstrate continuous compliance by . . .
	c. If demonstrating compliance through § 63.7791(c), (d), or (e), maintaining records pursuant to § 63.7842(e).

■ 25. Table 4 to Subpart FFFFF of Part 63 is revised to read as follows: As required in § 63.7850, you must comply with the requirements of the NESHAP General Provisions (40 CFR part 63, subpart A) shown in the following table:

TABLE 4 TO SUBPART FFFFF OF PART 63—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART FFFFF

Citation	Subject	Applies to Subpart FFFFF	Explanation
§ 63.1	Applicability	Yes	
§ 63.2	Definitions	Yes	
§ 63.3	Units and Abbreviations	Yes	
§ 63.4	Prohibited Activities	Yes	
§ 63.5	Construction/Reconstruction	Yes	
§ 63.6(a), (b), (c), (d), (e)(1)(iii), (f)(2)–(3), (g), (h)(2)(ii)–(h)(9).	Compliance with Standards and Maintenance Requirements.	Yes	
§ 63.6(e)(1)(i)	General Duty to Minimize Emissions.	No, for new or reconstructed sources which commenced construction or reconstruction after August 16, 2019. For all other affected sources, Yes on or before January 11, 2021 and No thereafter.	See § 63.7810(d) for general duty requirement.
§ 63.6(e)(1)(ii)	Requirement to Correct Malfunctions ASAP.	No, for new or reconstructed sources which commenced construction or reconstruction after August 16, 2019. For all other affected sources, Yes, on or before January 11, 2021 and No thereafter.	
§ 63.6(e)(3)	SSM Plan Requirements	No, for new or reconstructed sources which commenced construction or reconstruction after August 16, 2019. For all other affected sources, Yes on or before January 11, 2021 and No thereafter.	See § 63.7810(c)
§ 63.6(f)(1)	Compliance except during SSM	No	See § 63.7810(a).
§ 63.6(h)(1)	Compliance except during SSM	No	See § 63.7810(a).
§ 63.6(h)(2)(i)	Determining Compliance with Opacity and VE Standards.	No	Subpart FFFFF specifies methods and procedures for determining compliance with opacity emission and operating limits.
§ 63.6(i)	Extension of Compliance with Emission Standards.	Yes	
§ 63.6(j)	Exemption from Compliance with Emission Standards.	Yes	
§ 63.7(a)(1)–(2)	Applicability and Performance Test Dates.	No	Subpart FFFFF and specifies performance test applicability and dates.
§ 63.7(a)(3), (b)–(d), (e)(2)–(4), (f)–(h).	Performance Testing Requirements.	Yes	
§ 63.7(e)(1)	Performance Testing	No, for new or reconstructed sources which commenced construction or reconstruction after August 16, 2019. For all other affected sources, Yes on or before January 11, 2021 and No thereafter.	See §§ 63.7822(a), 63.7823(a), and 63.7825(a).
§ 63.8(a)(1)–(3), (b), (c)(1)(ii), (c)(2)–(3), (c)(4)(i)–(ii), (c)(5)–(6), (c)(7)–(8), (d)(1)–(2), (e), (f)(1)–(5), (g)(1)–(4).	Monitoring Requirements	Yes	CMS requirements in § 63.8(c)(4)(i)–(ii), (c)(5)–(6), (d)(1)–(2), and (e) apply only to COMS.
§ 63.8(a)(4)	Additional Monitoring Requirements for Control Devices in § 63.11.	No	Subpart FFFFF does not require flares.

TABLE 4 TO SUBPART FFFFF OF PART 63—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART FFFFF—Continued

Citation	Subject	Applies to Subpart FFFFF	Explanation
§ 63.8(c)(1)(i)	General Duty to Minimize Emissions and CMS Operation.	No, for new or reconstructed sources which commenced construction or reconstruction after August 16, 2019. For all other affected sources, Yes on or before January 11, 2021 and No thereafter.	
§ 63.8(c)(1)(iii)	Requirement to Develop SSM Plan for CMS.	No, for new or reconstructed sources which commenced construction or reconstruction after August 16, 2019. For all other affected sources, Yes on or before January 11, 2021 and No thereafter.	
§ 63.8(c)(4)	Continuous Monitoring System Requirements.	No	Subpart FFFFF specifies requirements for operation of CMS.
§ 63.8(d)(3)	Written procedures for CMS	No, for new or reconstructed sources which commenced construction or reconstruction after August 16, 2019. For all other affected sources, Yes on or before January 11, 2021 and No thereafter.	See § 63.7842(b)(3).
§ 63.8(f)(6)	RATA Alternative	No	
§ 63.8(g)(5)	Data Reduction	No	Subpart FFFFF specifies data reduction requirements.
§ 63.9	Notification Requirements	Yes	Additional notifications for CMS in § 63.9(g) apply only to COMS.
§ 63.10(a), (b)(1), (b)(2)(x), (b)(2)(xiv), (b)(3), (c)(1)–(6), (c)(9)–(14), (d)(1)–(4), (e)(1)–(2), (e)(4), (f).	Recordkeeping and Reporting Requirements.	Yes	Additional records for CMS in § 63.10(c)(1)–(6), (9)–(14), and reports in § 63.10(d)(1)–(2) apply only to COMS.
§ 63.10(b)(2)(i)	Recordkeeping of Occurrence and Duration of Startups and Shutdowns.	No, for new or reconstructed sources which commenced construction or reconstruction after August 16, 2019. For all other affected sources, Yes on or before January 11, 2021 and No thereafter.	
§ 63.10(b)(2)(ii)	Recordkeeping of Failures to Meet a Standard.	No, for new or reconstructed sources which commenced construction or reconstruction after August 16, 2019. For all other affected sources, Yes on or before January 11, 2021 and No thereafter.	See § 63.7842(a)(2)–(4) for recordkeeping of (1) date, time, and duration of failure to meet the standard; (2) listing of affected source or equipment, and an estimate of the quantity of each regulated pollutant emitted over the standard; and (3) actions to minimize emissions and correct the failure.
§ 63.10(b)(2)(iii)	Maintenance Records	Yes	
§ 63.10(b)(2)(iv)	Actions Taken to Minimize Emissions During SSM.	No, for new or reconstructed sources which commenced construction or reconstruction after August 16, 2019. For all other affected sources, Yes on or before January 11, 2021 and No thereafter.	See § 63.7842(a)(4) for records of actions taken to minimize emissions.
§ 63.10(b)(2)(v)	Actions Taken to Minimize Emissions During SSM.	No, for new or reconstructed sources which commenced construction or reconstruction after August 16, 2019. For all other affected sources, Yes on or before January 11, 2021 and No thereafter.	See § 63.7842(a)(4) for records of actions taken to minimize emissions.
§ 63.10(b)(2)(vi)	Recordkeeping for CMS Malfunctions.	Yes	
§ 63.10(b)(2)(vii)–(ix)	Other CMS Requirements	Yes	
§ 63.10(b)(2)(xiii)	CMS Records for RATA Alternative.	No	

TABLE 4 TO SUBPART FFFFF OF PART 63—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART FFFFF—Continued

Citation	Subject	Applies to Subpart FFFFF	Explanation
§ 63.10(c)(7)–(8)	Records of Excess Emissions and Parameter Monitoring Exceedances for CMS.	No	Subpart FFFFF specifies record requirements; see § 63.7842.
§ 63.10(c)(15)	Use of SSM Plan	No, for new or reconstructed sources which commenced construction or reconstruction after August 16, 2019. For all other affected sources, Yes on or before January 11, 2021 and No thereafter.	
§ 63.10(d)(5)(i)	Periodic SSM Reports	No, for new or reconstructed sources which commenced construction or reconstruction after August 16, 2019. For all other affected sources, Yes on or before January 11, 2021 and No thereafter.	See § 63.7841(b)(4) for malfunction reporting requirements.
§ 63.10(d)(5)(ii)	Immediate SSM Reports	No, for new or reconstructed sources which commenced construction or reconstruction after August 16, 2019. For all other affected sources, Yes on or before January 11, 2021 and No thereafter.	
§ 63.10(e)(3)	Excess Emission Reports	No	Subpart FFFFF specifies reporting requirements; see § 63.7841.
§ 63.11	Control Device Requirements	No	Subpart FFFFF does not require flares.
§ 63.12	State Authority and Delegations ..	Yes	
§ 63.13–§ 63.16	Addresses, Incorporations by Reference, Availability of Information and Confidentiality, Performance Track Provisions.	Yes	

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Part III

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 413

Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 413

[CMS–1732–P]

RIN 0938–AU08

Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would update and make revisions to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) for calendar year (CY) 2021. This rule also proposes to update the payment rate for renal dialysis services furnished by an ESRD facility to individuals with acute kidney injury (AKI). In addition, this rule proposes to update requirements for the ESRD Quality Incentive Program (QIP).

DATES: To be assured consideration, comments must be submitted at one of the addresses provided below, no later than September 4, 2020.

ADDRESSES: In commenting, please refer to file code CMS–1732–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the “Submit a comment” instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1732–P, P.O. Box 8010, Baltimore, MD 21244–8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1732–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: ESRDPayment@cms.hhs.gov, for issues related to the ESRD PPS and coverage and payment for renal dialysis services furnished to individuals with AKI.

Delia Houseal, (410) 786–2724, for issues related to the ESRD QIP.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that website to view public comments.

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I. Executive Summary

A. Purpose

This rule contains proposals related to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS), payment for renal dialysis services furnished to individuals with acute kidney injury (AKI), and the ESRD Quality Incentive Program (QIP).

1. End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

On January 1, 2011, we implemented the ESRD PPS, a case-mix adjusted, bundled PPS for renal dialysis services furnished by ESRD facilities as required by section 1881(b)(14) of the Social Security Act (the Act), as added by section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275). Section 1881(b)(14) (F) of the Act, as added by section 153(b) of MIPPA, and amended by section 3401(h) of the Patient Protection and Affordable Care Act (the Affordable Care Act) (Pub. L. 111–148), established that beginning calendar year (CY) 2012, and each subsequent year, the Secretary of the Department of Health and Human Services (the Secretary) shall annually increase payment amounts by an ESRD market basket increase factor, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. This rule proposes updates and revisions to the ESRD PPS for CY 2021.

2. Coverage and Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury (AKI)

On June 29, 2015, the President signed the Trade Preferences Extension Act of 2015 (TPEA) (Pub. L. 114–27). Section 808(a) of the TPEA amended section 1861(s)(2)(F) of the Act to provide coverage for renal dialysis services furnished on or after January 1, 2017, by a renal dialysis facility or a provider of services paid under section 1881(b)(14) of the Act to an individual with acute kidney injury (AKI). Section 808(b) of the TPEA amended section 1834 of the Act by adding a new subsection (r) that provides for payment for renal dialysis services furnished by renal dialysis facilities or providers of services paid under section 1881(b)(14) of the Act to individuals with AKI at the ESRD PPS base rate beginning January 1, 2017. This rule proposes to update the AKI payment rate for CY 2021.

3. End-Stage Renal Disease Quality Incentive Program (ESRD QIP)

The End-Stage Renal Disease Quality Incentive Program (ESRD QIP) is authorized by section 1881(h) of the Act. The Program fosters improved patient outcomes by establishing incentives for dialysis facilities to meet or exceed performance standards established by the Centers for Medicare & Medicaid Services (CMS). This proposed rule proposes several updates for the payment years (PY) 2023 and 2024 ESRD QIP.

B. Summary of the Major Provisions

1. ESRD PPS

- *Update to the ESRD PPS base rate for CY 2021:* The proposed CY 2021 ESRD PPS base rate is \$255.59. This proposed amount reflects the application of the wage index budget-neutrality adjustment factor (.998652), the proposed addition to the base rate of \$12.06 to include calcimimetics, and a productivity-adjusted market basket increase as required by section 1881(b)(14)(F)(i)(I) of the Act (1.8 percent), equaling \$255.59 ($(\$239.33 \times .998652) + \$12.06 \times 1.018 = \$255.59$).

- *Annual update to the wage index:* We adjust wage indices on an annual basis using the most current hospital wage data and the latest core-based statistical area (CBSA) delineations to account for differing wage levels in areas in which ESRD facilities are located. For CY 2021, we are proposing to update the wage index values based on the latest available data.

- *New Office of Management and Budget (OMB) delineations and 2-year transition policy:* We are proposing to adopt the Office of Management and Budget (OMB) delineations as described in the September 14, 2018 OMB Bulletin No. 18–04, beginning with the CY 2021 ESRD PPS wage index. In addition, we are proposing to apply a 5 percent cap on any decrease in an ESRD facility's wage index from the ESRD facility's wage index from the prior calendar year. This transition would be phased in over 2 years, such that the estimated reduction in an ESRD facility's wage index would be capped at 5 percent in CY 2021, and no cap would be applied to the reduction in the wage index for the second year, CY 2022.

- *Update to the outlier policy:* We are proposing to update the outlier policy using the most current data, as well as update the outlier services fixed-dollar loss (FDL) amounts for adult and pediatric patients and Medicare allowable payment (MAP) amounts for adult and pediatric patients for CY 2021 using CY 2019 claims data. Based on the

use of the latest available data, the proposed FDL amount for pediatric beneficiaries would increase from \$41.04 to \$47.73, and the MAP amount would increase from \$32.32 to \$33.08, as compared to CY 2020 values. For adult beneficiaries, the proposed FDL amount would increase from \$48.33 to \$133.52, and the MAP amount would increase from \$35.78 to \$54.26. The 1.0 percent target for outlier payments was not achieved in CY 2019. Outlier payments represented approximately 0.5 percent of total payments rather than 1.0 percent.

- *Inclusion of calcimimetics in the ESRD PPS base rate:* We are proposing the methodology for modifying the ESRD PPS base rate to include calcimimetics in the ESRD PPS bundled payment. Using the proposed methodology based on the latest available data, we are proposing to add \$12.06 to the ESRD PPS base rate beginning in CY 2021.

- *Changes to the eligibility criteria for the transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES):* We are proposing changes to the transitional add-on payment for new and innovative equipment and supplies (TPNIES) eligibility criteria in light of the changes implemented in CY 2020 to provide biannual coding cycles for code applications for new Healthcare Common Procedure Coding System (HCPCS) codes for durable medical equipment, orthotics, prosthetics and supplies (DMEPOS) items and services. We are proposing that for purposes of eligibility for the TPNIES, a complete HCPCS code application must be submitted by the HCPCS Level II code application deadline for biannual Coding Cycle 2 for DMEPOS items and services as specified in the HCPCS Level II coding guidance on the CMS website. In addition, the Food and Drug Administration (FDA) marketing authorization must be submitted to CMS by the HCPCS Level II code application deadline for biannual Coding Cycle 2 for DMEPOS items and services as specified in the HCPCS Level II coding guidance on the CMS website in order for the equipment or supply to be eligible for the TPNIES the following year. We are also proposing to define "new" for purposes of the TPNIES policy as within 3 years beginning on the date of the FDA marketing authorization.

- *Expansion of the TPNIES to include new and innovative capital-related assets that are home dialysis machines when used in the home for a single patient:* We are proposing to expand eligibility for the TPNIES to include certain capital-related assets that are

home dialysis machines when used in the home for a single patient. As with other renal dialysis equipment and supplies potentially eligible for the TPNIES, CMS would evaluate the application to determine whether the home dialysis machine represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries, and meets the other requirements under § 413.236(b). We are proposing additional steps the Medicare Administrative Contractors (MACs) would follow to establish the basis payment of the TPNIES for these capital-related assets that are home dialysis machines when used in the home. We would pay 65 percent of the MAC-determined pre-adjusted per treatment amount for 2-calendar years. We are proposing that after the 2-year TPNIES period ends, the home dialysis machines would not become eligible outlier services and no change would be made to the ESRD PPS base rate.

- *Low-Volume Payment Adjustment (LVPA):* We are proposing to hold harmless ESRD facilities that would otherwise qualify for the LVPA but for a temporary increase in dialysis treatments furnished in 2020 due to the Public Health Emergency (PHE) for the coronavirus disease 2019 (COVID–19) pandemic. For purposes of determining LVPA eligibility for payment years 2021, 2022, and 2023, we are proposing to only consider total dialysis treatments furnished for any 6 months of a facility's cost-reporting period ending in 2020; ESRD facilities would select those 6 months (consecutive or non-consecutive) during which treatments would be counted for purposes of the LVPA determination. We are proposing that ESRD facilities would attest that their total dialysis treatments for those 6 months of their cost-reporting period ending in 2020 are less than 2,000 and that, although the total number of treatments furnished in the entire year otherwise exceeded the LVPA threshold, the excess treatments furnished were due to temporary patient shifting resulting from the COVID–19 PHE. MACs would annualize the total dialysis treatments for the total treatments reported in those 6 months by multiplying by 2. ESRD facilities would be expected to provide supporting documentation to the MACs upon request.

2. Payment for Renal Dialysis Services Furnished to Individuals With AKI

We are proposing to update the AKI payment rate for CY 2021. The proposed CY 2021 payment rate is \$255.59, which

is the same as the base rate proposed under the ESRD PPS for CY 2021.

3. ESRD QIP

We propose to update the scoring methodology used to calculate the Ultrafiltration Rate reporting measure so that facilities are scored based on the number of eligible patient-months, instead of facility-months, and to reduce the number of records that facilities selected for National Health Safety Network (NHSN) validation are required to submit. This rule also clarifies the timeline for facilities to make changes to their NHSN Bloodstream Infection (BSI) clinical measure and NHSN Dialysis Event reporting measure data for purposes of the ESRD QIP. This rule also provides estimates for the performance standards and payment reductions that would apply for PY 2023.

This rule does not propose any new requirements beginning with the PY 2024 ESRD QIP.

C. Summary of Costs and Benefits

In section VII of this proposed rule, we set forth a detailed analysis of the impacts that the proposed changes would have on affected entities and beneficiaries. The impacts include the following:

1. Impacts of the Proposed ESRD PPS

The impact chart in section VII.B of this proposed rule displays the estimated change in payments to ESRD facilities in CY 2021 compared to estimated payments in CY 2020. The overall impact of the proposed CY 2021 changes is projected to be a 1.6 percent increase in payments. Hospital-based ESRD facilities have an estimated 0.4 percent decrease in payments compared with freestanding facilities with an estimated 1.6 percent increase.

We estimate that the aggregate ESRD PPS expenditures would increase by approximately \$190 million in CY 2021 compared to CY 2020. This reflects a \$230 million increase from the payment rate update, a \$40 million increase due to the updates to the outlier threshold amounts, and an \$80 million decrease from the proposed addition to the ESRD PPS base rate to include calcimimetics and no longer provide the transitional drug add-on payment adjustment (TDAPA) for calcimimetics. As a result of the projected 1.6 percent overall payment increase, we estimate there would be an increase in beneficiary co-insurance payments of 1.6 percent in CY 2021, which translates to approximately \$40 million.

These figures do not reflect estimated increases or decreases in expenditures

based on our proposal to expand the TPNIES to include certain capital-related assets that are home dialysis machines when used in the home. The fiscal impact of this proposal cannot be determined because these new and innovative home dialysis machines are not yet identified and would vary in uniqueness and costs.

2. Impacts of the Proposed Payment for Renal Dialysis Services Furnished to Individuals With AKI

The impact chart in section VII.B of this proposed rule displays the estimated change in proposed payments to ESRD facilities in CY 2021 compared to estimated payments in CY 2020. The overall impact of the proposed CY 2021 changes is projected to be a 6.9 percent increase in payments for individuals with AKI. Hospital-based and freestanding ESRD facilities both have an estimated 6.9 percent increase in payments for individuals with AKI. The overall impact reflects the effects of the updated wage index, the proposed addition to the ESRD PPS base rate of \$12.06 to include calcimimetics in the ESRD PPS bundled payment, and the payment rate update.

We estimate that the aggregate payments made to ESRD facilities for renal dialysis services furnished to AKI patients at the proposed CY 2021 ESRD PPS base rate would increase by \$5 million in CY 2021 compared to CY 2020.

3. Impacts of the Proposed ESRD QIP

We estimate that the overall economic impact of the PY 2023 ESRD QIP would be approximately \$221 million as a result of the policies we have previously finalized and the proposals in this proposed rule. The \$221 million figure for PY 2023 includes costs associated with the collection of information requirements, which we estimate would be approximately \$205 million, and \$16 million in estimated payment reductions across all facilities. We also estimate that the overall economic impact of the PY 2024 ESRD QIP would be approximately \$221 million as a result of the policies we have previously finalized. The \$221 million figure for PY 2024 includes costs associated with the collection of information requirements, which we estimate would be approximately \$205 million.

II. Calendar Year (CY) 2021 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

A. Background

1. Statutory Background

On January 1, 2011, we implemented the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS), a case-mix adjusted bundled PPS for renal dialysis services furnished by ESRD facilities, as required by section 1881(b)(14) of the Social Security Act (the Act), as added by section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). Section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Patient Protection and Affordable Care Act (the Affordable Care Act), established that beginning with CY 2012, and each subsequent year, the Secretary of the Department of Health and Human Services (the Secretary) shall annually increase payment amounts by an ESRD market basket increase factor, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

Section 632 of the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112–240) included several provisions that apply to the ESRD PPS. Section 632(a) of ATRA added section 1881(b)(14)(I) to the Act, which required the Secretary, by comparing per patient utilization data from 2007 with such data from 2012, to reduce the single payment for renal dialysis services furnished on or after January 1, 2014 to reflect the Secretary's estimate of the change in the utilization of ESRD-related drugs and biologicals (excluding oral-only ESRD-related drugs). Consistent with this requirement, in the CY 2014 ESRD PPS final rule we finalized \$29.93 as the total drug utilization reduction and finalized a policy to implement the amount over a 3- to 4-year transition period (78 FR 72161 through 72170).

Section 632(b) of ATRA prohibited the Secretary from paying for oral-only ESRD-related drugs and biologicals under the ESRD PPS prior to January 1, 2016. And section 632(c) of ATRA required the Secretary, by no later than January 1, 2016, to analyze the case-mix payment adjustments under section 1881(b)(14)(D)(i) of the Act and make appropriate revisions to those adjustments.

On April 1, 2014, the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93) was enacted. Section 217 of PAMA included several provisions that apply to the ESRD PPS. Specifically, sections 217(b)(1) and (2)

of PAMA amended sections 1881(b)(14)(F) and (I) of the Act and replaced the drug utilization adjustment that was finalized in the CY 2014 ESRD PPS final rule (78 FR 72161 through 72170) with specific provisions that dictated the market basket update for CY 2015 (0.0 percent) and how the market basket should be reduced in CY 2016 through CY 2018.

Section 217(a)(1) of PAMA amended section 632(b)(1) of ATRA to provide that the Secretary may not pay for oral-only ESRD-related drugs under the ESRD PPS prior to January 1, 2024. Section 217(a)(2) of PAMA further amended section 632(b)(1) of ATRA by requiring that in establishing payment for oral-only drugs under the ESRD PPS, the Secretary must use data from the most recent year available. Section 217(c) of PAMA provided that as part of the CY 2016 ESRD PPS rulemaking, the Secretary shall establish a process for (1) determining when a product is no longer an oral-only drug; and (2) including new injectable and intravenous products into the ESRD PPS bundled payment.

Finally, on December 19, 2014, the President signed the Stephen Beck, Jr., Achieving a Better Life Experience Act of 2014 (ABLE) (Pub. L. 113–295). Section 204 of ABLE amended section 632(b)(1) of ATRA, as amended by section 217(a)(1) of PAMA, to provide that payment for oral-only renal dialysis services cannot be made under the ESRD PPS bundled payment prior to January 1, 2025.

2. System for Payment of Renal Dialysis Services

Under the ESRD PPS, a single, per-treatment payment is made to an ESRD facility for all of the renal dialysis services defined in section 1881(b)(14)(B) of the Act and furnished to individuals for the treatment of ESRD in the ESRD facility or in a patient's home. We have codified our definitions of renal dialysis services at § 413.171, which is in 42 CFR part 413, subpart H, along with other ESRD PPS payment policies. The ESRD PPS base rate is adjusted for characteristics of both adult and pediatric patients and accounts for patient case-mix variability. The adult case-mix adjusters include five categories of age, body surface area, low body mass index, onset of dialysis, four comorbidity categories, and pediatric patient-level adjusters consisting of two age categories and two dialysis modalities (§ 413.235(a) and (b)).

The ESRD PPS provides for three facility-level adjustments. The first payment adjustment accounts for ESRD facilities furnishing a low volume of

dialysis treatments (§ 413.232). The second adjustment reflects differences in area wage levels developed from core based statistical areas (CBSAs) (§ 413.231). The third payment adjustment accounts for ESRD facilities furnishing renal dialysis services in a rural area (§ 413.233).

The ESRD PPS provides a training add-on for home and self-dialysis modalities (§ 413.235(c)) and an additional payment for high cost outliers due to unusual variations in the type or amount of medically necessary care when applicable (§ 413.237).

The ESRD PPS provides for a transitional drug add-on payment adjustment (TDAPA) for certain new renal dialysis drugs and biological products (§ 413.234(c)).

The ESRD PPS also provides for a transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES) for certain qualifying, new and innovative renal dialysis equipment and supplies (§ 413.236(d)).

3. Updates to the ESRD PPS

Policy changes to the ESRD PPS are proposed and finalized annually in the **Federal Register**. The CY 2011 ESRD PPS final rule was published on August 12, 2010 in the **Federal Register** (75 FR 49030 through 49214). That rule implemented the ESRD PPS beginning on January 1, 2011 in accordance with section 1881(b)(14) of the Act, as added by section 153(b) of MIPPA, over a 4-year transition period. Since the implementation of the ESRD PPS, we have published annual rules to make routine updates, policy changes, and clarifications.

On November 8, 2019, we published a final rule in the **Federal Register** titled, “Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule Amounts, DMEPOS Competitive Bidding Program (CBP) Amendments, Standard Elements for a DMEPOS Order, and Master List of DMEPOS Items Potentially Subject to a Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements,” referred to as the CY 2020 ESRD PPS final rule. In that rule, we updated the ESRD PPS base rate, wage index, and outlier policy, for CY 2020. We also finalized revisions to the eligibility criteria for the TDAPA for certain new renal dialysis drugs and biological products that fall within an existing ESRD PPS functional

category, modified the basis of payment for the TDAPA for calcimimetics, established a new policy to condition the TDAPA payment on our receipt of average sales price (ASP) data, established the TPNIES to support ESRD facilities in their uptake of certain new and innovative renal dialysis equipment and supplies, and discontinued the erythropoiesis-stimulating agent (ESA) monitoring policy under the ESRD PPS. For further detailed information regarding these updates, see 84 FR 60648.

B. Provisions of the Proposed Rule

1. Inclusion of Calcimimetics Into the ESRD PPS Bundled Payment

a. Background on Oral-Only Renal Dialysis Drugs

Section 1881(b)(14)(A)(i) of the Act requires the Secretary to implement a payment system under which a single payment is made to a provider of services or a renal dialysis facility for renal dialysis services in lieu of any other payment. Section 1881(b)(14)(B) of the Act defines renal dialysis services, and clause (iii) of such section states that these services include other drugs and biologicals that are furnished to individuals for the treatment of ESRD and for which payment was made separately under this title, and any oral equivalent form of such drug or biological.

We interpreted this provision as including not only injectable drugs and biological products used for the treatment of ESRD (other than erythropoiesis-stimulating agents (ESAs) and any oral form of ESAs, which are included under clause (ii) of section 1881(b)(14)(B) of the Act), but also all oral drugs and biological products used for the treatment of ESRD and furnished under title XVIII of the Act. We also concluded that, to the extent oral-only drugs or biological products used for the treatment of ESRD do not fall within clause (iii) of section 1881(b)(14)(B), such drugs or biological products would fall under clause (iv) of such section, and constitute other items and services used for the treatment of ESRD that are not described in clause (i) of section 1881(b)(14)(B) of the Act.

We finalized and promulgated the payment policies for oral-only renal dialysis service drugs and biological products in the CY 2011 ESRD PPS final rule (75 FR 49038 through 49053), where we defined renal dialysis services at § 413.171 as including other drugs and biological products that are furnished to individuals for the treatment of ESRD and for which payment was made separately prior to

January 1, 2011 under Title XVIII of the Act, including drugs and biological products with only an oral form. We further described oral-only drugs as those that have no injectable equivalent or other form of administration (75 FR 49038 through 49039). Although we included oral-only renal dialysis service drugs and biological products in the definition of renal dialysis services in the CY 2011 ESRD PPS final rule (75 FR 49044), we also finalized a policy to delay payment for these drugs under the PPS until January 1, 2014. In the CY 2011 ESRD PPS proposed and final rules (74 FR 49929 and 75 FR 49038, respectively), we noted that the only oral-only drugs and biological products that we identified were phosphate binders and calcimimetics, which fall into the bone and mineral metabolism ESRD PPS functional category. We stated that there were certain advantages to delaying the implementation of payment for oral-only drugs and biological products, including allowing ESRD facilities additional time to make operational changes and logistical arrangements in order to furnish oral-only renal dialysis service drugs and biological products to their patients. Accordingly, we codified the delay in payment for oral-only renal dialysis service drugs and biological products at § 413.174(f)(6), and provided that payment to an ESRD facility for renal dialysis service drugs and biological products with only an oral form is incorporated into the PPS payment rates effective January 1, 2014. Since oral-only drugs are generally not a covered service under Medicare Part B, this delay of payment under the ESRD PPS also allowed the coverage under Medicare to continue under Part D.

On January 3, 2013, ATRA was enacted. Section 632(b) of ATRA precluded the Secretary from implementing the policy under § 413.176(f)(6) relating to oral-only renal dialysis service drugs and biological products prior to January 1, 2016. Accordingly, in the CY 2014 ESRD PPS final rule (78 FR 72185 through 72186), we delayed payment for oral-only renal dialysis service drugs and biological products under the ESRD PPS until January 1, 2016. We implemented this delay by revising the effective date at § 413.174(f)(6) from January 1, 2014 to January 1, 2016. In addition, we changed the date when oral-only renal dialysis service drugs and biological products would be eligible for outlier services under the outlier policy described in § 413.237(a)(1)(iv) from January 1, 2014 to January 1, 2016.

On April 1, 2014, PAMA was enacted. Section 217(a)(1) of PAMA amended

section 632(b)(1) of ATRA and precluded the Secretary from implementing the policy under § 413.174(f)(6) relating to oral-only renal dialysis service drugs and biological products prior to January 1, 2024. We implemented this delay in the CY 2015 ESRD PPS final rule (79 FR 66262) by modifying the effective date for providing payment for oral-only renal dialysis service drugs and biological products under the ESRD PPS at § 413.174(f)(6) from January 1, 2016 to January 1, 2024. We also changed the date in § 413.237(a)(1)(iv) regarding outlier payments for oral-only renal dialysis service drugs made under the ESRD PPS from January 1, 2016 to January 1, 2024. Section 217(a)(2) of PAMA further amended section 632(b)(1) of ATRA by requiring that in establishing payment for oral-only drugs under the ESRD PPS, the Secretary must use data from the most recent year available.

On December 19, 2014, ABLE was enacted. Section 204 of ABLE amended section 632(b)(1) of ATRA, as amended by section 217(a)(1) of PAMA, and precluded the Secretary from implementing the policy under § 413.174(f)(6) relating to oral-only renal dialysis service drugs and biological products prior to January 1, 2025. We implemented this delay in the CY 2016 ESRD PPS final rule (80 FR 69027 through 69028) by modifying the effective date for providing payment for oral-only renal dialysis service drugs and biological products under the ESRD PPS at § 413.174(f)(6) from January 1, 2024 to January 1, 2025. We also changed the date in § 413.237(a)(1)(iv) regarding outlier payments for oral-only renal dialysis service drugs made under the ESRD PPS from January 1, 2024 to January 1, 2025.

b. ESRD PPS Drug Designation Process and Calcimimetics

In addition to delaying implementation of the policy for oral-only renal dialysis service drugs and biological products under the ESRD PPS, discussed previously in this proposed rule, PAMA included section 217(c), which provided that as part of the CY 2016 ESRD PPS rulemaking, the Secretary shall establish a process for (1) determining when a product is no longer an oral-only drug; and (2) including new injectable and intravenous products into the ESRD PPS bundled payment. Therefore, in the CY 2016 ESRD PPS final rule (80 FR 69013 through 69027), we finalized a process that allows us to recognize when an oral-only renal dialysis service drug or biological product is no longer oral-

only, and a process to include new injectable and intravenous (IV) products into the ESRD PPS bundled payment, and when appropriate, modify the ESRD PPS payment amount to reflect the costs of furnishing that product.

In accordance with section 217(c)(1) of PAMA, we established § 413.234(d), which provides that an oral-only drug is no longer considered oral-only if an injectable or other form of administration of the oral-only drug is approved by FDA. We defined an oral-only drug at § 413.234(a) to mean a drug or biological with no injectable equivalent or other form of administration other than an oral form.

Additionally, in accordance with section 217(c)(2) of PAMA, we codified the drug designation process at § 413.234(b). In the CY 2016 ESRD PPS final rule (80 FR 69024), we finalized that the drug designation process is dependent upon the ESRD PPS functional categories, consistent with our policy since the implementation of the PPS in 2011. We provided a detailed discussion on how we accounted for renal dialysis drugs and biological products in the ESRD PPS base rate since its implementation on January 1, 2011 (80 FR 69013 through 69015). We explained that, in the CY 2011 ESRD PPS final rule (75 FR 49044 through 49053), in order to identify drugs and biological products that are used for the treatment of ESRD and therefore meet the definition of renal dialysis services (defined at § 413.171) that would be included in the ESRD PPS base rate, we performed an extensive analysis of Medicare payments for Part B drugs and biological products billed on ESRD claims and evaluated each drug and biological product to identify its category by indication or mode of action. We stated in the CY 2011 ESRD PPS final rule that categorizing drugs and biological products on the basis of drug action allows us to determine which categories (and therefore, the drugs and biological products within the categories) would be considered used for the treatment of ESRD (75 FR 49047).

In the CY 2016 ESRD PPS final rule, we also explained that, in CY 2011 ESRD PPS rulemaking, we grouped the injectable and IV drugs and biological products into ESRD PPS functional categories based on their action (80 FR 69014). This was done for the purpose of adding new drugs or biological products with the same functions to the ESRD PPS bundled payment as expeditiously as possible after the drugs become commercially available so that beneficiaries have access to them. In the CY 2016 ESRD PPS final rule, we

finalized the definition of an ESRD PPS functional category in § 413.234(a) as a distinct grouping of drugs or biologicals, as determined by CMS, whose end action effect is the treatment or management of a condition or conditions associated with ESRD (80 FR 69077).

We finalized a policy in the CY 2016 ESRD PPS final rule (80 FR 69017 through 69022) that, effective January 1, 2016, if a new injectable or IV product is used to treat or manage a condition for which there is an ESRD PPS functional category, the new injectable or IV product is considered included in the ESRD PPS bundled payment and no separate payment is available. The new injectable or IV product qualifies as an outlier service. The ESRD bundled market basket updates the PPS base rate annually and accounts for price changes of the drugs and biological products reflected in the base rate.

We established in § 413.234(b)(2) that, if the new injectable or IV product is used to treat or manage a condition for which there is not an ESRD PPS functional category, the new injectable or IV product is not considered included in the ESRD PPS bundled payment and the following steps occur. First, an existing ESRD PPS functional category is revised or a new ESRD PPS functional category is added for the condition that the new injectable or IV product is used to treat or manage. Next, the new injectable or IV product is paid for using the TDAPA described in § 413.234(c). Finally, the new injectable or IV product is added to the ESRD PPS bundled payment following payment of the TDAPA.

In the CY 2016 ESRD PPS final rule, we finalized a policy in § 413.234(c) to base the TDAPA on pricing methodologies under section 1847A of the Act and pay the TDAPA until sufficient claims data for rate setting analysis for the new injectable or IV product are available, but not for less than 2 years. During the time a new injectable or IV product is eligible for the TDAPA, it is not eligible as an outlier service. We established that, following payment of the TDAPA, the ESRD PPS base rate will be modified, if appropriate, to account for the new injectable or IV product in the ESRD PPS bundled payment.

We also established, in the CY 2016 ESRD PPS final rule (80 FR 69024 through 69027), an exception to the drug designation process for calcimimetics. We noted that in the CY 2011 ESRD PPS proposed and final rules (74 FR 49929 and 75 FR 49038, respectively), the only oral-only drugs and biological products we identified

were phosphate binders and calcimimetics, which fall into the bone and mineral metabolism ESRD PPS functional category. We stated that we defined these oral-only drugs as renal dialysis services in our regulations at § 413.171 (75 FR 49044), delayed the Medicare Part B payment for these oral-only drugs until CY 2014 at § 413.174(f)(6), and continued to pay for them under Medicare Part D. We explained in the CY 2016 ESRD PPS final rule that, under § 413.234(b)(1), if injectable or IV forms of phosphate binders or calcimimetics are approved by FDA, these drugs would be considered reflected in the ESRD PPS bundled payment because these drugs are included in an existing functional category, so no additional payment would be available for inclusion of these drugs.

However, we recognized the uniqueness of these drugs and stated that we will not apply this process to injectable or IV forms of phosphate binders and calcimimetics when they are approved because payment for the oral forms of these drugs was delayed and dollars were never included in the ESRD PPS base rate to account for these drugs. Instead, we finalized a policy that once the injectable or IV phosphate binder or calcimimetic is FDA approved and has a Healthcare Common Procedure Coding System (HCPCS) code, we will issue a change request to pay for all forms of the phosphate binder or calcimimetic using the TDAPA based on the payment methodologies under section 1847A of the Act, which could include ASP + 6 percent, for a period of at least 2 years. We explained in the CY 2016 ESRD PPS final rule that this will allow us to collect data reflecting current utilization of both the oral and injectable or IV forms of the drugs, as well as payment patterns and beneficiary co-pays, before we add these drugs to the ESRD PPS bundled payment. We stated that during this period we will not pay outlier payments for these drugs. We further stated that at the end of the 2 or more years, we will adopt the methodology for including the phosphate binders and calcimimetics into the ESRD PPS bundled payment through notice-and-comment rulemaking.

In 2017, FDA approved an injectable calcimimetic. In accordance with the policy finalized in the CY 2016 ESRD PPS final rule, we issued a change request to implement payment under the ESRD PPS for both the oral and injectable forms of calcimimetics using the TDAPA. Change Request 10065, Transmittal 1889, issued August 4, 2017, replaced by Transmittal 1999,

issued January 10, 2018, implemented the TDAPA for calcimimetics effective January 1, 2018.

In CYs 2019 and 2020 ESRD PPS final rules (83 FR 56927 through 56949 and 84 FR 60653 through 60677, respectively), we made several revisions to the drug designation process regulations at § 413.234. In the CY 2019 ESRD PPS final rule, for example, we revised regulations at § 413.234(a), (b), and (c) to reflect that the process applies for all new renal dialysis drugs and biological products that are FDA approved regardless of the form or route of administration, that is, new injectable, IV, oral, or other form or route of administration (83 FR 56932). In addition, we revised § 413.234(b) and (c) to expand the TDAPA to all new renal dialysis drugs and biological products, not just those in new ESRD PPS functional categories (83 FR 56942 through 56943). We also revised § 413.234(c) to reflect that we base the TDAPA on 100 percent of ASP (ASP + 0) instead of the pricing methodologies available under section 1847A of the Act (which includes ASP + 6). We explained that the 6 percent add-on to ASP has been used to cover administrative and overhead costs, however, the ESRD PPS base rate includes dollars for administrative complexities and overhead costs for drugs and biological products, so we believe ASP + 0 is a reasonable basis for the TDAPA under the ESRD PPS (83 FR 56943 through 56944). For circumstances when ASP data is not available, we finalized that the TDAPA is based on wholesale acquisition cost (WAC) + 0 and, when WAC is not available, the TDAPA is based on the drug manufacturer's invoice (83 FR 56948). We also finalized a revision to § 413.234(c) to reflect that the basis of payment for the TDAPA for calcimimetics would continue to be based on the pricing methodologies available under section 1847A of the Act, which includes ASP + 6 (83 FR 56948). These provisions all had an effective date of January 1, 2020.

In the CY 2020 ESRD PPS final rule, we made several additional revisions to the ESRD PPS drug designation process regulations at § 413.234. For example, we revised § 413.234(b) and added paragraph (e) to codify certain eligibility criteria changes for new renal dialysis drugs and biological products that fall within an existing ESRD PPS functional category. That is, we excluded certain drugs from being eligible for the TDAPA, effective January 1, 2020 (84 FR 60672). Specifically, as detailed in the CY 2020 ESRD PPS final rule (85 FR 60565 through 60673), we excluded

generic drugs approved by FDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and drugs for which the new drug application (NDA) is classified by FDA as Type 3, 5, 7 or 8, Type 3 in combination with Type 2 or Type 4, or Type 5 in combination with Type 2, or Type 9 when the “parent NDA” is a Type 3, 5, 7 or 8—from being eligible for the TDAPA. We also established at § 413.234(c) a policy to condition application of the TDAPA on our receipt of ASP data (84 FR 60681).

In the CY 2020 ESRD PPS final rule (84 FR 60673), we also discussed the duration of payment of the TDAPA for calcimimetics and changed the basis of the TDAPA for such products. We stated that in accordance with our policy for calcimimetics under the drug designation process, we would pay for calcimimetics using the TDAPA for a minimum of 2 years until sufficient claims data for rate setting analysis is available for these products. We noted that at the time of the CY 2020 ESRD PPS proposed rule we were still in the process of collecting utilization claims data for both the oral and injectable form of calcimimetics. Therefore, in the CY 2020 ESRD PPS proposed rule, we stated that we would continue to pay for calcimimetics using the TDAPA in CY 2020 (84 FR 38347).

However, we also noted in the CY 2020 ESRD PPS proposed rule that we had provided the TDAPA for calcimimetics at ASP + 6 percent for 2-full years (that is, January 1, 2018 through December 31, 2019), and we believed that was sufficient time for ESRD facilities to address any administrative complexities and overhead costs that may have arisen with regard to furnishing the calcimimetics. We noted that it was clear that ESRD facilities were furnishing calcimimetics because payment for them using the TDAPA had increased Medicare expenditures by \$1.2 billion in CY 2018 (84 FR 60673). We explained that one of the rationales for the 6 percent add-on to ASP was to cover administrative and overhead costs, however, the ESRD PPS base rate has dollars included for administrative complexities and overhead costs for drugs and biological products. Therefore, in the CY 2020 ESRD PPS final rule, we finalized a revision to § 413.234(c) to reflect that the basis of payment for the TDAPA for calcimimetics, beginning in CY 2020, would be 100 percent of ASP (84 FR 60676). We explained this policy change provided a balance between supporting ESRD facilities in their uptake of these products and limiting the financial

burden that increased payments place on beneficiaries and Medicare expenditures. We also noted that this policy is consistent with the policy finalized for all other new renal dialysis drugs and biological products in the CY 2019 ESRD PPS final rule (83 FR 56948).

c. Proposed Methodology for Modifying the ESRD PPS Base Rate to Account for Calcimimetics in the ESRD PPS Bundled Payment

As we discussed previously in section II.B.1.b of this proposed rule, under § 413.234(d), calcimimetics were no longer considered to be an oral-only drug once FDA approved an injectable calcimimetic in 2017. We have paid for calcimimetics under the ESRD PPS using the TDAPA since January 1, 2018. We stated in the CY 2016 ESRD PPS final rule that for calcimimetics—for which there is an ESRD PPS functional category, but no money is in the base rate—we will utilize the TDAPA to collect utilization data before adding this drug to the ESRD PPS base rate. This will allow us to collect data reflecting current utilization of both the oral and injectable or IV forms of the drug, as well as payment patterns and beneficiary co-pays, and at the end of the 2 or more years, we will adopt the methodology for including this drug in the ESRD PPS bundled payment through notice-and-comment rulemaking.

We believe we have collected sufficient claims data for a rate setting analysis for calcimimetics. Specifically, we have collected robust claims data for 2-full years and analyzed the utilization of every generic and brand name oral calcimimetic, along with the utilization of the injectable calcimimetic. We monitored the ASP data available during the specific utilization periods. Our overall analysis of ESRD claims data for CYs 2018 and 2019 indicated an increase in the utilization of the oral generic calcimimetic drugs with a steep decline in the brand-name oral calcimimetic. This resulted in an overall decrease in ASP as the generic calcimimetic drugs entered the market in late 2018 and the beginning of 2019, since the generic version is less expensive than the brand-name version. Since beneficiaries have a 20 percent co-pay under the ESRD PPS, a decrease in the payment for calcimimetics results in a decrease in the beneficiary co-pay.

Therefore, we believe that we are at the step of the ESRD PPS drug designation process where we propose to adopt the methodology for modifying the ESRD PPS base rate to account for calcimimetics in the ESRD PPS bundled payment through CY 2021 notice-and-

comment rulemaking. That is, in this proposed rule, we are proposing to add a per treatment amount to the ESRD PPS base rate to include the calcimimetics in the ESRD PPS bundled payment amount.

In developing the proposed methodology for including calcimimetics into the ESRD PPS base rate, we considered the methodology that we used when we included Part B drugs and biological products in the ESRD PPS base rate as part of our implementation of the ESRD PPS. In the CY 2011 ESRD PPS final rule (75 FR 49074 through 49079), we discussed how we established which renal dialysis drugs and biological products would be reflected in the ESRD PPS base rate. We used the utilization of those drugs and biological products from Medicare claims data and applied ASP + 6 percent to establish the price for each drug. Then we inflated each drug's price to 2011 using the Producer Price Index (PPI) for prescription drugs.

In addition, as discussed in the CY 2011 ESRD PPS final rule (75 FR 49064), we established a dialysis treatment as the unit of payment. Consistent with the approach we used initially to include drugs and biological products into the ESRD PPS base rate and the ESRD PPS unit of payment, we are proposing a similar methodology in this rule to calculate a one-time modification to the ESRD PPS base rate on a per-treatment basis to account for calcimimetics. We believe the proposed methodology is similar to the CY 2011 approach because we would determine utilization of the drug, in this case, calcimimetics, along with the payment amounts associated with each oral and injectable form based on the ASP + 0 instead of ASP + 6, as discussed in the CY 2020 ESRD PPS final rule.

The following sections discuss each element of our proposed methodology in detail. As an overview, we are proposing to calculate a per-treatment amount for calcimimetics that would be added to the ESRD PPS base rate. We would apply the value from the most recent calendar quarter ASP calculations at 100 percent of ASP (that is, ASP + 0) available to the public for calcimimetics to the utilization data for calcimimetics from CYs 2018 and 2019 Medicare ESRD claims data. This would provide the calcimimetic expenditure amount. We would divide the calcimimetic expenditure amount by the total number of hemodialysis-equivalent dialysis treatments paid in CYs 2018 and 2019 under the ESRD PPS. We would reduce this average per treatment amount by 1 percent to account for the outlier policy, since calcimimetics

would be ESRD outlier services eligible for outlier payments beginning January 1, 2021. We propose to add the resulting amount to the ESRD PPS base rate. We note that this amount will stay in the base rate and be subject to the annual updates (productivity adjusted market basket increase and application of wage index budget neutrality adjustment factor). Under this proposal, CMS would stop paying for these drugs using the TDAPA for dates of service on or after January 1, 2021.

We are proposing to revise our drug designation regulation at § 413.234, by adding paragraph (f), to describe the methodology for modifying the ESRD PPS base rate to account for the costs of calcimimetics, including the data sources and the steps we would take to calculate a per treatment amount. We propose, for dates of service on or after January 1, 2021, calcimimetics would no longer be paid for under the ESRD PPS using the TDAPA (§ 413.234(c)) and would be paid for through the ESRD PPS base rate and eligible for outlier payments as ESRD outlier services under § 413.237.

We note that the methodology proposed in this rule is only for modifying the ESRD PPS base rate to include calcimimetic drugs. We stated in the CY 2016 ESRD PPS final rule (80 FR 69022) that the TDAPA will be paid for a minimum of 2 years, during which time we will gather utilization data. At the end of that time, the drug will be included within its new functional category and the base rate may or may not be modified to account for the cost of the drug, depending upon what the utilization data show. Accordingly, our policy is to propose and adopt the methodology for including any future eligible new renal dialysis drugs and biological products into the ESRD PPS base rate through notice-and-comment rulemaking.

(1) Determining Utilization of Calcimimetics

For use in the proposed calculation, we analyzed the utilization of both the oral and injectable forms of calcimimetics reported on the ESRD facility claims for CYs 2018 and 2019. ESRD facilities report this information to CMS on Medicare ESRD facility claims, that is, the 837-institutional form with bill type 072X. The oral calcimimetic is reported as HCPCS J0604 (Cinacalcet, oral, 1 mg, (for ESRD on dialysis)) and the injectable calcimimetic is reported as HCPCS J0606 (Injection, etelcalcetide, 0.1 mg), that is, one unit of J0604 is 1 mg, and one unit of J0606 is 0.1 mg. For purposes of this rate setting analysis, we

consider utilization of calcimimetics as the units of the product furnished to an ESRD beneficiary.

For the CY 2018 utilization data for calcimimetics, we propose to use the latest available claims data based on the CY 2018 ESRD facility claims updated through June 30, 2019 (that is, claims with dates of service from January 1 through December 31, 2018, that were received, processed, paid, and passed to the National Claims History (NCH) File as of June 30, 2019) to calculate 2018 utilization. Claims that are received, processed, paid, and passed to the NCH file are considered to be “complete” because they have been adjudicated.

For the CY 2019 utilization data for calcimimetics, we propose to use the latest available claims data based on the CY 2019 ESRD facility claims to calculate 2019 utilization. For this proposed rule, the latest available CY 2019 ESRD facility claims used were updated through January 31, 2020 (that is, claims with dates of service from January 1 through December 31, 2019, that were received, processed, paid, and passed to the NCH File as of January 31, 2020). For the CY 2021 ESRD PPS final rule, the latest available CY 2019 ESRD facility claims we would use for purposes of our final calculation would be updated through June 30, 2020 (that is, claims with dates of service from January 1 through December 31, 2019, that were received, processed, paid, and passed to the NCH File as of June 30, 2020).

While we have continued to pay the TDAPA for calcimimetics for dates of service in CY 2020, we are not proposing to use utilization data from this period because practice patterns in CY 2020 have been altered due to the COVID-19 pandemic and the resulting impact on data is unknown at this time. However, our policy to continue paying for calcimimetics using the TDAPA in CY 2020 has allowed us to analyze 2 full years of adjudicated Medicare claims since CY 2019 claims include those claims from January 1, 2019 through December 31, 2019.

We solicit comments on the proposed use of CYs 2018 and 2019 claims data to determine the utilization of calcimimetics for purposes of calculating the proposed addition to the ESRD PPS base rate to account for calcimimetics at proposed § 413.234(f). While we believe using claims data from CYs 2018 and 2019 is appropriate because those years provide us with not only the most complete data set, but also the most accurate data set reflecting paid claims, we are also soliciting comments as to whether we should instead use a single year (CY 2018 or CY

2019) rather than both CYs 2018 and 2019 in our methodology.

(2) Pricing of Calcimimetics—Methodology

For use in the proposed calculation, we would set the price for calcimimetics using values from the most recent calendar quarter of ASP calculations available to the public, at 100 percent of ASP (ASP + 0). The ASP-based value is a CMS-derived weighted average of all of the National Drug Code (NDC) sales prices submitted by drug manufacturers and assigned by CMS to the two existing HCPCS codes for calcimimetics. For each billing code, CMS calculates a weighted average sales price using data submitted by manufacturers, which includes the following: ASP data at the 11-digit NDC level, the number of units of the 11-digit NDC sold and the ASP for those units. Next, the number of billing units in an NDC is determined by the amount of drug in the package. CMS uses the following weighting methodology to determine the payment limit: (1) Sums the product of the manufacturer's ASP and the number of units of the 11-digit NDC sold for each NDC assigned to the billing and payment code; (2) Divides this total by the sum of the product of the number of units of the 11-digit NDC sold and the number of billing units in that NDC for each NDC assigned to the billing and payment code, and (3) Weights the ASP for an NDC by the number of billing units sold for that NDC. This calculation methodology is discussed in the CY 2009 Physician Fee Schedule (PFS) final rule (73 FR 69752). The general methodology for determining ASP-based payments for the PFS is authorized in section 1847A of the Act.

ASP-based payment limits published in the quarterly ASP Drug Pricing files include a 6 percent add-on as required in section 1847A of the Act. However, consistent with the TDAPA basis of payment for CY 2020, we use 100 percent of the weighted ASP value, in other words, ASP + 0. In the CY 2020 ESRD PPS final rule, we noted that the ESRD PPS accounts for storage and administration costs and that ESRD facilities do not have acquisition price variation issues when compared to physicians. We explained that we believed ASP + 0 is reasonable for new renal dialysis drugs and biological products that fall within an existing functional category because there are already dollars in the per treatment base rate for a new drug's respective category. We also explained that we believed ASP + 0 is a reasonable basis for payment for the TDAPA for new renal dialysis drugs and biological

products that do not fall within the existing functional category because the ESRD PPS base rate has dollars built in for administrative complexities and overhead costs for drugs and biological products (83 FR 56946).

We believe using a value based on the most recent calendar quarter ASP calculations available to the public for both oral and injectable versions of the calcimimetics would provide an accurate representation of the price of calcimimetics for ESRD facilities because it uses manufacturer sales information that includes discounts (that is, rebates, volume discounts, prompt payment, cash payment specified in section 1847A of the Act). Every calendar quarter, CMS publishes ASP-based payment limits for certain Part B drugs and biological products that are used for payment of such Part B covered drugs and biological products for a specific quarter. The amount that we propose to use for the base rate modifications associated with the oral and injectable versions of the calcimimetics is based on the most recent information on average sales prices net of discounts specified in section 1847A submitted by the manufacturers of each of the drugs.

For this proposed rule, using values from the most recent calendar quarter of ASP calculations available to the public at the time that this rule is being written is the second quarter of 2020,¹ and as a result of two-quarter data lag this reflects manufacturer sales data submitted into CMS for the fourth quarter of 2019. For the CY 2021 ESRD PPS final rule, the most recent calendar quarter of ASP calculations available to the public would be the fourth quarter of 2020, which reflects manufacturer sales data submitted into CMS for the second quarter of 2020, and we would use that value for purposes of our final calculation.

We would update these prices by the proposed CY 2021 ESRD PPS base rate update to reflect the estimated costs in CY 2021. That is, we would first add the calculated per treatment payment amount to the ESRD PPS base rate to include calcimimetics, and then we would apply the annual payment rate update. The proposed calculation for the addition to the ESRD PPS base rate is discussed in the following section.

Therefore, we propose to add § 413.234(f) that CMS would use 100 percent of the values from the most recent calendar quarter ASP calculations available to the public for

the oral and injectable calcimimetic to calculate a price for each form of the drug. We solicit comments on the proposed use of the values from the most recent calendar quarter ASP + 0 calculations available to the public for calcimimetics for setting the price and the proposed language at § 413.234(f).

(3) Calculation of the Addition to the ESRD PPS Base Rate To Include Calcimimetics

To calculate the proposed amount for calcimimetics that would be added to the ESRD PPS base rate, we applied the values from the most recent calendar quarter 2020 ASP + 0 calculations available to the public for calcimimetics to CYs 2018 and 2019 calcimimetic utilization data to calculate the calcimimetic expenditure amount for both years. As stated in section II.B.1.c.(1) of this proposed rule, one unit of J0604 (oral calcimimetic, cinacalcet) is 1 mg and one unit of J0606 (injectable calcimimetic etelcalcetide) is 0.1 mg. That is, we determined that 1,824,370,957 total units (mg) of oral calcimimetics were used in CYs 2018 and 2019. With regard to injectable calcimimetics, we determined that 306,714,207 total units (0.1 mg) were used in CYs 2018 and 2019. This use indicates that 33.9 percent of ESRD beneficiaries received calcimimetics in CYs 2018 and 2019. For this proposed rule, we used the values from the most recent calendar quarter ASP + 0 calculations available to the public, which is the second quarter of 2020. This information can be found on the ESRD Payment website: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/ESRD-Transitional-Drug>. We used \$0.231 per mg for the oral calcimimetic and \$2.20 per 0.1 mg for the injectable calcimimetic. The prices per unit correspond to 1 mg and 0.1 mg for cinacalcet and etelcalcetide respectively. (We note that, for the CY 2021 ESRD PPS final rule, we would update the ASP + 0 based value on the most recent calendar quarter calculations available to the public.) Multiplying the utilization of the oral and injectable calcimimetics by their respective ASP and then adding the expenditure amount for both forms of calcimimetics together would be the total 2-year (CYs 2018 and 2019) calculated calcimimetic expenditure amount. That is, for this proposed rule, we calculated the total calcimimetic expenditure amount of \$1,096,200,947. The total number of paid hemodialysis-equivalent dialysis treatments furnished to Medicare ESRD beneficiaries in CYs 2018 and 2019 was 90,014,098. This

total number of paid treatments reflects all paid dialysis treatments regardless of whether a calcimimetic was furnished. Dividing the calcimimetic expenditure amount by the total number of paid hemodialysis-equivalent dialysis treatments provides an average per treatment payment amount of \$12.18.

We then reduced this amount by 1 percent to account for the outlier policy under § 413.237 to get a total of \$12.06 ($\$12.18 \times .99 = \12.06). Under our proposal, we would apply this 1 percent reduction before increasing the base rate to account for outlier payments that would be paid beginning January 1, 2021 for calcimimetics since they would become ESRD outlier services eligible for outlier payments under § 413.237. As we discussed in section II.B.1.c of this proposed rule, in developing the proposed methodology for including calcimimetics in the ESRD PPS base rate, we considered the methodology applied when we developed the ESRD PPS base rate. In the CY 2011 ESRD PPS final rule (75 FR 49074 through 49075), we explained the budget neutrality adjustments applied to the unadjusted ESRD PPS base rate to account for statutorily mandated reductions. Because we are proposing to modify the ESRD PPS base rate to include calcimimetics, which beginning January 1, 2021 would become ESRD outlier services, we focused on the outlier adjustment. That is, in CY 2011 we applied a 1 percent reduction to the unadjusted ESRD PPS base rate to account for outlier payments. In order for the application of the 1 percent outlier to be maintained, we believe the 1 percent must be excluded from the addition to the ESRD PPS base rate for calcimimetics.

Then, to determine the estimated costs in CY 2021 we would inflate the average per treatment payment amount for calcimimetics (\$12.06) to 2021 using the CY 2021 ESRD PPS base rate update. As discussed in section II.B.4.d of this proposed rule, the proposed CY 2021 ESRD PPS base rate is \$255.59. This amount reflects a proposed CY 2021 wage index budget-neutrality adjustment factor of .998652, a proposed base rate addition of \$12.06 to include calcimimetics, and the proposed CY 2021 ESRD PPS payment rate update of 1.8 percent. We believe that using the annual payment rate update effectively updates the prices set for calcimimetics from CY 2020 to CY 2021 because this is consistent with how the other components of the base rate are updated for inflation each year, which includes drugs. We note, that the inflation factor used for drugs and biological products for the ESRD bundled market basket is

¹ <https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/2020-asp-drug-pricing-files>, April 2020 ASP Pricing File.

the Producer Price Index as discussed in the CY 2019 ESRD PPS final rule (83 FR 56958 through 56959).

Therefore, we propose to add § 413.234(f) that CMS would multiply the utilization of the oral and injectable calcimimetics by their respective prices and add the expenditure amount for both forms together to calculate the total calcimimetic expenditure amount. Then, CMS would divide the total calcimimetic expenditure amount by the total number of paid hemodialysis-equivalent dialysis treatments in CYs 2018 and 2019, to calculate the average per-treatment payment amount. CMS would reduce the average per-treatment payment amount by 1 percent to account for the outlier policy under § 413.237 in order to determine the amount added to the ESRD PPS base rate.

In keeping with the principles of a PPS, which include motivating healthcare providers to structure cost-effective, efficient patient care that avoids unnecessary services, thereby reining in costs, we believe the cost of the calcimimetics should be spread across all the dialysis treatments, rather than be directed only to the patients receiving the calcimimetics.

We solicit comments on the proposed revisions to § 413.234 to add paragraph (f) to § 413.234 to establish the methodology for modifying the ESRD PPS base rate to account for calcimimetics in the ESRD PPS bundled payment.

As an alternative methodology, we considered dividing the total Medicare expenditures for all calcimimetics in CYs 2018 and 2019 (approximately \$2.3 billion) by the total number of paid hemodialysis-equivalent dialysis treatments furnished during that same time period. However, this approach would not factor in the impact of oral generic calcimimetics, which entered the market from late December 2018 through early January 2019. For example, under the proposed methodology, the ASP calculations incorporate the more recent pricing of the oral generic calcimimetics into the weighting which has resulted in a significant decline in the ASP-based value. In addition, this alternative methodology would not reflect our current policy to base the TDAPA on ASP + 0, since in CYs 2018 and 2019 we paid for calcimimetics using the TDAPA at ASP + 6. We believe it is more appropriate for the ESRD PPS base rate to reflect the values from the most recent calendar quarter of ASP calculations available since that aligns with how ESRD facilities would be purchasing and furnishing the oral

calcimimetics rather than using expenditure data from previous periods. We believe that ESRD facilities would want to support CMS's goal of lower drug and biological products prices for its beneficiaries. In addition, this alternative methodology would have a more significant impact on beneficiary cost sharing in terms of a higher 20 percent co-pay than the proposed methodology in this proposed rule. We solicit comment on this alternative methodology, which would entail dividing the total Medicare expenditures (that is, actual spend) for all calcimimetics in CYs 2018 and 2019 by the total number of paid hemodialysis-equivalent dialysis treatments furnished during that same time period.

2. Proposed Changes to the TPNIES Eligibility Criteria

a. Background

In the CY 2020 ESRD PPS final rule (84 FR 60681 through 60698), CMS established a transitional add-on payment adjustment for certain new and innovative renal dialysis equipment and supplies under the ESRD PPS, under the authority of section 1881(b)(14)(D)(iv) of the Act, in order to support ESRD facility use and beneficiary access to these new technologies. We established this payment adjustment to help address the unique circumstances experienced by ESRD facilities when incorporating new and innovative equipment and supplies into their businesses and to support ESRD facilities transitioning or testing these products during the period when they are new to market. We added § 413.236 to establish the eligibility criteria and payment policies for the transitional add-on payment adjustment for new and innovative renal dialysis equipment and supplies, which we call the TPNIES.

We established in § 413.236(b) that for dates of service occurring on or after January 1, 2020, CMS will provide the TPNIES to an ESRD facility for furnishing a covered equipment or supply only if the item: (1) Has been designated by CMS as a renal dialysis service under § 413.171, (2) is new, meaning it is granted marketing authorization by FDA on or after January 1, 2020, (3) is commercially available by January 1 of the particular calendar year, meaning the year in which the payment adjustment would take effect, (4) has a HCPCS application submitted in accordance with the official Level II HCPCS coding procedures by September 1 of the particular calendar year, (5) is innovative, meaning it meets the criteria

specified in § 412.87(b)(1) and related guidance, and (6) is not a capital-related asset that an ESRD facility has an economic interest in through ownership (regardless of the manner in which it was acquired).

Regarding the innovation requirement in § 413.236(b)(5), in the CY 2020 ESRD PPS final rule (84 FR 60690), we stated that CMS will use the following criteria to evaluate substantial clinical improvement (SCI) for purposes of the TPNIES under the ESRD PPS, based on the inpatient hospital prospective payment system (IPPS) SCI criteria in § 412.87(b)(1) and related guidance: Section 412.87(b)(1) includes the criteria used under the IPPS new technology add-on payment (NTAP) to determine whether a new technology represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries. First, and most importantly, the totality of the circumstances is considered when making a determination that a new renal dialysis equipment or supply represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries. Second, a determination that a new renal dialysis equipment or supply represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries means one of the following:

- The new renal dialysis equipment or supply offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments; or
- The new renal dialysis equipment or supply offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable, or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods, and there must also be evidence that use of the new renal dialysis service to make a diagnosis affects the management of the patient; or
- The use of the new renal dialysis equipment or supply significantly improves clinical outcomes relative to renal dialysis services previously available as demonstrated by one or more of the following: (1) A reduction in at least one clinically significant adverse event, including a reduction in mortality or a clinically significant complication; (2) a decreased rate of at least one subsequent diagnostic or

therapeutic intervention; (3) a decreased number of future hospitalizations or physician visits; (4) a more rapid beneficial resolution of the disease process treatment including, but not limited to, a reduced length of stay or recovery time; (5) an improvement in one or more activities of daily living; (6) an improved quality of life; or (7) a demonstrated greater medication adherence or compliance; or,

- The totality of the circumstances otherwise demonstrates that the new renal dialysis equipment or supply substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries.

Third, evidence from the following published or unpublished information sources from within the United States (U.S.) or elsewhere may be sufficient to establish that a new renal dialysis equipment or supply represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries: Clinical trials, peer reviewed journal articles; study results; meta-analyses; consensus statements; white papers; patient surveys; case studies; reports; systematic literature reviews; letters from major healthcare associations; editorials and letters to the editor; and public comments. Other appropriate information sources may be considered.

Fourth, the medical condition diagnosed or treated by the new renal dialysis equipment or supply may have a low prevalence among Medicare beneficiaries. Fifth, the new renal dialysis equipment or supply may represent an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of a subpopulation of patients with the medical condition diagnosed or treated by the new renal dialysis equipment or supply.

We also established a process modeled after IPPS's process of determining if a new medical service or technology meets the SCI criteria specified in § 412.87(b)(1). Specifically, similar to the IPPS NTAP, we wanted to align our goals with the agency's efforts to transform the healthcare delivery system for the ESRD beneficiary through competition and innovation to provide patients with better value and results. We believe it is appropriate to facilitate access to new and innovative equipment and supplies through add-on payments similar to the IPPS NTAP program and to provide innovators with standard criteria for both inpatient and outpatient settings. In § 413.236(c), we established

a process for our announcement of TPNIES determinations and a deadline for consideration of new renal dialysis equipment or supply applications under the ESRD PPS. CMS will consider whether a new renal dialysis equipment or supply meets the eligibility criteria specified in § 413.236(b) and summarize the applications received in the annual ESRD PPS proposed rules. Then, after consideration of public comments, we will announce the results in the **Federal Register** as part of our annual updates and changes to the ESRD PPS in the ESRD PPS final rule. The TPNIES applications for CY 2021 are discussed in section II.C. of this proposed rule. CMS will only consider a complete application received by CMS by February 1 prior to the particular calendar year, meaning the year in which the payment adjustment would take effect, and FDA marketing authorization for the equipment or supply must occur by September 1 prior to the particular calendar year. We stated in the CY 2020 ESRD PPS final rule (80 FR 60690) that we would establish a workgroup of CMS medical and other staff to review the studies and papers submitted as part of the TPNIES application, the public comments we receive, and the FDA marketing authorization and HCPCS application information and assess the extent to which the product provides SCI over current technologies.

We established § 413.236(d) to provide a payment adjustment for a new and innovative renal dialysis equipment or supply. Section 413.236(d)(1) states that the TPNIES is paid for 2-calendar years. Section 413.236(d)(2) provides that, following payment of the TPNIES, the ESRD PPS base rate will not be modified and the new and innovative renal dialysis equipment or supply will become an eligible outlier service as provided in § 413.237.

Under § 413.236(e)(1), the Medicare Administrative Contractors (MACs) on behalf of CMS will establish prices for the new and innovative renal dialysis equipment and supplies that meet the eligibility criteria specified in § 413.236(b) using verifiable information from the following sources of information, if available: (1) The invoice amount, facility charges for the item, discounts, allowances, and rebates; (2) the price established for the item by other MACs and the sources of information used to establish that price; (3) payment amounts determined by other payers and the information used to establish those payment amounts; and (4) charges and payment amounts required for other equipment and

supplies that may be comparable or otherwise relevant.

b. Proposed Changes to Eligibility for the TPNIES

Currently, in § 413.236(b)(2), one eligibility requirement for the TPNIES is that an equipment or supply must be new, meaning it is granted marketing authorization by FDA on or after January 1, 2020. In establishing this requirement, we tied what is considered new to January 1, 2020, the effective date of the TPNIES policy. We explained in the CY 2020 ESRD PPS final rule (84 FR 60685) that by including FDA marketing authorizations on or after January 1, 2020, we intended to support ESRD facility use and beneficiary access to the latest technological improvements to renal dialysis equipment and supplies. While we continue to believe it is appropriate to tie the newness requirement to the date of the FDA marketing authorization for the reasons discussed in the CY 2020 ESRD PPS final rule, we do not believe newness should be tied to the effective date of the TPNIES policy going forward, for the reasons discussed below. In addition, we believe this eligibility criterion should address when an equipment or supply is no longer considered new. Under the current requirement at § 413.236(b)(2), we could receive an application for the TPNIES for equipment and supplies many years after FDA marketing authorization, when the equipment is no longer new.

In the CY 2020 ESRD PPS proposed rule (84 FR 38353), while we proposed to define new renal dialysis equipment and supplies as those that are granted marketing authorization by FDA on or after January 1, 2020, we also solicited comment on whether a different FDA marketing authorization date, for example, on or after January 1, 2019, might be appropriate. We explained in the CY 2020 ESRD PPS final rule (84 FR 60688 through 60689) that while some commenters expressed support for the proposed definition, most of the comments were focused on the merits of establishing a date for newness that precedes the effective date of the TPNIES policy and whether all renal dialysis equipment and supplies must seek FDA marketing authorization. None of the comments addressed whether tying TPNIES eligibility to the TPNIES policy effective date or any fixed date would limit the TPNIES to new and innovative equipment and supplies.

After careful consideration of these comments, we decided to finalize the proposed definition of new to mean the

renal dialysis equipment or supply was granted marketing authorization by FDA on or after January 1, 2020. We stated that while we appreciated that manufacturers of renal dialysis equipment and supplies that were granted FDA marketing authorization in prior years would want these products to be eligible for the TPNIES, our goal is not to provide a payment adjustment for all the products that have received FDA marketing authorization or for products that have had limited market uptake, but rather to establish an add-on payment adjustment for certain new and innovative products in order to support uptake by ESRD facilities of new and innovative renal dialysis equipment and supplies. In addition, we stated that we appreciated the complex issues the commenters raised if we were to select an earlier FDA marketing authorization date, and believed our approach will avoid the need to address those issues. We noted that the ESRD PPS is a prospective payment system, in which changes are generally made prospectively, including eligibility requirements for add-on payment adjustments. In addition, we noted that this FDA marketing authorization date of January 1, 2020 or later is consistent with the TDAPA's definition of a new renal dialysis drug or biological product.

After further consideration, we no longer believe an item should be considered new based on the TPNIES policy effective date of January 1, 2020. Rather, we believe that it is important for the TPNIES policy to provide a window of time when a new renal dialysis equipment or supply is considered new to provide transparency to potential applicants. We note that, under this proposal, the TPNIES policy would still be effective as of January 1, 2020 and therefore no equipment or supply receiving FDA marketing authorization before January 1, 2020 would be eligible for the TPNIES. However, we are proposing to revise § 413.236(b)(2) to remove "on or after January 1, 2020" and to reflect the definition of new to mean, within 3 years beginning on the date of FDA marketing authorization. By defining new in this manner, we would be giving entities wishing to apply for the TPNIES for their equipment or supply 3 years beginning on the date of FDA marketing authorization in which to submit their applications, while still limiting eligibility for the TPNIES to new technologies. We are proposing a 3-year newness window to be consistent with the timeframes under the IPPS NTAP requirements in § 412.87(b)(2). Under

the NTAP, new technologies are considered to be new for 2 or 3 years after the point at which data begin to become available reflecting the inpatient hospital code assigned to the new service or technology. We note, under the hospital outpatient PPS, the pass-through payment application for a medical device must also be submitted within 3 years from the date of the initial FDA approval or clearance, if required, unless there is a documented, verifiable delay in U.S. market availability after FDA approval or clearance is granted, in which case CMS will consider the pass-through payment application if it is submitted within 3 years from the date of market availability.

In addition, we propose to revise § 413.236(b) to remove "For dates of service occurring on or after January 1, 2020" and to revise § 413.236(a) to reflect the January 1, 2020 effective date of the TPNIES policy finalized in the CY 2020 ESRD PPS final rule. We also are proposing other revisions to this paragraph, which are discussed in section II.B.3.b.(1) of this proposed rule.

We are seeking comment on our proposal to define new for purposes of the TPNIES eligibility as within 3 years beginning on the date of FDA marketing authorization. In addition, it is our understanding that there may be situations in which a manufacturer has FDA marketing authorization for an item, but the process of manufacturing the item has been delayed, for example, by a Public Health Emergency (PHE), such as the current COVID-19 pandemic. Therefore, we are also seeking comment on the number of years for an item to be considered new, or if newness should be based on different criteria such as the later of marketing availability or the date of FDA marketing authorization.

Currently, § 413.236(b)(4) requires applicants for the TPNIES to have a HCPCS application submitted in accordance with the official Level II HCPCS coding procedures by September 1 of the particular calendar year. Section 413.236(c) currently requires applicants for TPNIES to have the FDA marketing authorization for the equipment or supply by September 1 prior to the particular calendar year.

After publication of the CY 2020 ESRD PPS final rule, CMS updated its HCPCS Level II coding procedures to enable shorter and more frequent HCPCS code application cycles. Beginning in January 2020, CMS implemented quarterly HCPCS code application opportunities for drugs and biological products, and biannual application opportunities for DMEPOS

and other non-drug, non-biological items and services.

As the Administrator of CMS announced² in May 2019, this change is part of CMS' broader, comprehensive initiative to foster innovation and expedite adoption of and patient access to new medical technologies. CMS' delivery on this important goal necessitated procedural changes that balance the need to code more frequently with the amount of time necessary to accurately process applications. CMS has released two documents with detailed information on the updated HCPCS Level II coding procedures, application instructions, and deadlines for 2020. Both documents, Healthcare Common Procedure Coding System (HCPCS) Level II Coding Procedures,³ and Healthcare Common Procedure Coding System (HCPCS) Level II Code Modification Application Instructions for the 2020 Coding Cycle⁴ are available on the CMS website. Under the new guidance, coding cycles for DMEPOS items and services will occur no less frequently than biannually. For 2020, the deadline for HCPCS Level II code applications for biannual Coding Cycle 1 for DMEPOS items and services was January 6, 2020 with issuance of final code decisions occurring July 2020. These final code decisions are effective October 1, 2020. For biannual Coding Cycle 2, the code application deadline for DMEPOS items and services is June 29, 2020 with issuance of final code decisions occurring January 2021 or earlier. These final code decisions are effective April 1, 2021. These dates are specific for 2020 and may change annually. Specific dates for biannual Coding Cycles 1 and 2 for future years will be published on the HCPCS website annually.

Under the new biannual Coding Cycle 2 for DMEPOS items and services, in order to obtain a final HCPCS Level II code decision by January 1, 2021, the applicant must submit a complete HCPCS Level II code application along with the FDA marketing authorization documentation to CMS by June 29, 2020. In light of the change to biannual coding cycles, we have reassessed the TPNIES eligibility criterion in § 413.236(b)(4), which is related to submission of the HCPCS Level II code

² <https://www.cms.gov/newsroom/press-releases/cms-outlines-comprehensive-strategy-foster-innovation-transformative-medical-technologies>.

³ <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/2018-11-30-HCPCS-Level2-Coding-Procedure.pdf>.

⁴ <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/2020-HCPCS-Application-and-Instructions.pdf>.

application as well as § 413.236(c), which discusses the deadlines for consideration of new renal dialysis equipment or supply applications and have found that they conflict with the current HCPCS Level II coding guidelines.

Because our HCPCS Level II coding guidelines require that applicants submit complete code applications for DMEPOS items and services to CMS by the deadline for biannual Coding Cycle 2 as specified in the HCPCS Level II coding guidance on the CMS website in order for a final HCPCS Level II code decision to be made by the following January 1 and require that documentation of FDA marketing authorization be submitted by the applicant to CMS by the HCPCS Level II code application deadline, we propose to align the TPNIES regulation at § 413.236(b)(4) and (c) with these guidelines. We believe this alignment would provide consistency across CMS processes and transparency on deadlines for applicants for the TPNIES. In the event of a delay in the final HCPCS Level II coding decision, a miscellaneous code will be used in the interim until a final coding decision is made.

We are also proposing to correct a technical error in § 413.236(b)(4), which requires the HCPCS application to be submitted by September 1 “of” the particular calendar year, meaning the year in which the payment adjustment would take effect. In accordance with the TPNIES policy, we would need to have the HCPCS application submitted “prior to” the particular calendar year to be able to make a determination of TPNIES eligibility for payment to occur in the particular calendar year.

Therefore, we propose to revise at § 413.236(b)(4) to add the word “complete” and to replace “September 1” with “the HCPCS Level II code application deadline for biannual Coding Cycle 2 for DMEPOS items and services as specified in the HCPCS Level II coding guidance on the CMS website,” and replace the word “of” with “prior to” to reflect that the HCPCS code application for biannual Coding Cycle 2 must be complete and submitted as specified in the HCPCS Level II coding guidance on the CMS website prior to the particular calendar year. This HCPCS application submission deadline for a HCPCS Level II code application may result in a final HCPCS code determination by January 1, when the TPNIES payment would begin. We note that, for 2020 biannual Coding Cycle 2, final decisions on HCPCS Level II codes issued by January 1, 2021 are not effective until April 1, 2021. For this

reason, during this interim period, we propose to use a miscellaneous HCPCS code to provide the TPNIES payment. In the event of a delay in the final HCPCS Level II coding decision, a miscellaneous code will be used in the interim until the later effective date. In addition, we propose a technical change to § 413.236(b)(4) to be consistent with how CMS references the HCPCS Level II coding procedures. That is, we propose to revise § 413.236(b)(4) from “official Level II HCPCS coding procedures” to “HCPCS Level II coding procedures on the CMS website”.

In addition, we propose to revise § 413.236(c) to replace “September 1” with “the HCPCS Level II code application deadline for biannual Coding Cycle 2 for DMEPOS items and services as specified in the HCPCS Level II coding guidance on the CMS website” to reflect that FDA marketing authorization for the new and innovative equipment or supply must accompany the HCPCS application prior to the particular calendar year in order for the item to qualify for the TPNIES in the next calendar year. Although applicants for TPNIES may submit a TPNIES application while the equipment or supply is undergoing the FDA marketing authorization process (since the deadline for the TPNIES application is February 1), under our proposal, FDA marketing authorization of the equipment or supply must be granted prior to the HCPCS Level II code application deadline. If FDA marketing authorization is not granted prior to the HCPCS Level II code application deadline, the TPNIES application would be denied and the applicant would need to reapply and submit an updated application by February 1 of the following year or within 3 years beginning on the date of FDA marketing authorization, in accordance with the proposed revisions to § 413.236(b)(2) discussed previously in this proposed rule.

Currently, § 413.236(b)(5) requires that the new equipment or supply be innovative, meaning it meets the criteria specified in § 412.87(b)(1) of this chapter and related guidance. As discussed previously in this proposed rule, § 412.87(b)(1) includes the criteria used under the IPPS NTAP to determine whether a new technology represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. In § 413.236(b)(5) we adopt the same SCI criteria to determine if a new renal dialysis equipment or supply is innovative for purposes of the TPNIES under the ESRD PPS. We also stated in

the CY 2020 ESRD PPS final rule (84 FR 60690) our intention to adopt any future modifications to the IPPS SCI criteria so that innovators would have standard criteria to meet for both settings. While we adopted the IPPS SCI criteria under § 412.87(b)(1), we did not adopt the alternative pathway for breakthrough devices (84 FR 42296) under the ESRD PPS.

In the fiscal year (FY) 2020 IPPS final rule (84 FR 42180 through 42181), CMS codified additional SCI criteria that had been included in manuals and other sub-regulatory guidance. In accordance with the reference to § 412.87(b)(1), we adopted the FY 2020 IPPS changes to the SCI criteria, and any future changes to the SCI criteria, by reference, unless and until we make any changes to the criteria through notice-and-comment rulemaking. Although the codification of the related guidance for the IPPS SCI occurred prior to the publication of the CY 2020 ESRD PPS final rule, we inadvertently included a reference to related guidance in § 413.236(b)(5). Therefore, we propose to revise § 413.236(b)(5) to remove “and related guidance” to reflect that all related SCI guidance has now been incorporated into § 412.87(b)(1).

3. Proposed Expansion of the TPNIES for New and Innovative Capital-Related Assets That are Home Dialysis Machines When Used in the Home for a Single Patient

a. Background

In response to the proposed expansion of the TDAPA in the CY 2019 ESRD PPS proposed rule, we received several comments regarding payment under the ESRD PPS for certain new, innovative equipment and supplies used in the treatment of ESRD. For example, as we described in the CY 2019 ESRD PPS final rule (83 FR 56972), a device manufacturer and device manufacturer association asked CMS to establish a transitional add-on payment adjustment for new FDA approved devices. They commented on the lack of FDA approved or authorized new devices for use in an ESRD facility, highlighting the need to promote dialysis device innovation.

Other commenters, including a professional association and a large dialysis organization (LDO) urged CMS and other relevant policymakers to prioritize the development of a clear pathway to add new devices to the ESRD PPS bundled payment (83 FR 56973). A home dialysis patient group also expressed concern regarding the absence of a pathway for adding new devices to the ESRD PPS bundled

payment, stating that it left investors and industry wary of investing in the development of new devices for patients. In response, we expressed appreciation for the commenters' thoughts regarding payment for new and innovative devices, and stated that because we did not include any proposals regarding this issue in the CY 2019 ESRD PPS proposed rule, we considered these suggestions to be beyond the scope of that rule.

However, in response to this feedback, in the CY 2020 ESRD PPS proposed rule (84 FR 38354 through 38355), we agreed that additional payment for certain renal dialysis equipment and supplies may be warranted under specific circumstances. We proposed to provide the TPNIES for certain new and innovative renal dialysis equipment and supplies furnished by ESRD facilities, but exclude from eligibility capital-related assets, which are defined in the Provider Reimbursement Manual (Pub. L. 15-1) (chapter 1, section 104.1) as assets that a provider has an economic interest in through ownership (regardless of the manner in which they were acquired). The Provider Reimbursement Manual is available on the CMS website at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021929>. Examples of capital-related assets for ESRD facilities are dialysis machines and water purification systems.

As we explained in the CY 2020 ESRD PPS proposed rule (84 FR 38354), we did not believe capital-related assets should be eligible for additional payment through the TPNIES because the cost of these items is captured in cost reports, they depreciate over time, and they are generally used for multiple patients. In addition, we noted that since the costs of these items are reported in the aggregate, there is considerable complexity in establishing a cost on a per treatment basis. For these reasons, we therefore believed capital-related assets should be excluded from eligibility for the TPNIES at that time, and we proposed an exclusion to the eligibility criteria in § 413.236(b)(6). However, we noted that CMS uses capital-related asset cost data from cost reports in regression analyses to refine the ESRD PPS so that the cost of any new capital-related assets is accounted for in the ESRD PPS payment.

In response to the proposed exclusion of capital-related assets, we received comments from a device manufacturers' association, which stated that since most medical equipment is purchased as a capital-related asset, the TPNIES

effectively would exclude the innovative equipment identified in the title of the adjustment. The association asserted that meaningful clinical improvements and patient experience improvements are arguably more likely to come from innovation outside single-use supplies. The association maintained that expanding the TPNIES to include medical equipment, regardless of how it is purchased by the provider, would stimulate greater investment in a broader array of new technologies for ESRD patients.

In response, we stated in the CY 2020 ESRD PPS final rule (84 FR 60688) that we recognize that accounting for renal dialysis service equipment can vary depending on the individual ESRD facility's business model. For example, when the owner of the capital-related asset retains title, then the renal dialysis service equipment is a depreciable asset and depreciation expense could be itemized. When there is no ownership of the renal dialysis service equipment, then the item is recorded as an operating expense.

In addition, in response to comments regarding capital leases, we noted that regulations at § 413.130(b)(1) specify that leases and rentals are includable in capital-related costs if they relate to the use of assets that would be depreciable if the provider owned them outright. We stated that in the future, we will be closely examining the treatment of capital-related assets under Medicare, including our regulations at § 412.302 regarding capital costs in inpatient hospitals and § 413.130, as they relate to accounting for capital-related assets, including capital leases and the newly implemented guidance for finance lease arrangements, to determine if similar policies would be appropriate under the ESRD PPS.

b. Proposed Additional Payment for New and Innovative Capital-Related Assets That are Home Dialysis Machines When Used in the Home for a Single Patient

Following publication of the CY 2020 ESRD PPS final rule, in which we finalized the TPNIES policy, we continued to study the issue of payment for capital-related assets under the ESRD PPS, taking into account information from a wide variety of stakeholders and recent developments and initiatives regarding kidney care. For example, we received additional comments and information from dialysis equipment and supply manufacturers, and a Technical Expert Panel (TEP) meeting held in December 2019, regarding the need for additional

payment for capital-related assets under the ESRD PPS.

We also took into account the President's Executive Order, signed on July 10, 2019, aimed at transforming kidney care in America. The Executive Order discussed many new initiatives, including the launch of a public awareness campaign to prevent patients from going into kidney failure and proposals for the Secretary to support research regarding preventing, treating, and slowing progression of kidney disease and encouraging the development of breakthrough technologies to provide patients suffering from kidney disease with better options for care than those that are currently available. Currently, most dialysis is furnished at ESRD facilities. In-center dialysis can be time-consuming and burdensome for patients. In addition, the current system prioritizes payment to in-center dialysis and the goal of the agency is to incentivize in-home dialysis. A key focus of the Executive Order is the effort to encourage in-home dialysis.

The Executive Order is available at: <https://www.whitehouse.gov/presidential-actions/executive-order-advancing-american-kidney-health/>.

In conjunction with the Executive Order, HHS laid out three goals for improving kidney health (see <https://www.hhs.gov/about/news/2019/07/10/hhs-launches-president-trump-advancing-american-kidney-health-initiative.html>):

- Reducing the number of Americans developing ESRD by 25 percent by 2030.
- Having 80 percent of new ESRD patients in 2025 either receiving dialysis at home or receiving a transplant; and
- Doubling the number of kidneys available for transplant by 2030.

In addition, in connection with the President's Executive Order, on July 10, 2019, CMS issued a proposed rule (84 FR 34478) to implement a new mandatory payment model, known as the ESRD Treatment Choices (ETC) Model, which would provide new incentives to encourage the provision of dialysis in the home. The proposed ETC Model would be a mandatory payment model, focused on encouraging greater use of home dialysis and kidney transplants for ESRD beneficiaries among ESRD facilities and Managing Clinicians located in selected geographic areas.

Lastly, we note that ESRD patients who receive in-center dialysis are particularly vulnerable during a PHE and other disasters, and that greater use of home dialysis modalities may expose these patients to less risk. The U.S. is responding to an outbreak of respiratory

disease caused by a novel (new) coronavirus that was first detected in China and which has now been detected in more than 190 countries internationally, and all 50 States and the District of Columbia. The virus has been named “severe acute respiratory syndrome coronavirus 2” (SARS-CoV-2) and the disease it causes has been named “coronavirus disease 2019” (“COVID-19”).

On January 30, 2020, the International Health Regulations Emergency Committee of the World Health Organization (WHO) declared the outbreak a “Public Health Emergency of international concern.” On January 31, 2020, the Secretary determined that a PHE exists for the U.S. to aid the nation’s healthcare community in responding to COVID-19 and on April 21, 2020, the Secretary renewed, effective April 26, 2020, the determination that a PHE exists. On March 11, 2020, the WHO publicly declared COVID-19 a pandemic. On March 13, 2020, the President of the U.S. declared the COVID-19 pandemic a national emergency.

The experience of multiple countries across the globe has demonstrated that older patients and patients with multiple comorbidities and underlying health conditions are patients who are more susceptible to the virus and have a higher risk of morbidity than younger patients without underlying health conditions. Per the CDC, the risk factors for COVID-19 include older adults and people of any age who have serious underlying medical conditions, such as diabetes and chronic kidney disease undergoing dialysis. Medicare’s ESRD population aligns with the profile of patients who are more susceptible to COVID-19. Therefore, it is important to reduce the risk of infection and this can be done through isolating patients from in-center exposure by encouraging home dialysis.

Home dialysis would mitigate the risks associated with dialysis for these patients if the pandemic lasts longer than expected or is refractory in some way.

(1) Proposed Expansion of the TPNIES to Certain New and Innovative Capital-Related Assets That are Home Dialysis Machines When Used in the Home for a Single Patient

In response to the President’s Executive Order, the various HHS home dialysis initiatives, and the particular benefits of home dialysis for ESRD beneficiaries during PHEs like the current COVID-19 pandemic, which we discussed in the previous section, and in consideration of the feedback we

have received from stakeholders, we agree that additional payment through the TPNIES for certain capital-related assets may be warranted under specific circumstances outlined in this section of the proposed rule. We note that in the CY 2020 ESRD PPS final rule (84 FR 60607), we specifically excluded capital-related assets from the TPNIES. In commenting on the proposed rule, most stakeholders expressed concern that the TPNIES would exclude capital-related assets. In our response to commenters, we acknowledged that significant innovation and technology improvement is occurring with dialysis machines and peritoneal dialysis cyclers, as well as innovation in the efficiency and effectiveness of water systems. However, at that time we did not have enough information regarding current usage of the various financial and leasing arrangements, such as those involving capital leases for depreciable assets versus operating leases recorded as operating expenses. In addition, we noted that we would need to assess methodological issues regarding depreciation to determine whether TPNIES eligibility for these items would be appropriate.

We stated in the CY 2020 ESRD PPS final rule that we needed to further study the specifics of the various business arrangements for equipment related to renal dialysis services. This would include items that are: (1) Purchased in their entirety and owned as capital-related assets; (2) assets that are acquired through a capital lease arrangement; (3) equipment obtained through a finance lease and recorded as an asset per the Financial Accounting Standards Board (FASB) guidance on leases (Topic 842) effective for fiscal years beginning after December 15, 2018;⁵ or (4) equipment obtained through an operating lease and recorded as an operating expense. In addition to the variety of business arrangements, we noted, there are unknown issues relating to ownership of the item and who retains title, which may affect the equipment’s maintenance expenses for capital-related assets.

Further, there is the issue of single use versus multiple use for capital-related assets used for renal dialysis services. For example, some capital-related assets used in-center and in the home setting, such as skilled nursing facilities (SNFs) and nursing facilities, may be used by multiple patients in a day, and by multiple patients over their useful lifetime. Specifically, equipment

classified as capital-related assets may be refurbished and used by another patient. For example, capital-related assets used by multiple patients in a day could be Hoyer lifts to transfer patients and wheelchair scales. In this proposed rule, we are not proposing to include capital-related assets with multi-patient usage as being eligible for the TPNIES because we are supporting the President’s Executive Order and HHS goals of promoting home dialysis, which involves a single machine for patient use. In addition, as we discussed earlier in this section, it is more complicated to develop a per treatment payment amount for those items. However, we seek comments on this aspect of our proposal, and we intend to gather additional information about how ESRD facilities obtain their capital-related assets that have multi-patient usage in future meetings with the TEP.

As we further studied this issue, we determined that one business arrangement, that is, where the capital-related assets are purchased in their entirety and owned as capital-related assets, could be considered for TPNIES eligibility. We continue to analyze other business arrangements, but we understand that this arrangement is more straightforward due to ownership being clear, retained at the end of the TPNIES period, and on the facility’s balance sheet. CMS’ intent would be to pay for assets that are owned, whether purchased or attained through a capital lease. The entity who holds the title to the asset is the legal owner. At the end of the TPNIES period, the entity retains ownership of the asset. We would not pay TPNIES for equipment that is leased, as the ESRD facility has no ownership rights. We believe this is an appropriate initial step to support home dialysis.

In support of the HHS goals and initiatives to increase home dialysis following the President’s Executive Order, we propose to provide the TPNIES for eligible new and innovative capital-related assets that are home dialysis machines when used in the home. We would limit the payment for new and innovative dialysis machines to those used for home dialysis in order to target the additional payment through the TPNIES to equipment that supports the various home dialysis initiatives currently underway, as discussed previously in this section of the proposed rule. As more ESRD patients and their nephrologists and other clinicians opt for home dialysis modalities, we would seek to support ESRD facility use and beneficiary access to the latest technological improvements to hemodialysis and peritoneal dialysis

⁵ https://www.fasb.org/jsp/FASB/Document_C/DocumentPage?cid=1176167901010&acceptedDisclaimer=true.

home dialysis machines. As we explained in prior ESRD PPS rules establishing the TDAPA and TPNIES, ESRD facilities face unique challenges in incorporating new renal dialysis drugs, biological products, equipment and supplies into their businesses and these add-on payment adjustments are intended to support ESRD facilities' use of new technologies during the uptake period for these new products.

To codify our proposals for expanding the TPNIES to include capital-related assets that are home dialysis machines when used in the home for a single patient, we are proposing further revisions to § 413.236, in addition to the revisions proposed earlier in section II.B.2 of this proposed rule.

Specifically, we propose to revise the heading at § 413.236(a) and adding paragraphs (a)(1) and (2) to distinguish this paragraph as both the "basis and definitions." We propose to define "capital-related asset" at § 413.236(a)(2) as an asset that an ESRD facility has an economic interest in through ownership (regardless of the manner in which it was acquired) and is subject to depreciation. Equipment obtained by the ESRD facility through operating leases are not considered capital-related assets. This proposed definition is based on the definition of "depreciable assets" in the Provider Reimbursement Manual (chapter 1, section 104.1). The Provider Reimbursement Manual is available on the CMS website at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021929>.

We propose to define "home dialysis machines" at § 413.236(a)(2) as hemodialysis machines and peritoneal dialysis cyclers in their entirety, meaning that one new part of a machine does not make the entire capital-related asset new, that receive FDA marketing authorization for home use and when used in the home for a single patient. FDA provides a separate marketing authorization for equipment intended for home use, and this proposal is focused on supporting efforts to increase home dialysis.

We propose to define "particular calendar year" at § 413.236(a)(2) as the year in which the payment adjustment specified in paragraph (d) of § 413.236 would take effect. We also propose to include definitions for the terms "depreciation," "straight-line depreciation method," and "useful life," which are discussed in section II.B.3.b.(2) of this proposed rule.

We propose to revise § 413.236(b)(6) to provide an exception to the general exclusion for capital-related assets from eligibility for the TPNIES for capital-

related assets that are home dialysis machines when used in the home for a single patient and that meet the other eligibility criteria in the proposed revisions to § 413.236(b). We also propose to remove "that an ESRD facility has an economic interest in through ownership (regardless of the manner in which it was acquired)" in § 413.236(b)(6) since we are proposing a separate definition for "capital-related asset" at § 413.236(a)(2).

Under this proposal, we would continue to exclude other capital-related assets from the TPNIES that are not home dialysis machines when used in the home because those items would not be advancing HHS's goal of increasing home dialysis. Examples of capital-related assets that would continue to be excluded from TPNIES are water purification systems and dialysis machines when they are used in-center. We continue to believe that we should not provide additional payment for these capital-related assets because the cost of these items are captured in cost reports and reported in the aggregate, depreciate over time, are generally used for multiple patients and, most importantly, it would not support the goal of increasing use of home dialysis. However, capital-related assets that are home dialysis machines when used in the home are intended for use by a single patient and can be reported on a per treatment basis on the ESRD facility's claim. These characteristics provide for a simple methodology for aligning the use of the asset with the per treatment TPNIES payment.

As we stated previously in this section, we are not proposing to expand the TPNIES eligibility to in-center dialysis machines or home dialysis machines when they are used in-center. Currently, our focus is promoting the increase in home dialysis rather than in-center dialysis. In addition, in-center dialysis machines are used by multiple patients each day and would require additional analysis, along with 72X claims and cost report modifications, in order to provide payment. For this same reason, we are not proposing to provide the TPNIES for home dialysis machines when they are used in SNFs and nursing facilities and are used by multiple patients each day.

We believe the SCI criteria required under § 413.236(b)(5), with our proposed revisions, and the process used to evaluate SCI currently applicable to TPNIES equipment and supplies are also appropriate for identifying new and innovative capital-related assets that are home dialysis machines that are worthy of temporary additional payment under the ESRD

PPS. This approach would provide consistent criteria and evaluation for all equipment and supplies that are potentially eligible for the TPNIES. In addition, we want to ensure that we do not pay the TPNIES for new home dialysis machines that are substantially similar to existing machines and not truly innovative.

Under our proposal, we would utilize the determination process we established last year for the TPNIES and those requirements we are proposing to revise in section II.B.2 of this proposed rule. That is, pursuant to § 413.236(c), interested parties would submit all information necessary for determining that the home dialysis machine meets the TPNIES eligibility criteria listed in § 413.236(b). This would include FDA marketing authorization information, the HCPCS application information, and studies submitted as part of these two standardized processes, an approximate date of commercial availability, and any information necessary for SCI criteria evaluation. For example, clinical trials, peer reviewed journal articles, study results, meta-analyses, systematic literature reviews, and any other appropriate information sources can be considered. We note, for purposes of determining whether the home dialysis machine is new under § 413.236(b)(2), we would look at the date the machine is granted marketing authorization by FDA for home use.

Using our current process at § 413.236(c), we would provide a description of the new home dialysis machine and pertinent facts in the ESRD PPS proposed rule so the public may comment on them and then publish the results in the ESRD PPS final rule. We would consider whether the new home dialysis machine meets the eligibility criteria specified in the proposed revisions to § 413.236(b) and announce the results in the **Federal Register** as part of our annual updates and changes to the ESRD PPS. Per § 413.236(c), we would only consider, for additional payment using the TPNIES for a particular calendar year, an application for a capital-related asset that is a home dialysis machine we receive by February 1 prior to the particular calendar year. If the application is not received by February 1, the application would be denied and the applicant would need to reapply within 3 years beginning on the date of FDA marketing authorization in order to be considered for the TPNIES, in accordance with the proposed revisions to § 413.236(b)(2). We note, applicants are expected to submit information on the price of their home dialysis machine as part of the TPNIES application. While we

recognize this information is proprietary, CMS requests this information along with the equipment or supply's projected utilization.

For example, under our proposed revisions to § 413.236, in order for a particular home dialysis machine to be eligible for the TPNIES under the ESRD PPS beginning in CY 2022, CMS must receive a complete application meeting our requirements no later than February 1, 2021. FDA marketing authorization and submission of the HCPCS Level II code application for Coding Cycle 2 for DMEPOS items and services must occur as specified in the HCPCS Level II coding guidance on the CMS website. We would include a discussion of the new capital-related asset that is a home dialysis machine in the CY 2022 ESRD PPS proposed rule and the CMS final determination would be announced in the CY 2022 ESRD PPS final rule. If the home dialysis machine qualifies for the TPNIES, the payment adjustment would begin January 1, 2022 with a miscellaneous code and the designated HCPCS code would be effective April 1, 2022.

(2) Pricing of New and Innovative Capital-Related Assets That are Home Dialysis Machines When Used in the Home

As we explained in the CY 2020 ESRD PPS final rule (84 FR 60692), we are not aware of pricing compendia currently available to price renal dialysis equipment and supplies for the TPNIES. We also noted that, unlike new renal dialysis drugs and biological products eligible for the TDAPA, ASP and WAC pricing do not exist for renal dialysis equipment and supplies, including capital-related assets that are home dialysis machines.

In addition, as we explained in the CY 2020 ESRD PPS final rule (84 FR 60692), ESRD facility charges are gross values; that is, charges before the application of allowances and discounts deductions. We believe the TPNIES payment amount should reflect the discounts, rebates and other allowances the ESRD facility (or its parent company) receives. These terms are defined in the Provider Reimbursement Manual (chapter 8).⁶ If the TPNIES payment amount does not reflect discounts, rebates and other allowances, the price would likely exceed the facility's cost for the item and result in higher co-insurance obligations for beneficiaries.

For this reason, in § 413.236(e), we established an invoice-based approach

for MACs to use on behalf of CMS to price new and innovative renal dialysis equipment and supplies that meet the eligibility criteria for the TPNIES. We require the MACs to establish a price, using verifiable information from the following sources of information, if available: (1) The invoice amount, facility charges for the item, discounts, allowances, and rebates; (2) the price established for the item by other MACs and the sources of information used to establish that price; (3) payment amounts determined by other payers and the information used to establish those payment amounts; and (4) charges and payment amounts required for other equipment and supplies that may be comparable or otherwise relevant. As discussed in the CY 2020 ESRD PPS final rule (84 FR 60692 through 60693), in order to maintain consistency with the IPPS NTAP payment policy and to mitigate the Medicare expenditures incurred as a result of the TPNIES, we finalized a policy at § 413.236(d) to base the TPNIES payment on 65 percent of the MAC-determined price.

We believe that the invoice-based approach established for the TPNIES also should be applied to capital-related assets that are home dialysis machines, which are the focus of this proposal. However, capital-related assets that are home dialysis machines when used in the home for a single patient are depreciable assets as defined in the Provider Reimbursement Manual (chapter 1, section 104), which defines depreciation as "that amount which represents a portion of the depreciable asset's cost or other basis which is allocable to a period of operation." The Provider Reimbursement Manual provides the American Institute of Certified Public Accountant's definition of depreciation as a process of cost allocation: "Depreciation accounting is a system of accounting which aims to distribute the cost or other basic value of tangible capital assets, less salvage (if any), over the estimated useful life of the unit (which may be a group of assets) in a systematic and rational manner. It is a process of allocation, not of valuation. Depreciation for the year is the portion of the total charge under such a system that is allocated to the year."

Because capital-related assets that are home dialysis machines when used in the home for a single patient are depreciable assets, we are proposing to apply a 5-year straight-line depreciation method to determine the basis of the TPNIES for these items. The Provider Reimbursement Manual, (chapter 1, section 116.1) discusses the straight-line depreciation method as a method where

the annual allowance is determined by dividing the cost of the capital-related asset by the years of useful life. Section 104.17 of the Provider Reimbursement Manual discusses that the useful life of a capital-related asset is its expected useful life to the provider, not necessarily the inherent useful or physical life. Further, the manual provides that under the Medicare program, only the American Hospital Association (AHA) guidelines may be used in selecting a proper useful life for computing depreciation.

Using the Provider Reimbursement Manual definitions as the basis, we propose to define the following terms at § 413.236(a)(2): "depreciation" as the amount that represents a portion of the capital-related asset's cost and that is allocable to a period of operation; "straight-line depreciation method" as a method in accounting in which the annual allowance is determined by dividing the cost of the capital-related asset by the years of useful life; and "useful life" as the estimated useful life of a capital-related asset is its expected useful life to the ESRD facility, not necessarily the inherent useful or physical life.

In keeping with the Medicare policy, we propose to rely on the AHA guidelines to determine the useful life of a capital-related asset that is a home dialysis machine. That is, the useful life of a home dialysis machine is 5 years. Since we are proposing a methodology using the Provider Reimbursement Manual's guidance, we believe these terms are appropriate to codify for purposes of calculating the price of a home dialysis machine that is a capital-related asset.

That is, under § 413.236(e), MACs, on behalf of CMS, would establish prices, using verifiable information as described above, for new and innovative capital-related assets that are home dialysis machines when used in the home for a single patient that meet the eligibility criteria specified in § 413.236(b). This price would be the only element used to determine the total cost basis for applying the straight-line depreciation method. For example, we would exclude financing, sales tax, freight, installation and testing, excise taxes, legal or accounting fees, and maintenance. This specific price element would act as the proxy for the all-encompassing cost basis in other accounting methodologies. Using the straight-line depreciation method, we would divide the MAC-determined price by the useful life of the capital-related asset that is a home dialysis machine when used in the home for a

⁶ Medicare Provider Reimbursement Manual (chapter 8). Available at: <https://www.cms.gov/Regulations-and-Guidance/Transmittals/Downloads/R450PR1.pdf>.

single patient. The resulting number is the annual allowance.

We considered other depreciation methods, such as units of production and accelerated depreciation methods such as double declining balance and sum-of-the-years-digits, but concluded that these methods would be more complex to implement and that the simpler method would be preferable for the calculation of an add-on payment adjustment. In addition, since we are not reimbursing the cost of the equipment, nor are we revising the ESRD PPS at the end of the two-year add-on payment period, based on the information gathered, we believe this policy is appropriate for encouraging and supporting the uptake of new and innovative renal dialysis equipment and supplies.

In order to determine the basis of payment for capital-related assets that are home dialysis machines when used in the home for a single patient, we are proposing certain additional steps that MACs would take after determining the price to develop the TPNIES per treatment payment amount. That is, we propose to add paragraph (f) to § 413.236 to establish the pricing for the TPNIES for capital-related assets that are home dialysis machines when used in the home for a single patient that meet the eligibility criteria in § 413.236(b). We are proposing in § 413.236(f)(1) that, using the price determined under § 413.236(e), the MACs would follow a 2-step methodology for calculating a pre-adjusted per treatment amount.

Under the first step, the MACs would determine the annual allowance, that represents the amount of the MAC-determined price that is allocable to 1 year. To calculate the annual allowance, we propose that the MACs would use the straight-line depreciation method by dividing the MAC-determined price by the useful life of the home dialysis machine. In accordance with the straight-line depreciation method, the MAC would divide the MAC-determined price by 5 (the useful life for dialysis machines established by the AHA is 5 years).

Under the second step, the MACs would calculate a pre-adjusted per treatment amount by dividing the annual allowance by the expected number of treatments to yield a pre-adjusted per treatment amount. That is, the MACs would establish a pre-adjusted per treatment amount by dividing the annual allowance by the number of treatments expected to be furnished in a year. For home dialysis machines that are expected to be used 3 times per week, the annual number of

treatments is 156 (3 treatments/week \times 52 weeks = 156 treatments/year). We note, for purposes of calculating this TPNIES add-on payment adjustment, MACs do not determine the number of expected treatments. This information will be provided by CMS through the Change Request.

We note, below in section II.B.3.b.(3) of this proposed rule, we are considering an alternative to our proposal. The alternative is a methodology that would offset the pre-adjusted per treatment amount by a value that would reflect the amount already included in the ESRD PPS base rate.

Finally, consistent with the policies finalized last year in § 413.236(d) for the TPNIES, we propose to revise § 413.236(d) to reflect that we would pay 65 percent of the pre-adjusted per treatment amount for capital-related assets that are home dialysis machines when used in the home for a single patient. That is, as discussed in the CY 2020 ESRD PPS final rule (84 FR 60692 through 60693), we finalized a policy to base the TPNIES payment on 65 percent of the MAC-determined price in order to maintain consistency with the IPPS NTAP payment policy and to mitigate the Medicare expenditures incurred as a result of the TPNIES. Therefore, we propose to pay 65 percent of the pre-adjusted per treatment amount for these machines.

For example, for a home dialysis machine that has a MAC-determined price of \$25,000 and a 5-year useful life, using the proposed straight-line depreciation method, the annual allowance would equate to \$5,000 per year. At 156 treatments per year, the pre-adjusted per treatment amount is \$32.05 ($\$5,000/156$) and 65 percent of that amount equals a TPNIES per treatment add-on payment amount of \$20.83 ($\$32.05 \times .65$). We note that at this time the useful life of 5 years and the expected number of treatments of 156 is fixed since these variables have been established by CMS. That is, as we discussed above in this section with regard to the use of the AHA guidance that dialysis machines have a 5-year useful life. With regard to the expected number of treatments, this is based on the current payment policy of 3 treatments per week.

In the future, if an innovative home dialysis machine is designed to require fewer treatments per week relative to existing machines, MACs, using the same methodology could account for fewer treatments in the denominator in the calculation of the pre-adjusted per treatment amount. This change to the denominator would allow the total

TPNIES amount paid at the end of the year to be equivalent to the annual allowance and we would then proceed with the calculation to achieve the targeted 65 percent of that annual allowance. The following example demonstrates that the annual allowance stays fixed even if there is a change in the number of treatments the machine is expected to deliver per year. The TPNIES payment adjustment would increase because the annual allowance would be spread over less treatments so that the targeted amount would pay out by the end of the year.

For a home dialysis machine that is used two times per week, using the same example as above, the annual allowance for TPNIES would remain at \$5,000 per year. Two treatments per week equals 104 treatments per year (2 treatments per week \times 52 weeks = 104 treatments per year). The annual allowance (numerator) would be divided by the number of treatments (denominator). At 104 treatments per year, the pre-adjusted per treatment amount would be \$48.08 ($\$5,000/104$ treatments = \$48.08); and 65 percent of that amount would yield a TPNIES per treatment add-on payment of \$31.25.

For a peritoneal dialysisycler that is used 7 times per week, using the same example as above, the annual allowance for TPNIES would remain at \$5,000 per year. A daily modality, or 7 treatments per week, equals 364 treatments per year (7 treatments per week \times 52 weeks = 364 treatments per year). The annual allowance (numerator) would be divided by the number of treatments (denominator). At 364 treatments per year, the pre-adjusted per treatment amount would be \$13.74 ($\$5,000/364$ treatments = \$13.74); and 65 percent of that amount would yield a TPNIES per treatment add-on payment of \$8.93.

The methodology is the same. The two variables, regardless of modality, are: (1) The cost of the machine used to calculate annual allowance (2) the number of treatments the machine is expected to deliver per year.

We are inviting public comment on using this proposed method for determining the pricing of capital-related assets that are home dialysis machines when used in the home for a single patient and that meet the eligibility criteria in § 413.236(b), including the proposed revisions discussed in section II.B.3.b.(1) of this proposed rule.

Consistent with the TPNIES policy and in accordance with § 413.236(d)(1), we would apply the TPNIES for these home dialysis machines for 2-calendar years from the effective date of the change request, which would coincide

with the effective date of a CY ESRD PPS final rule. In the change request we would specify that the add-on payment adjustment would be applicable to home dialysis treatments and provide the billing guidance on how to report the miscellaneous code for the eligible item on the claim until a permanent HCPCS is available.

We believe the duration of the application of the TPNIES for all equipment and supplies determined eligible for this payment adjustment should be consistent, and that 2 years would be a sufficient timeframe for ESRD facilities to set up or adjust business practices so that there is seamless access to the new and innovative home dialysis machines. In addition, in light of the current COVID-19 pandemic, stakeholders are increasingly aware of the importance of having home dialysis readily available and in place to prevent ESRD patients from being exposed to asymptomatic or pre-symptomatic infections that contribute to COVID-19 transmission by having to utilize in-center dialysis.

We further believe providing the TPNIES for 2 years for these machines would address the stakeholders' concerns regarding additional payment to account for higher cost of more new and innovative home dialysis machines that they believe may not be adequately captured by the dollars allocated in the ESRD PPS base rate. That is, this TPNIES would give these new and innovative home dialysis machines a foothold in the market and the opportunity to compete with the other dialysis machines. We note that this proposal would increase Medicare expenditures, which would result in increases to ESRD beneficiary co-insurance, since we have not previously provided a payment adjustment for any capital-related assets in the past. However, to support HHS's goals and initiatives to increase home dialysis and the President's Executive Order of July 10, 2019, we believe that the proposed expansion of the TPNIES to capital-related assets that are home dialysis machines when used in the home for a single patient would be appropriate to support ESRD facility uptake in furnishing new and innovative renal dialysis equipment to ESRD patients.

The intent of the proposed TPNIES for new and innovative capital-related assets that are home dialysis machines when used in the home would be to provide a transition period to support ESRD facility use of these machines when they are new and innovative to the market. At this time, we do not believe that it would be appropriate to add dollars to the ESRD PPS base rate

for new and innovative home dialysis machines because, as noted previously in this proposed rule, the ESRD PPS base rate includes the cost of equipment and supplies used to furnish a dialysis treatment.

While we would monitor renal dialysis service utilization trends during the TPNIES payment period, we propose that these capital-related assets that are home dialysis machines when used in the home would not be eligible outlier services as provided in § 413.237. As assets, capital-related home dialysis machines are distinct from operating expenses such as the disposable supplies and leased equipment with no conveyed ownership rights. These expenses are generally accounted for on a per patient basis and therefore, when used in excess of the average constitute outlier use, which makes them eligible for outlier payments.

Therefore, we are proposing revisions at § 413.236(d)(2) to reflect that following payment of the TPNIES for new and innovative capital-related assets that are home dialysis machines when used in the home for a single patient, the ESRD PPS base rate will not be modified and the equipment would not be an eligible outlier service as provided in § 413.237. In addition, we propose revisions at § 413.237(a)(1)(v) to exclude capital-related assets that are home dialysis machines when used in the home for a single patient from outlier eligibility after the TPNIES period ends. We also propose minor editorial changes to paragraph (a)(1)(i) to remove the semicolon at the end of the sentence and adding a period in its place; and in paragraph (a)(1)(iv) to remove “; and” and adding a period in its place.

With regard to the TPNIES application, we would post any final changes to both the timing of the various eligibility criteria and the content of the TPNIES application to the TPNIES website, along with information about all renal dialysis equipment and supplies that CMS has determined are eligible for the TPNIES, consistent with the policies we finalize in the CY 2021 ESRD PPS final rule. The TPNIES website is available at: <https://www.cms.gov/medicare/esrd-pps/esrd-pps-transitional-add-payment-adjustment-new-and-innovative-equipment-and-supplies-tpnies>.

(3) Alternative To Offset the Proposed Pre-Adjusted per Treatment Amount

In the CY 2011 ESRD PPS final rule (75 FR 49075), we stated that when we computed the ESRD PPS base rate, we used the composite rate payments made

under Part B in 2007 for dialysis in computing the ESRD PPS base rate. These are identified in Table 19 of the CY 2011 ESRD PPS final rule (75 FR 49075) as “composite rate services.” Sections 1881(b)(14)(A)(i) and 1881(b)(14)(B) of the Act specify the renal dialysis services that must be included in the ESRD PPS bundled payment, which includes items and services that were part of the composite rate for renal dialysis services as of December 31, 2010. As we indicated in the CY 2011 ESRD PPS proposed rule (74 FR 49928), the case-mix adjusted composite payment system represents a limited PPS for a bundle of outpatient renal dialysis services that includes maintenance dialysis treatments and all associated services including historically defined dialysis-related drugs, laboratory tests, equipment, supplies and staff time (74 FR 49928). In the CY 2011 ESRD PPS final rule (75 FR 49062), we noted that total composite rate costs in the per treatment calculation included costs incurred for training expenses, as well as all home dialysis costs.

In addition, as we discussed in section II.B.3.(a) of this proposed rule, these composite rate payments, and consequently the ESRD PPS base rate, include an amount associated with the costs of capital-related assets that are home dialysis machines. We believe that capital-related assets are distinguishable from drugs and biological products and supplies, which are single-use or disposable items, whereas ESRD facilities can continually use a home dialysis machine past its expected useful life and for multiple patients (consecutively). Therefore, we believe that an offset of the proposed TPNIES pre-adjusted per treatment amount may be warranted so that the TPNIES would cover the estimated marginal costs of new and innovative home dialysis machines. That is, ESRD facilities using the new and innovative home dialysis machine would receive a per treatment payment to cover some of the cost of the new machine per treatment minus a per treatment payment amount that we estimate to be included in the ESRD PPS base rate for current home dialysis machines that they already own.

To account for the costs already paid through the ESRD PPS base rate for current home dialysis machines that ESRD facilities already own, we are considering an alternative to our proposal that would include an additional step to calculating the TPNIES. That is, we could apply an offset to the pre-adjusted per treatment amount. The following section discusses

the methodology that we would use for determining the offset. If we were to adopt an offset in the final rule, we would add language to the proposed § 413.236(f) specifying the methodology used to compute the offset and its place—the final step—in the computation of the TPNIES for new and innovative home dialysis machines that meet the eligibility criteria.

(4) Methodology for Estimating Home Machine and Equipment Cost per Home Treatment

As we stated in the previous section, we considered proposing an alternative to our proposed methodology for calculating the pre-adjusted per treatment amount, which would involve applying an offset to the pre-adjusted per treatment amount. This section discusses the methodology we would use for determining the value of that offset, which would be an estimate of an average home dialysis machine and equipment cost per hemodialysis (HD)-equivalent home dialysis treatment to use as the offset amount. First, we would estimate annualized dialysis machine and equipment cost and treatment counts from cost reports for each ESRD facility for 2018. Next, we would compute an HD-equivalent home dialysis treatment percentage for each ESRD facility by dividing the annualized HD-equivalent home treatment counts by the annualized HD-equivalent treatment counts across all modalities. Then we would apply the home dialysis treatment percentage to the annualized dialysis machine and equipment cost to derive an estimated home dialysis machine and equipment cost for each ESRD facility. Next, we would aggregate the home dialysis machine and equipment costs and the HD-equivalent home treatment counts to derive an average home dialysis machine and equipment cost per home dialysis treatment across all ESRD facilities. Finally, we would scale the 2018 average home dialysis machine and equipment cost per home treatment to 2021 using the ESRDB market basket less productivity update for CY 2019, CY 2020, and CY 2021.

We would obtain annualized dialysis machine and equipment cost and treatment counts from freestanding and hospital-based ESRD cost reports. For independent/freestanding ESRD facilities, we would use renal facility cost reports (CMS form 265–11). We would obtain dialysis machine and equipment cost⁷ from Worksheet B,

Column 4, and sum up Lines 8.01 through 17.02. We would obtain dialysis treatment counts by modality from Worksheet D, Column 1, Lines 1 through 10. Since home continuous ambulatory peritoneal dialysis (CAPD) and continuous cycling peritoneal dialysis (CCPD) treatment counts are reported in patient weeks, we would multiply them by 3 to get HD-equivalent counts. Finally, we would aggregate all home dialysis treatment counts to obtain each ESRD facility's HD-equivalent home dialysis treatment counts and we would aggregate the treatment counts to obtain each freestanding ESRD facility's HD-equivalent dialysis treatment counts for all modalities.

For hospital-based ESRD facilities, we would use hospital cost reports (CMS form 2552–10). We would obtain dialysis machine and equipment cost from Worksheet I–2, Column 2, and then sum up Lines 2 through 11. We would derive dialysis treatment counts by modality from Worksheet I–4, Column 1, Lines 1 through 10. Home CAPD and CCPD treatment counts are reported in patient weeks, so we would multiply them by 3 to get HD-equivalent counts. We would aggregate all home treatment counts to obtain each hospital-based ESRD facility's HD-equivalent home dialysis treatment counts. Then we would aggregate all treatment counts to obtain each hospital-based ESRD facility's HD-equivalent dialysis treatment counts for all modalities.

Using this methodology for both freestanding and hospital-based ESRD facilities, it would result in an offset of \$9.23. If we were to adopt this approach, the MAC would apply this additional step in calculating the pre-adjusted per treatment amount. That is, the MAC would offset the pre-adjusted per treatment amount by deducting \$9.23 to account for the costs already paid through the ESRD PPS base rate for current home dialysis machines that ESRD facilities already own. We believe that this methodology would provide an approximation of the cost of the home dialysis machine in the base rate. Further, we believe that deducting it from the calculated pre-adjusted per treatment amount would be reasonable because the beneficiary would not be using two home dialysis machines at the same time and at the end of the 2 years, the ESRD facility would retain

maintenance on the dialysis machine and any support equipment. This also includes the equipment and associated maintenance and repair and installation costs necessary to render the water acceptable for use in dialysis.

ownership of the asset, specifically, the home dialysis machine.

Using the example from section II.B.3.b.(2), for a home dialysis machine that has a MAC-determined price of \$25,000 and a 5-year useful life, using the proposed straight-line depreciation method, the annual allowance would equate to \$5,000 per year. At 156 treatments per year, the pre-adjusted per treatment amount is \$32.05 (\$5,000/156). Under the alternative to our proposal, we would offset the pre-adjusted per treatment amount of \$32.05 by deducting \$9.23. This would result in a per treatment amount of \$22.82 (\$32.05 – \$9.23). Then 65 percent of that amount would equal a TPNIES per treatment add-on payment amount of \$14.83 (\$22.82 × .65). After the TPNIES per treatment add-on payment amount is determined, there would be no change in the policy as described in section II.B.3.b.(2) with regard to the TPNIES duration, process, and the ESRD PPS base rate, that is, no change to the base rate would be made.

We are soliciting comment on this alternative approach to apply an offset to the proposed pre-adjusted per treatment amount. We are specifically soliciting comment on the methodology we would use to compute the value of the offset.

4. Proposed CY 2021 ESRD PPS Update

a. Proposed CY 2021 ESRD Bundled (ESRDB) Market Basket Update, Productivity Adjustment, and Labor-Related Share

In accordance with section 1881(b)(14)(F)(i) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Affordable Care Act, beginning in 2012, the ESRD PPS payment amounts are required to be annually increased by an ESRD market basket increase factor and reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. The application of the productivity adjustment may result in the increase factor being less than 0.0 for a year and may result in payment rates for a year being less than the payment rates for the preceding year. The statute also provides that the market basket increase factor should reflect the changes over time in the prices of an appropriate mix of goods and services used to furnish renal dialysis services.

As required under section 1881(b)(14)(F)(i) of the Act, CMS developed an all-inclusive ESRD Bundled (ESRDB) input price index (75 FR 49151 through 49162). In the CY 2015 ESRD PPS final rule we rebased and revised the ESRDB input price

⁷ Here dialysis machine and equipment cost includes capital-related costs of moveable equipment, rented and/or purchased, and

index to reflect a 2012 base year (79 FR 66129 through 66136). Subsequently, in the CY 2019 ESRD PPS final rule, we finalized a rebased ESRDB input price index to reflect a 2016 base year (83 FR 56951 through 56962).

Although “market basket” technically describes the mix of goods and services used for ESRD treatment, this term is also commonly used to denote the input price index (that is, cost categories, their respective weights, and price proxies combined) derived from a market basket. Accordingly, the term “ESRDB market basket,” as used in this document, refers to the ESRDB input price index.

We propose to use the CY 2016-based ESRDB market basket as finalized and described in the CY 2019 ESRD PPS final rule (83 FR 56951 through 56962) to compute the CY 2021 ESRDB market basket increase factor based on the best available data. Consistent with historical practice, we propose to estimate the ESRDB market basket update based on IHS Global Inc.’s (IGI), forecast using the most recently available data. IGI is a nationally recognized economic and financial forecasting firm that contracts with CMS to forecast the components of the market baskets. Using this methodology and the IGI first quarter 2020 forecast of the CY 2016-based ESRDB market basket (with historical data through the fourth quarter of 2019), the proposed CY 2021 ESRDB market basket increase factor is 2.2 percent.

Under section 1881(b)(14)(F)(i) of the Act, for CY 2012 and each subsequent year, the ESRD market basket percentage increase factor shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. The multifactor productivity (MFP) is derived by subtracting the contribution of labor and capital input growth from output growth. We finalized the detailed methodology for deriving the MFP projection in the CY 2012 ESRD PPS final rule (76 FR 40503 through 40504). The most up-to-date MFP projection methodology is available on the CMS website at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/Downloads/MFPMethodology.pdf>. Using this methodology and the IGI first quarter 2020 forecast, the proposed MFP adjustment for CY 2021 (the 10-year moving average of MFP for the period ending CY 2021) is projected to be 0.4 percent.

As a result of these provisions, the proposed CY 2021 ESRD market basket adjusted for MFP is 1.8 percent (2.2 – 0.4). This market basket increase

is calculated by starting with the proposed CY 2021 ESRDB market basket percentage increase factor of 2.2 percent and reducing it by the proposed MFP adjustment (the 10-year moving average of MFP for the period ending CY 2021) of 0.4 percent.

As is our general practice, we are proposing that if more recent data become available after the publication of this proposed rule and before the publication of the final rule (for example, a more recent estimate of the market basket update or MFP), we would use such data, if appropriate, to determine the final CY 2021 market basket update and/or MFP adjustment.

For the CY 2021 ESRD payment update, we propose to continue using a labor-related share of 52.3 percent for the ESRD PPS payment, which was finalized in the CY 2019 ESRD PPS final rule (83 FR 56963).

b. The Proposed CY 2021 ESRD PPS Wage Indices

(1) Background

Section 1881(b)(14)(D)(iv)(II) of the Act provides that the ESRD PPS may include a geographic wage index payment adjustment, such as the index referred to in section 1881(b)(12)(D) of the Act, as the Secretary determines to be appropriate. In the CY 2011 ESRD PPS final rule (75 FR 49200), we finalized an adjustment for wages at § 413.231. Specifically, CMS adjusts the labor-related portion of the base rate to account for geographic differences in the area wage levels using an appropriate wage index, which reflects the relative level of hospital wages and wage-related costs in the geographic area in which the ESRD facility is located. We use the Office of Management and Budget’s (OMB’s) core-based statistical area (CBSA)-based geographic area designations to define urban and rural areas and their corresponding wage index values (75 FR 49117). OMB publishes bulletins regarding CBSA changes, including changes to CBSA numbers and titles. The bulletins are available online at <https://www.whitehouse.gov/omb/information-for-agencies/bulletins/>.

For CY 2021, we would update the wage indices to account for updated wage levels in areas in which ESRD facilities are located using our existing methodology. We use the most recent pre-floor, pre-reclassified hospital wage data collected annually under the inpatient PPS. The ESRD PPS wage index values are calculated without regard to geographic reclassifications authorized under sections 1886(d)(8) and (d)(10) of the Act and utilize pre-

floor hospital data that are unadjusted for occupational mix. For CY 2021, the updated wage data are for hospital cost reporting periods beginning on or after October 1, 2016 and before October 1, 2017 (FY 2017 cost report data).

We have also adopted methodologies for calculating wage index values for ESRD facilities that are located in urban and rural areas where there is no hospital data. For a full discussion, see CY 2011 and CY 2012 ESRD PPS final rules at 75 FR 49116 through 49117 and 76 FR 70239 through 70241, respectively. For urban areas with no hospital data, we compute the average wage index value of all urban areas within the state to serve as a reasonable proxy for the wage index of that urban CBSA, that is, we use that value as the wage index. For rural areas with no hospital data, we compute the wage index using the average wage index values from all contiguous CBSAs to represent a reasonable proxy for that rural area. We apply the statewide urban average based on the average of all urban areas within the state to Hinesville-Fort Stewart, Georgia (78 FR 72173), and we apply the wage index for Guam to American Samoa and the Northern Mariana Islands (78 FR 72172). We note that for the CY 2020 ESRD PPS final rule, we did not apply the statewide urban average to Carson City, Nevada because hospital data was available to compute the wage index.

A wage index floor value (0.5000) is applied under the ESRD PPS as a substitute wage index for areas with very low wage index values. Currently, all areas with wage index values that fall below the floor are located in Puerto Rico. However, the wage index floor value is applicable for any area that may fall below the floor. A description of the history of the wage index floor under the ESRD PPS can be found in the CY 2019 ESRD PPS final rule (83 FR 56964 through 56967).

An ESRD facility’s wage index is applied to the labor-related share of the ESRD PPS base rate. In the CY 2019 ESRD PPS final rule (83 FR 56963), we finalized a labor-related share of 52.3 percent, which is based on the 2016-based ESRDB market basket. Thus, for CY 2021, the labor-related share to which a facility’s wage index would be applied is 52.3 percent.

For CY 2021, in addition to proposing to update the ESRD PPS wage index to use more recent hospital wage data, we are also proposing to adopt new OMB delineations and a transition policy in a budget-neutral manner as discussed in sections II.B.4.b.(2) and II.B.4.b.(3), respectively, of this proposed rule. The proposed CY 2021 ESRD PPS wage

index is set forth in Addendum A and is available on the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices.html>. Addendum A provides a crosswalk between the CY 2020 wage index for an ESRD facility using the current OMB delineations in effect in CY 2020, the CY 2021 wage index using the current OMB delineations in effect in CY 2020, and the CY 2021 wage index using the proposed new OMB delineations. Addendum B provides an ESRD facility-level impact analysis. In Addendum B are the proposed transition wage index values that would be in effect in CY 2021 if these proposed changes are finalized. Addendum B is available on the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices.html>.

(2) Proposed Implementation of New OMB Labor Market Delineations

As discussed previously in this proposed rule, the wage index used for the ESRD PPS is calculated using the most recent pre-floor, pre-reclassified hospital wage data collected annually under the inpatient PPS and is assigned to an ESRD facility on the basis of the labor market area in which the ESRD facility is geographically located. ESRD facility labor market areas are delineated based on the CBSAs established by the OMB. In accordance with our established methodology, we have historically adopted through rulemaking CBSA changes that are published in the latest OMB bulletin. Generally, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. However, OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses.

In the CY 2015 ESRD PPS final rule (79 FR 66137 through 66142), we finalized changes to the ESRD PPS wage index based on the newest OMB delineations, as described in OMB Bulletin No. 13–01⁸ issued on February 28, 2013. We implemented these changes with a 2-year transition period (79 FR 66142). OMB Bulletin No. 13–01 established revised delineations for U.S. Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas based on the 2010 Census. OMB Bulletin No. 13–01

⁸ <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2013/b13-01.pdf>.

also provided guidance on the use of the delineations of these statistical areas using standards published on June 28, 2010 in the **Federal Register** (75 FR 37246 through 37252).

On July 15, 2015, OMB issued OMB Bulletin No. 15–01,⁹ which updated and superseded OMB Bulletin No. 13–01 issued on February 28, 2013. The attachment to OMB Bulletin No. 15–01 provided detailed information on the update to statistical areas since February 28, 2013. These updates were based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to the U.S. Census Bureau population estimates for July 1, 2012 and July 1, 2013.

On August 15, 2017, OMB issued OMB Bulletin No. 17–01,¹⁰ which updated and superseded OMB Bulletin No. 15–01 issued on July 15, 2015. The attachment to OMB Bulletin No. 17–01 provided detailed information on the update to statistical areas since July 15, 2015. These updates were based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to the U.S. Census Bureau population estimates for July 1, 2014 and July 1, 2015. In OMB Bulletin No. 17–01, OMB announced a new urban CBSA, Twin Falls, Idaho (CBSA 46300).

On April 10, 2018, OMB issued OMB Bulletin No. 18–03¹¹ which updated and superseded OMB Bulletin No. 17–01 issued on August 15, 2017. The attachment to OMB Bulletin No. 18–03 provided detailed information on the update to statistical areas since August 15, 2017. On September 14, 2018, OMB issued OMB Bulletin No. 18–04,¹² which updated and superseded OMB Bulletin No. 18–03 issued on April 10, 2018. OMB Bulletin Numbers 18–03 and 18–04 established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and provided guidance on the use of the delineations of these statistical areas. These updates were based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to the U.S. Census Bureau population

⁹ <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2015/15-01.pdf>.

¹⁰ <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2017/b-17-01.pdf>.

¹¹ <https://www.whitehouse.gov/wp-content/uploads/2018/04/OMB-BULLETIN-NO.-18-03-Final.pdf>.

¹² <https://www.whitehouse.gov/wp-content/uploads/2018/09/Bulletin-18-04.pdf>.

estimates for July 1, 2015 and July 1, 2016.

While OMB Bulletin No. 18–04 is not based on new census data, there were some material changes to the CBSA-based geographic area designations based on the new OMB delineations. For example, if we adopt the new OMB delineations, there would be new CBSAs, urban counties that would become rural, rural counties that would become urban, and some existing CBSAs would be split apart. We believe that the new OMB delineations accurately reflect the local economies and wage levels of the areas where ESRD facilities are located. We believe it is important for the ESRD PPS to use the new OMB delineations available in order to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts and labor market conditions. We further believe that using the new OMB delineations would increase the integrity of the ESRD PPS wage index system by creating a more accurate representation of geographic variations in wage levels.

Therefore, we are proposing to adopt the new OMB delineations established in OMB Bulletin No. 18–04 effective for CY 2021 under the ESRD PPS. We are also proposing a wage index transition applicable to all ESRD facilities that experience negative impacts due to the proposed implementation of the new OMB delineations. This transition policy is discussed in section II.B.4.b.(3) of this proposed rule.

We note that, on March 6, 2020, OMB issued OMB Bulletin 20–01 (available at <https://www.whitehouse.gov/wp-content/uploads/2020/03/Bulletin-20-01.pdf>). While the March 6, 2020 OMB Bulletin 20–01 was not issued in time for development of this proposed rule, we were able to review the updates it provides and have determined that they are minor. While we do not believe the minor updates included in OMB Bulletin 20–01 would impact our CY 2021 proposed updates to the CBSA-based labor market area delineations, if appropriate, we would propose any updates from this Bulletin in the CY 2022 ESRD PPS proposed rule.

For CY 2021, to implement the new OMB delineations established in OMB Bulletin No. 18–04 under the ESRD PPS, it is necessary to identify the new labor market area delineation for each affected county and ESRD facility in the U.S. We discuss these changes in more detail in the following sections.

(a) Urban Counties That Would Become Rural Under the New OMB Delineations

As previously discussed in this proposed rule, we are proposing to

implement the new OMB labor market area delineations (based upon the 2010 Decennial Census data) beginning in CY 2021. Our analysis of the new OMB delineations shows that a total of 34

counties (and county equivalents) that are currently considered part of an urban CBSA would be considered located in a rural area, beginning in CY 2021. Table 1 shows the 34 urban

counties that would be rural if we finalize our proposal to adopt the new OMB delineations beginning in CY 2021.

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TABLE 1: CY 2021 Proposed Urban to Rural CBSA Crosswalk

FIPS County Code	County/County Equivalent	State	Current CBSA	CBSA Title
01127	WALKER	AL	13820	Birmingham-Hoover, AL
12045	GULF	FL	37460	Panama City, FL
13007	BAKER	GA	10500	Albany, GA
13235	PULASKI	GA	47580	Warner Robins, GA
15005	KALAWAO	HI	27980	Kahului-Wailuku-Lahaina, HI
17039	DE WITT	IL	14010	Bloomington, IL
17053	FORD	IL	16580	Champaign-Urbana, IL
18143	SCOTT	IN	31140	Louisville/Jefferson County, KY-IN
18179	WELLS	IN	23060	Fort Wayne, IN
19149	PLYMOUTH	IA	43580	Sioux City, IA-NE-SD
20095	KINGMAN	KS	48620	Wichita, KS
21223	TRIMBLE	KY	31140	Louisville/Jefferson County, KY-IN
22119	WEBSTER	LA	43340	Shreveport-Bossier City, LA
26015	BARRY	MI	24340	Grand Rapids-Wyoming, MI
26159	VAN BUREN	MI	28020	Kalamazoo-Portage, MI
27143	SIBLEY	MN	33460	Minneapolis-St. Paul-Bloomington, MN-WI
28009	BENTON	MS	32820	Memphis, TN-MS-AR
29119	MC DONALD	MO	22220	Fayetteville-Springdale-Rogers, AR-MO
30037	GOLDEN VALLEY	MT	13740	Billings, MT
31081	HAMILTON	NE	24260	Grand Island, NE
38085	SIOUX	ND	13900	Bismarck, ND
40079	LE FLORE	OK	22900	Fort Smith, AR-OK
45087	UNION	SC	43900	Spartanburg, SC
46033	CUSTER	SD	39660	Rapid City, SD
47081	HICKMAN	TN	34980	Nashville-Davidson--Murfreeseboro--Franklin, TN
48007	ARANSAS	TX	18580	Corpus Christi, TX
48221	HOOD	TX	23104	Fort Worth-Arlington, TX
48351	NEWTON	TX	13140	Beaumont-Port Arthur, TX
48425	SOMERVELL	TX	23104	Fort Worth-Arlington, TX
51029	BUCKINGHAM	VA	16820	Charlottesville, VA
51033	CAROLINE	VA	40060	Richmond, VA
51063	FLOYD	VA	13980	Blacksburg-Christiansburg-Radford, VA
53013	COLUMBIA	WA	47460	Walla Walla, WA
53051	PEND OREILLE	WA	44060	Spokane-Spokane Valley, WA

We are proposing that the wage data for all ESRD facilities located in the counties listed above would now be considered rural, beginning in CY 2021, when calculating their respective State's rural wage index. We recognize that rural areas typically have lower area wage index values than urban areas, and ESRD facilities located in these counties may experience a negative impact in their payment under the ESRD PPS due to the proposed adoption of the new

OMB delineations. A discussion of the proposed wage index transition policy due to these proposed changes is available in section II.B.4.b.(3) of this proposed rule.

(b) Rural Counties That Would Become Urban Under the New OMB Delineations

As previously discussed in this proposed rule, we are proposing to implement the new OMB labor market area delineations (based upon the 2010

Decennial Census data) beginning in CY 2021. Our analysis of the new OMB delineations shows that a total of 47 counties (and county equivalents) that are currently considered located in rural areas would be considered located in urban CBSAs, beginning in CY 2021. Table 2 shows the 47 rural counties that would be urban if we finalize our proposal to adopt the new OMB delineations beginning in CY 2021.

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TABLE 2: CY 2021 Proposed Rural to Urban CBSA Crosswalk

FIPS County Code	County/County Equivalent	State Name	Proposed CBSA	Proposed CBSA Title
01063	GREENE	AL	46220	Tuscaloosa, AL
01129	WASHINGTON	AL	33660	Mobile, AL
05047	FRANKLIN	AR	22900	Fort Smith, AR-OK
12075	LEVY	FL	23540	Gainesville, FL
13259	STEWART	GA	17980	Columbus, GA-AL
13263	TALBOT	GA	17980	Columbus, GA-AL
16077	POWER	ID	38540	Pocatello, ID
17057	FULTON	IL	37900	Peoria, IL
17087	JOHNSON	IL	16060	Carbondale-Marion, IL
18047	FRANKLIN	IN	17140	Cincinnati, OH-KY-IN
18121	PARKE	IN	45460	Terre Haute, IN
18171	WARREN	IN	29200	Lafayette-West Lafayette, IN
19015	BOONE	IA	11180	Ames, IA
19099	JASPER	IA	19780	Des Moines-West Des Moines, IA
20061	GEARY	KS	31740	Manhattan, KS
21043	CARTER	KY	26580	Huntington-Ashland, WV-KY-OH
22007	ASSUMPTION	LA	12940	Baton Rouge, LA
22067	MOREHOUSE	LA	33740	Monroe, LA
25011	FRANKLIN	MA	44140	Springfield, MA
26067	IONIA	MI	24340	Grand Rapids-Kentwood, MI
26155	SHIAWASSEE	MI	29620	Lansing-East Lansing, MI
27075	LAKE	MN	20260	Duluth, MN-WI
28031	COVINGTON	MS	25620	Hattiesburg, MS
28051	HOLMES	MS	27140	Jackson, MS
28131	STONE	MS	25060	Gulfport-Biloxi, MS
29053	COOPER	MO	17860	Columbia, MO
29089	HOWARD	MO	17860	Columbia, MO
30095	STILLWATER	MT	13740	Billings, MT
37007	ANSON	NC	16740	Charlotte-Concord-Gastonia, NC-SC
37029	CAMDEN	NC	47260	Virginia Beach-Norfolk-Newport News, VA-NC
37077	GRANVILLE	NC	20500	Durham-Chapel Hill, NC
37085	HARNETT	NC	22180	Fayetteville, NC
39123	OTTAWA	OH	45780	Toledo, OH
45027	CLARENDON	SC	44940	Sumter, SC
47053	GIBSON	TN	27180	Jackson, TN
47161	STEWART	TN	17300	Clarksville, TN-KY
48203	HARRISON	TX	30980	Longview, TX

FIPS County Code	County/County Equivalent	State Name	Proposed CBSA	Proposed CBSA Title
48431	STERLING	TX	41660	San Angelo, TX
51097	KING AND QUEEN	VA	40060	Richmond, VA
51113	MADISON	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV
51175	SOUTHAMPTON	VA	47260	Virginia Beach-Norfolk-Newport News, VA-NC
51620	FRANKLIN CITY	VA	47260	Virginia Beach-Norfolk-Newport News, VA-NC
54035	JACKSON	WV	16620	Charleston, WV
54065	MORGAN	WV	25180	Hagerstown-Martinsburg, MD-WV
55069	LINCOLN	WI	48140	Wausau-Weston, WI
72001	ADJUNTAS	PR	38660	Ponce, PR
72083	LAS MARIAS	PR	32420	Mayagüez, PR

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We are proposing that when calculating the area wage index, beginning with CY 2021, the wage data for ESRD facilities located in these counties would be included in their new respective urban CBSAs. Typically, ESRD facilities located in an urban area receive a higher wage index value than or equal wage index value to ESRD facilities located in their state's rural area. A discussion of the proposed wage index transition policy due to these

proposed changes is available in section II.B.4.b.(3) of this proposed rule.

(c) Urban Counties That Would Move to a Different Urban CBSA Under the New OMB Delineations

In certain cases, adopting the new OMB delineations would involve a change only in CBSA name and/or number, while the CBSA continues to encompass the same constituent counties. For example, CBSA 19380 (Dayton, OH) would experience both a

change to its number and its name, and become CBSA 19430 (Dayton-Kettering, OH), while all of its three constituent counties would remain the same. In other cases, only the name of the CBSA would be modified, and none of the currently assigned counties would be reassigned to a different urban CBSA. Table 3 shows the current CBSA code and our proposed CBSA code where we are proposing to change either the name or CBSA number only.

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TABLE 3: CY 2021 Proposed Change in CBSA Name and/or Number Crosswalk

Current CBSA Code	Current CBSA Title	Proposed CBSA Code	Proposed CBSA Title
10540	Albany, OR	10540	Albany-Lebanon, OR
11500	Anniston-Oxford-Jacksonville, AL	11500	Anniston-Oxford, AL
12060	Atlanta-Sandy Springs-Roswell, GA	12060	Atlanta-Sandy Springs-Alpharetta, GA
12420	Austin-Round Rock, TX	12420	Austin-Round Rock-Georgetown, TX
13460	Bend-Redmond, OR	13460	Bend, OR
13980	Blacksburg-Christiansburg-Radford, VA	13980	Blacksburg-Christiansburg, VA
14740	Bremerton-Silverdale, WA	14740	Bremerton-Silverdale-Port Orchard, WA
15380	Buffalo-Cheektowaga-Niagara Falls, NY	15380	Buffalo-Cheektowaga, NY
19430	Dayton-Kettering, OH	19380	Dayton, OH
24340	Grand Rapids-Wyoming, MI	24340	Grand Rapids-Kentwood, MI
24860	Greenville-Anderson-Mauldin, SC	24860	Greenville-Anderson, SC
25060	Gulfport-Biloxi-Pascagoula, MS	25060	Gulfport-Biloxi, MS
25540	Hartford-West Hartford-East Hartford, CT	25540	Hartford-East Hartford-Middletown, CT
25940	Hilton Head Island-Bluffton-Beaufort, SC	25940	Hilton Head Island-Bluffton, SC
28700	Kingsport-Bristol-Bristol, TN-VA	28700	Kingsport-Bristol, TN-VA
31860	Mankato-North Mankato, MN	31860	Mankato, MN
33340	Milwaukee-Waukesha-West Allis, WI	33340	Milwaukee-Waukesha, WI
34940	Naples-Immokalee-Marco Island, FL	34940	Naples-Marco Island, FL
35660	Niles-Benton Harbor, MI	35660	Niles, MI
36084	Oakland-Hayward-Berkeley, CA	36084	Oakland-Berkeley-Livermore, CA
36500	Olympia-Tumwater, WA	36500	Olympia-Lacey-Tumwater, WA
38060	Phoenix-Mesa-Scottsdale, AZ	38060	Phoenix-Mesa-Chandler, AZ
39150	Prescott Valley-Prescott, AZ	39140	Prescott, AZ
23224	Frederick-Gaithersburg-Rockville, MD	43524	Silver Spring-Frederick-Rockville, MD
44420	Staunton-Waynesboro, VA	44420	Staunton, VA

Current CBSA Code	Current CBSA Title	Proposed CBSA Code	Proposed CBSA Title
44700	Stockton-Lodi, CA	44700	Stockton, CA
45940	Trenton, NJ	45940	Trenton-Princeton, NJ
46700	Vallejo-Fairfield, CA	46700	Vallejo, CA
47300	Visalia-Porterville, CA	47300	Visalia, CA
48140	Wausau, WI	48140	Wausau-Weston, WI
48424	West Palm Beach-Boca Raton-Delray Beach, FL	48424	West Palm Beach-Boca Raton-Boynton Beach, FL

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As we explained previously in this proposed rule, ESRD facilities located in an urban area that, due to the new OMB delineations, involves a change only in the CBSA name or number would not experience a consequential change in their wage index value.

However, in other cases, if we adopt the new OMB delineations, counties would shift between existing and new CBSAs, changing the constituent makeup of the CBSAs. We consider these types of changes, where CBSAs are split into multiple new CBSAs or a CBSA loses one or more counties to

another urban CBSAs, to be significant modifications.

Table 4 (CY 2021 Proposed Urban to a Different Urban CBSA Crosswalk) shows the urban counties that would move from one urban CBSA to another a newly proposed or modified CBSA, if we adopt the new OMB delineations.

TABLE 4: CY 2021 Proposed Urban to a Different Urban CBSA Crosswalk

FIPS County Code	County/ County Equivalent	State	Current CBSA	Current CBSA Name	Proposed CBSA Code	Proposed CBSA Name
17031	COOK	IL	16974	Chicago-Naperville-Arlington Heights, IL	16984	Chicago-Naperville-Evanston, IL
17043	DU PAGE	IL	16974	Chicago-Naperville-Arlington Heights, IL	16984	Chicago-Naperville-Evanston, IL
17063	GRUNDY	IL	16974	Chicago-Naperville-Arlington Heights, IL	16984	Chicago-Naperville-Evanston, IL
17093	KENDALL	IL	16974	Chicago-Naperville-Arlington Heights, IL	20994	Elgin, IL
17111	MC HENRY	IL	16974	Chicago-Naperville-Arlington Heights, IL	16984	Chicago-Naperville-Evanston, IL
17197	WILL	IL	16974	Chicago-Naperville-Arlington Heights, IL	16984	Chicago-Naperville-Evanston, IL
34023	MIDDLESEX	NJ	35614	New York-Jersey City-White Plains, NY-NJ	35154	New Brunswick-Lakewood, NJ
34025	MONMOUTH	NJ	35614	New York-Jersey City-White Plains, NY-NJ	35154	New Brunswick-Lakewood, NJ
34029	OCEAN	NJ	35614	New York-Jersey City-White Plains, NY-NJ	35154	New Brunswick-Lakewood, NJ
34035	SOMERSET	NJ	35084	Newark, NJ-PA	35154	New Brunswick-Lakewood, NJ
36027	DUTCHESS	NY	20524	Dutchess County-Putnam County, NY	39100	Poughkeepsie-Newburgh-Middletown, NY
36071	ORANGE	NY	35614	New York-Jersey City-White Plains, NY-NJ	39100	Poughkeepsie-Newburgh-Middletown, NY
36079	PUTNAM	NY	20524	Dutchess County-Putnam County, NY	35614	New York-Jersey City-White Plains, NY-NJ
47057	GRAINGER	TN	28940	Knoxville, TN	34100	Morristown, TN
54043	LINCOLN	WV	26580	Huntington-Ashland, WV-KY-OH	16620	Charleston, WV
72055	GUANICA	PR	38660	Ponce, PR	49500	Yauco, PR
72059	GUAYANILLA	PR	38660	Ponce, PR	49500	Yauco, PR
72111	PENUELAS	PR	38660	Ponce, PR	49500	Yauco, PR
72153	YAUCO	PR	38660	Ponce, PR	49500	Yauco, PR

If ESRD facilities located in these counties move from one CBSA to another under the new OMB delineations, there may be impacts, both negative and positive, to their specific wage index values. A discussion of the proposed wage index transition policy due to these proposed changes is available in section II.B.4.b.(3) of this proposed rule.

(d) Changes to the Statewide Rural Wage Index

ESRD facilities currently located in a rural area may remain rural under the new OMB delineations but experience a

change in their rural wage index value due to the movement of constituent counties. If ESRD facilities located in these counties move from one CBSA to another under the new OMB delineations, there may be impacts, both negative and positive, upon their specific wage index values. A discussion of the proposed wage index transition policy due to these proposed changes is available in section II.B.4.b.(3) of this proposed rule.

We believe these revisions to the CBSA-based labor market area delineations as established in OMB Bulletin 18-04 would ensure that the

ESRD PPS area wage level adjustment most appropriately accounts for and reflects the relative wage levels in the geographic area of the ESRD facility. Therefore, we are proposing to adopt the new OMB delineations under the ESRD PPS, effective January 1, 2021.

We invite public comment on the proposal to adopt the new OMB delineations, effective beginning with the CY 2021 ESRD PPS wage index.

(3) Proposed Transition for ESRD Facilities Negatively Impacted

To mitigate the potential impacts of proposed policies on ESRD facilities, we

have in the past provided for transition periods when adopting changes that have significant payment implications, particularly large negative impacts. For example, we have proposed and finalized budget-neutral transition policies to help mitigate negative impacts on ESRD facilities following the adoption of the new OMB delineations as described in the February 28, 2013 OMB Bulletin No. 13–01 (79 FR 66142). Specifically, as part of the CY 2015 ESRD PPS rulemaking, we implemented a 2-year transition blended wage index for all ESRD facilities. ESRD facilities received 50 percent of their CY 2015 wage index value based on the OMB delineations for CY 2014 and 50 percent of their CY 2015 wage index value based on the new OMB delineations. This resulted in an average of the two values. Then, in CY 2016, an ESRD facility's wage index value was based 100 percent on the new OMB delineations.

We considered having no transition period and fully implementing the proposed new OMB delineations beginning in CY 2021, which would mean that all ESRD facilities would have payments based on updated hospital wage data and the new OMB delineations starting on January 1, 2021. However, because the overall amount of ESRD PPS payments would increase slightly due to the new OMB delineations, the wage index budget neutrality factor would be higher. This higher factor would reduce the ESRD PPS per treatment base rate for all ESRD facilities paid under the ESRD PPS, despite the fact that the majority of ESRD facilities would be unaffected by the new OMB delineations. Thus, we believe it would be appropriate to provide for a transition period to mitigate the resulting short-term instability of a lower ESRD PPS base rate as well as consequential negative impacts to ESRD facilities that experience reduced payments. For example, ESRD facilities currently located in CBSA 35614 (New York-Jersey City-White Plains, NY-NJ) that would be located in new CBSA 35154 (New Brunswick-Lakewood, NJ) under the proposed changes to the OMB delineations would experience a nearly 17 percent decrease in the wage index as a result of the proposed change.

Therefore, under the authority of section 1881(b)(14)(D)(iv)(II) of the Act and consistent with past practice, we are proposing a transition policy to help mitigate any significant, negative impacts that ESRD facilities may experience due to our proposal to adopt the new OMB delineations under the ESRD PPS. Specifically, as a transition for CY 2021, we are proposing to apply

a 5 percent cap on any decrease in an ESRD facility's wage index from the ESRD facility's wage index from the prior calendar year. This transition would allow the effects of our proposed adoption of the new OMB delineations to be phased in over 2 years, where the estimated reduction in an ESRD facility's wage index would be capped at 5 percent in CY 2021, and no cap would be applied to the reduction in the wage index for the second year, CY 2022. We believe a 5 percent cap on the overall decrease in an ESRD facility's wage index value, regardless of the circumstance causing the decline, would be an appropriate transition for CY 2021 as it would provide predictability in payment levels from CY 2020 to the upcoming CY 2021 and additional transparency because it is administratively simpler than our prior 2-year 50/50 blended wage index approach. We believe 5 percent is a reasonable level for the cap because it would effectively mitigate any significant decreases in an ESRD facility's wage index for CY 2021. We solicit comment on the proposal to apply a 5 percent cap on any decrease in an ESRD facility's wage index for CY 2021 from the ESRD facility's wage index from the prior calendar year, CY 2020.

(4) Proposed Budget Neutrality Adjustments for Changes to the ESRD PPS Wage Index

Consistent with the historical wage index budget-neutrality adjustment policy finalized in the CY 2012 ESRD PPS final rule (76 FR 70241 through 70242) under the authority of section 1881(b)(14)(D)(iv)(II) of the Act, we are proposing that the proposed adoption of the new OMB delineations and the proposed transition policy would not result in any change of estimated aggregate ESRD PPS payments by applying a budget neutrality factor to the ESRD PPS base rate. We note budget neutrality was also applied to the adoption of new OMB delineations and transition policy in the CY 2015 ESRD PPS final rule (79 FR 66128 through 66129). Our proposed methodology for calculating this proposed budget neutrality factor is discussed in section II.B.4.d.(2) of this proposed rule.

The proposed CY 2021 ESRD PPS wage index is set forth in Addendum A and is available on the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices.html>. Addendum A provides a crosswalk between the CY 2020 wage index for an ESRD facility

using the current OMB delineations in effect in CY 2020, the CY 2021 wage index using the current OMB delineations in effect in CY 2020, and the CY 2021 wage index using the proposed new OMB delineations. Addendum B provides an ESRD facility-level impact analysis. In Addendum B are the proposed transition wage index values that would be in effect in CY 2021 if these proposed changes are finalized. Addendum B is available on the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices.html>.

c. Proposed CY 2021 Update to the Outlier Policy

Section 1881(b)(14)(D)(ii) of the Act requires that the ESRD PPS include a payment adjustment for high cost outliers due to unusual variations in the type or amount of medically necessary care, including variability in the amount of ESAs necessary for anemia management. Some examples of the patient conditions that may be reflective of higher facility costs when furnishing dialysis care would be frailty, obesity, and comorbidities, such as secondary hyperparathyroidism. The ESRD PPS recognizes high cost patients, and we have codified the outlier policy and our methodology for calculating outlier payments at § 413.237. The policy provides that the following ESRD outlier items and services are included in the ESRD PPS bundle: (1) Renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (2) Renal dialysis laboratory tests that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (3) Renal dialysis medical/surgical supplies, including syringes, used to administer renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (4) Renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, covered under Medicare Part D, including renal dialysis oral-only drugs effective January 1, 2025; and (5) Renal dialysis equipment and supplies that receive the transitional add-on payment adjustment as specified in § 413.236 after the payment period has ended.

In the CY 2011 ESRD PPS final rule (75 FR 49142), we stated that for purposes of determining whether an ESRD facility would be eligible for an outlier payment, it would be necessary for the facility to identify the actual

ESRD outlier services furnished to the patient by line item (that is, date of service) on the monthly claim. Renal dialysis drugs, laboratory tests, and medical/surgical supplies that are recognized as outlier services were originally specified in Attachment 3 of Change Request 7064, Transmittal 2033 issued August 20, 2010, rescinded and replaced by Transmittal 2094, dated November 17, 2010. Transmittal 2094 identified additional drugs and laboratory tests that may also be eligible for ESRD outlier payment. Transmittal 2094 was rescinded and replaced by Transmittal 2134, dated January 14, 2011, which included one technical correction.

Furthermore, we use administrative issuances and guidance to continually update the renal dialysis service items available for outlier payment via our quarterly update CMS Change Requests, when applicable. We use this separate guidance to identify renal dialysis service drugs that were or would have been covered under Medicare Part D for outlier eligibility purposes and in order to provide unit prices for calculating imputed outlier services. In addition, we identify through our monitoring efforts items and services that are either incorrectly being identified as eligible outlier services or any new items and services that may require an update to the list of renal dialysis items and services that qualify as outlier services, which are made through administrative issuances.

Under § 413.237, an ESRD facility is eligible for an outlier payment if its actual or imputed Medicare allowable payment (MAP) amount per treatment for ESRD outlier services exceeds a threshold. The MAP amount represents the average incurred amount per treatment for services that were or would have been considered separately billable services prior to January 1, 2011. The threshold is equal to the ESRD facility's predicted ESRD outlier services MAP amount per treatment (which is case-mix adjusted and described in the following paragraphs) plus the fixed-dollar loss (FDL) amount. In accordance with § 413.237(c), facilities are paid 80 percent of the per treatment amount by which the imputed

MAP amount for outlier services (that is, the actual incurred amount) exceeds this threshold. ESRD facilities are eligible to receive outlier payments for treating both adult and pediatric dialysis patients.

In the CY 2011 ESRD PPS final rule and at § 413.220(b)(4), using 2007 data, we established the outlier percentage, which is used to reduce the per treatment base rate to account for the proportion of the estimated total payments under the ESRD PPS that are outlier payments, at 1.0 percent of total payments (75 FR 49142 through 49143). We also established the FDL amounts that are added to the predicted outlier services MAP amounts. The outlier services MAP amounts and FDL amounts are different for adult and pediatric patients due to differences in the utilization of separately billable services among adult and pediatric patients (75 FR 49140). As we explained in the CY 2011 ESRD PPS final rule (75 FR 49138 through 49139), the predicted outlier services MAP amounts for a patient are determined by multiplying the adjusted average outlier services MAP amount by the product of the patient-specific case-mix adjusters applicable using the outlier services payment multipliers developed from the regression analysis used to compute the payment adjustments.

In the CY 2020 ESRD PPS final rule (84 FR 60705), we stated that based on the CY 2018 claims data, outlier payments represented approximately 0.5 percent of total payments. We also noted that, beginning in CY 2020, the total expenditure amount includes add-on payment adjustments made for calcimimetics under the TDAPA policy. We projected that for each dialysis treatment furnished, the average amount attributed to the TDAPA was \$21.03 (84 FR 60704).

For CY 2021, we propose that the outlier services MAP amounts and FDL amounts would be derived from claims data from CY 2019. Because we believe that any adjustments made to the MAP amounts under the ESRD PPS should be based upon the most recent data year available in order to best predict any future outlier payments, we propose the outlier thresholds for CY 2021 would be

based on utilization of renal dialysis items and services furnished under the ESRD PPS in CY 2019. We note that, for CY 2020, the total expenditure amount includes add-on payment adjustments made for calcimimetics under the TDAPA policy (calculated to be \$14.87 per treatment). However, as discussed in section II.B.1 of this proposed rule, for CY 2021 we propose to modify the ESRD PPS base rate by adding \$12.06 to account for calcimimetics in the ESRD PPS bundled payment and no longer pay for these drugs using the TDAPA. In addition, we are proposing that beginning January 1, 2021, calcimimetics would be eligible outlier services.

As discussed in section II.B.4.c.(2) of this proposed rule, CY 2019 claims data show outlier payments represented approximately 0.5 percent of total payments. We recognize that the utilization of ESAs and other outlier services have continued to decline under the ESRD PPS, and that we have lowered the MAP amounts and FDL amounts every year under the ESRD PPS. For CY 2021, the predicted outlier services MAP amounts and FDL amounts have increased as a result of our proposal to incorporate oral and injectable calcimimetics into the outlier policy.

(1) CY 2021 Update to the Outlier Services MAP Amounts and FDL Amounts

For CY 2021, we propose to update the outlier services MAP amounts and FDL amounts to reflect the utilization of outlier services reported on 2019 claims. For this proposed rule, the outlier services MAP amounts and FDL amounts were updated using 2019 claims data. The impact of this update is shown in Table 5, which compares the outlier services MAP amounts and FDL amounts used for the outlier policy in CY 2020 with the updated proposed estimates for this rule. The estimates for the proposed CY 2021 outlier policy, which are included in Column II of Table 5, were inflation adjusted to reflect projected 2021 prices for outlier services.

TABLE 5: Outlier Policy: Impact of Using Updated Data to Define the Outlier Policy

	Column I Final outlier policy for CY 2020 (based on 2018 data, price inflated to 2020)*		Column II Proposed outlier policy for CY 2021 (based on 2019 data, price inflated to 2021)	
	Age < 18	Age >= 18	Age < 18	Age >= 18
Average outlier services MAP amount per treatment	\$30.95	\$37.33	\$32.12	\$56.50
Adjustments				
Standardization for outlier services	1.0655	0.9781	1.0509	0.9801
MIPPA reduction	0.98	0.98	0.98	0.98
Adjusted average outlier services MAP amount	\$32.32	\$35.78	\$33.08	\$54.26
FDL amount that is added to the predicted MAP to determine the outlier threshold	\$41.04	\$48.33	\$47.73	\$133.52
Patient-months qualifying for outlier payment	11.35%	10.38%	8.65%	4.91%

*Note that Column I was obtained from Column II of Table 2 from the CY 2020 ESRD PPS final rule (84 FR 60705).

As demonstrated in Table 5, the estimated FDL amount per treatment that determines the CY 2021 outlier threshold amount for adults (Column II; \$133.52) is higher than that used for the CY 2020 outlier policy (Column I; \$48.33). The higher threshold is accompanied by an increase in the adjusted average MAP for outlier services from \$35.78 to \$54.26. For pediatric patients, there is an increase in the FDL amount from \$41.04 to \$47.73. There is a corresponding increase in the adjusted average MAP for outlier services among pediatric patients, from \$32.32 to \$33.08.

As we stated previously, the predicted outlier services MAP amounts and FDL amounts have increased as a result of our proposal to incorporate oral and injectable calcimimetics into the outlier policy. Approximately 30 percent of ESRD beneficiaries receive calcimimetics and a subset of these beneficiaries tend to have the highest ESRD PPS expenditures, which trigger outlier payments under the ESRD PPS. Since the highest per-beneficiary ESRD PPS expenditures would increase under our proposal for calcimimetics to become eligible ESRD outlier services, the outlier FDL would increase to ensure that total outlier payments project to 1 percent of total Medicare ESRD PPS expenditures.

We estimate that the percentage of patient months qualifying for outlier payments in CY 2021 would be 4.91 percent for adult patients and 8.65 percent for pediatric patients, based on the 2019 claims data. The outlier MAP and FDL amounts continue to be lower for pediatric patients than adults due to the continued lower use of outlier services (primarily reflecting lower use of calcimimetics, ESAs and other injectable drugs).

(2) Outlier Percentage

In the CY 2011 ESRD PPS final rule (75 FR 49081) and under § 413.220(b)(4), we reduced the per treatment base rate by 1 percent to account for the proportion of the estimated total payments under the ESRD PPS that are outlier payments as described in § 413.237. Based on the 2019 claims, outlier payments represented approximately 0.5 percent of total payments, which is below the 1 percent target due to declines in the use of outlier services. Recalibration of the thresholds using 2019 data is expected to result in aggregate outlier payments close to the 1 percent target in CY 2021.

We believe the update to the outlier MAP and FDL amounts for CY 2021 would increase payments for ESRD beneficiaries requiring higher resource utilization and move us closer to meeting our 1 percent outlier policy

because we are using more current data for computing the MAP and FDL, which is more in line with current outlier services utilization rates. The proposed inclusion of calcimimetics as ESRD outlier services in CY 2021 would fundamentally change the per-treatment distribution of outlier services relative to previous CYs. In 2019 claims, roughly 33 percent of ESRD beneficiaries and 28 percent of dialysis treatments are associated with calcimimetics and those that often have significantly higher utilization of ESRD outlier services relative to beneficiaries who do not receive calcimimetics. The MAP and FDL increases account for this change. We note that recalibration of the FDL amounts in this proposed rule would result in no change in payments to ESRD facilities for beneficiaries with renal dialysis items and services that are not eligible for outlier payments.

d. Proposed Impacts to the CY 2021 ESRD PPS Base Rate

(1) ESRD PPS Base Rate

In the CY 2011 ESRD PPS final rule (75 FR 49071 through 49083), we established the methodology for calculating the ESRD PPS per-treatment base rate, that is, ESRD PPS base rate, and the determination of the per-treatment payment amount, which are codified at §§ 413.220 and 413.230. The

CY 2011 ESRD PPS final rule also provides a detailed discussion of the methodology used to calculate the ESRD PPS base rate and the computation of factors used to adjust the ESRD PPS base rate for projected outlier payments and budget neutrality in accordance with sections 1881(b)(14)(D)(ii) and 1881(b)(14)(A)(ii) of the Act, respectively. Specifically, the ESRD PPS base rate was developed from CY 2007 claims (that is, the lowest per patient utilization year as required by section 1881(b)(14)(A)(ii) of the Act), updated to CY 2011, and represented the average per treatment MAP for composite rate and separately billable services. In accordance with section 1881(b)(14)(D) of the Act and our regulation at § 413.230, the per-treatment payment amount is the sum of the ESRD PPS base rate, adjusted for the patient specific case-mix adjustments, applicable facility adjustments, geographic differences in area wage levels using an area wage index, any applicable outlier payment and training adjustment add-on, the TDAPA, and the TPNIES.

(2) Annual Payment Rate Update for CY 2021

We are proposing an ESRD PPS base rate for CY 2021 of \$255.59. This update reflects several factors, described in more detail as follows:

- **Wage Index Budget-Neutrality Adjustment Factor:** We compute a wage index budget-neutrality adjustment factor that is applied to the ESRD PPS base rate. For CY 2021, we are not proposing any changes to the methodology used to calculate this factor, which is described in detail in the CY 2014 ESRD PPS final rule (78 FR 72174). We computed the proposed CY 2021 wage index budget-neutrality adjustment factor using treatment counts from the 2019 claims and facility-specific CY 2020 payment rates to estimate the total dollar amount that each ESRD facility would have received in CY 2020. The total of these payments became the target amount of expenditures for all ESRD facilities for CY 2021. Next, we computed the estimated dollar amount that would have been paid for the same ESRD facilities using the ESRD PPS wage index for CY 2021. As discussed in section II.B.4.b of this proposed rule, the proposed ESRD PPS wage index for CY 2021 includes an update to the most recent hospital wage data, the proposed adoption of the new OMB delineations, and a 5 percent cap on wage index decreases applied for CY 2021. The total of these payments becomes the new CY 2021 amount of wage-adjusted expenditures for all ESRD facilities. The

wage index budget-neutrality factor is calculated as the target amount divided by the new CY 2021 amount. When we multiplied the wage index budget-neutrality factor by the applicable CY 2021 estimated payments, aggregate payments to ESRD facilities would remain budget neutral when compared to the target amount of expenditures. That is, the wage index budget-neutrality adjustment factor ensures that wage index adjustments do not increase or decrease aggregate Medicare payments with respect to changes in wage index updates. The CY 2021 proposed wage index budget-neutrality adjustment factor is .998652. This application would yield a CY 2021 ESRD PPS proposed base rate of \$239.01, ($\$239.33 \times .998652 = \239.01), prior to the proposed addition to the ESRD PPS base rate to include calcimimetics and the application of the proposed market basket increase.

- **Addition to the ESRD PPS Base Rate to Include Calcimimetics:** As discussed in section II.B.1 of this proposed rule, for CY 2021 we are proposing to modify the ESRD PPS base rate by adding \$12.06 to account for calcimimetics in the ESRD PPS bundled payment. This application would yield a CY 2021 ESRD PPS proposed base rate of \$251.07 ($\$239.01 + \$12.06 = \251.07), prior to the application of the proposed market basket increase.

- **Market Basket Increase:** Section 1881(b)(14)(F)(i)(I) of the Act provides that, beginning in 2012, the ESRD PPS payment amounts are required to be annually increased by the ESRD market basket percentage increase factor. The latest CY 2021 projection for the proposed ESRDB market basket is 2.2 percent. In CY 2021, this amount must be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, as required by section 1881(b)(14)(F)(i)(II) of the Act. As discussed previously, the proposed MFP adjustment for CY 2021 is 0.4 percent, thus yielding a proposed update to the base rate of 1.8 percent for CY 2021. Therefore, the CY 2021 ESRD PPS proposed base rate is \$255.59 ($\$251.07 \times 1.018 = \255.59).

In summary, we are proposing a CY 2021 ESRD PPS base rate of \$255.59. This amount reflects a proposed CY 2021 wage index budget-neutrality adjustment factor of .998652, a proposed addition of \$12.06 to the ESRD PPS base rate to include calcimimetics, and the CY 2021 ESRD PPS payment update of 1.8 percent.

5. Proposed Changes to the Low-Volume Payment Adjustment

a. Background

As required by section 1881(b)(14)(D)(iii) of the Act, the ESRD PPS includes a payment adjustment that reflects the extent to which costs incurred by low-volume facilities in furnishing renal dialysis services exceed the costs incurred by other facilities in furnishing such services. We have established a LVPA factor of 23.9 percent for ESRD facilities that meet the definition of a low-volume facility. Under § 413.232(b), a low-volume facility is an ESRD facility that, based on the submitted documentation—(1) Furnished less than 4,000 treatments in each of the 3 cost reporting years (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent) preceding the payment year; and (2) Has not opened, closed, or received a new provider number due to a change in ownership in the 3 cost reporting years (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent) preceding the payment year. Under § 413.232(c), for purposes of determining the number of treatments furnished by the ESRD facility, the number of treatments considered furnished by the ESRD facility equals the aggregate number of treatments furnished by the ESRD facility and the number of treatments furnished by other ESRD facilities that are both under common ownership with, and 5 road miles or less from, the ESRD facility in question.

For purposes of determining eligibility for the LVPA, “treatments” mean total hemodialysis (HD) equivalent treatments (Medicare and non-Medicare as well as ESRD and non-ESRD). For peritoneal dialysis (PD) patients, 1 week of PD is considered equivalent to 3 HD treatments. As noted, we base eligibility on the 3 years preceding the payment year and those years are based on cost reporting periods. Specifically, under § 413.232(g), the ESRD facility’s cost reports for the periods ending in the 3 years preceding the payment year must report costs for 12-consecutive months (76 FR 70237).

In order to receive the LVPA under the ESRD PPS, an ESRD facility must submit a written attestation statement to its Medicare Administrative Contractor (MAC) confirming that it meets all of the requirements specified in § 413.232 and qualifies as a low-volume ESRD facility. The attestation is required because: (1) ESRD facility’s cost reporting periods vary and may not be based on the

calendar year; and (2) the cost reports are due 5 months after the close of the cost reporting period (that is, there is a lag in the cost reporting submission). Thus, the MACs may not have the cost report for the third year to determine eligibility and would need to rely on the attestation for that year until the cost report is available. Section 413.232(e) imposes a yearly November 1 deadline for attestation submissions, with a few exceptions where the deadline is December 31. The November 1 timeframe provides 60 days for a MAC to verify that an ESRD facility meets the LVPA eligibility criteria (76 FR 70236).

As stated in the Medicare Benefit Policy Manual, (Pub. L. 100–02), (chapter 11, section 60.B.1),¹³ once the attested ESRD facility's cost report is submitted to the MAC, the MAC verifies the as-filed cost report for the third eligibility year and finds that the ESRD facility met the eligibility criteria, the ESRD facility would then receive the LVPA payment for all the Medicare-eligible treatments in the payment year. However, if the attested ESRD facility's cost report for the third eligibility year exceeds the total dialysis treatment threshold, then the MAC recoups by reprocessing claims paid during the payment year in which the ESRD facility incorrectly received the LVPA. Recoupment also occurs if any cost reports used for eligibility are subsequently found to have not met the low-volume criteria, for example, reopening or appeals.

Further information regarding the administration of the LVPA is provided in the Medicare Benefit Policy Manual, chapter 11, section 60.B.1.¹⁴

b. Revisions to the LVPA Requirements and Regulations

As we discussed in the CY 2019 ESRD PPS final rule (83 FR 56949), we have heard from stakeholders that low-volume facilities rely on the low-volume adjustment and loss of the adjustment could result in beneficiary access issues. Specifically, stakeholders expressed concern that the eligibility criteria in the LVPA regulations are very explicit and leave little room for flexibility in certain circumstances.

As discussed in section II.B.2 of this proposed rule, according to the Centers for Disease Control and Prevention (CDC), the risk factors for COVID–19 include older adults and people of any age who have serious underlying

medical conditions, such as diabetes and chronic kidney disease undergoing dialysis. Medicare's ESRD population aligns with the profile of patients who are more susceptible to COVID–19. As a result, ESRD facilities are working together to keep the risk of spreading COVID–19 down as much as possible by shifting patients among the ESRD facilities in the same area. In some cases, this shifting of patients has caused some low-volume ESRD facilities to temporarily dialyze patients that they otherwise would not have dialyzed if there had not been a PHE. In addition, since cases of acute kidney injury (AKI) have increased in certain areas of the country due to COVID–19, there is also an increase in the number of patients discharged that need outpatient dialysis for some period of time while their kidneys regain normal function. We are concerned that these increases in dialysis treatments due to the COVID–19 PHE in CY 2020 may put certain low-volume facilities over the LVPA's treatment threshold causing the loss of, or the inability to qualify for, the 23.9 percent per treatment payment adjustment for payment years 2021, 2022, and 2023. We note that in CY 2020, 338 ESRD facilities receive the LVPA. We also note that in a typical year, we estimate that between 50–60 facilities lose their LVPA status. That is, there are between 50–60 ESRD facilities that typically lose their LVPA status because their patient population grew for reasons other than the COVID–19 PHE.

In light of the unique circumstance due to the COVID–19 PHE, we are proposing to hold ESRD facilities harmless if an increase in their treatment counts in 2020 is COVID–19-related such that the increase would prevent them from qualifying for the LVPA. We propose that the ESRD facility would attest that the increase in treatments, meaning total HD equivalent treatments (for ESRD and AKI), was temporary and related to the redistribution of patients in response to the COVID–19 PHE. When this occurs, instead of using total dialysis treatments furnished in cost reporting periods ending in 2020, CMS would rely on the facility's attestation that the increase in total dialysis treatments was due to the PHE for the COVID–19 pandemic. We propose for purposes of determining LVPA eligibility for payment years 2021, 2022, and 2023, we would only consider total dialysis treatments furnished for 6 months of a facility's cost-reporting period ending in 2020, and that an ESRD facility would decide which 6 months to use (consecutive or

non-consecutive) for purposes of reporting total treatments. That is, ESRD facilities would attest that, while it furnished 4,000 or more treatments in its cost-reporting period ending in 2020, the number of treatments exceeding the allowed threshold to otherwise qualify for the LVPA was due to temporary patient shifting as a result of the COVID–19 PHE, and that their total dialysis treatments for any 6 months of that period is less than 2,000. MACs would annualize the total dialysis treatments for those 6 months by multiplying by 2. ESRD facilities would be expected to provide supporting documentation to the MACs upon request.

This proposal is responsive to requests we have received from stakeholders, and would prevent the loss of, or the inability to qualify for, the LVPA for facilities who accommodated additional patients in 2020 because of the COVID–19 PHE. We believe this proposal targets just those facilities that would not qualify for the LVPA for the reason that they accommodated additional patients in response to the COVID–19 PHE to, for example, prevent the spread of the infection.

We propose to revise § 413.232(g) by adding paragraph (g)(4) to reflect that, for purposes of determining LVPA eligibility for payment years 2021, 2022, and 2023, an ESRD facility's attestation must indicate that the ESRD facility meets all the LVPA criteria except that, for a facility that does not otherwise meet the number-of-treatments criterion (that is, less than 4,000 in a year) because of the COVID–19 PHE, the facility furnished less than 2,000 treatments in any 6 months during its cost-reporting period ending in 2020 due to temporary patient shifting as a result of the COVID–19 PHE. We also propose that the MAC would rely on the facility's attestation and would annualize the total dialysis treatments for the 6 months by multiplying those collective 6 month treatments by 2.

In addition, since CMS changed cost reporting deadlines due to the COVID–19 PHE, we believe the extraordinary circumstances of the COVID–19 pandemic justify an exception to the November 1, 2020 attestation deadline. Therefore, for payment year 2021, we propose to allow more time for ESRD facilities to submit attestations by extending the deadline to December 31, 2020. We would reflect this change in § 413.232(e) by reformatting the section to reflect already established exceptions to the November 1 attestation deadline in paragraphs (e)(1) through (3), and to include in new paragraph (e)(4) that, for

¹³ <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c11.pdf>.

¹⁴ <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c11.pdf>.

payment year 2021, the attestation must be provided by December 31, 2020.

We are proposing a technical change at § 413.232(b) to remove the heading “Definition of low-volume facility” to be consistent with the current CFR requirements.¹⁵

We are also proposing a technical change at § 413.232(e) and (g). We propose to add “MAC” in § 413.232(e) to establish the acronym for Medicare Administrative Contractor. We propose to replace “Medicare Administrative Contractor (MAC)” with “MAC” in § 413.232(g) since the acronym would now be established in § 413.232(e).

c. Clarification for MAC LVPA Determinations

As we discuss in section II.B.5.(a) of this proposed rule, in order to receive the LVPA, an ESRD facility must meet the requirements of § 413.232, including submitting attestations to the MACs indicating its eligibility for the adjustment. In its attestation for the third eligibility year, which is the cost-reporting year immediately preceding the payment year, a facility attests that it will be eligible for the adjustment; this attestation typically occurs prior to the MAC having the facility’s cost report for the third eligibility year, in which case the MAC relies on the facility’s attestation to determine if the facility qualifies for the LVPA. When an ESRD facility qualifies for the adjustment, the LVPA would be applied to all the Medicare-eligible treatments for the entire payment year. If the MAC subsequently determines, however, that the ESRD facility failed to qualify for the LVPA, and the facility had already begun to receive the adjustment to which the MAC has determined it is not entitled, the MAC would reprocess the claims to remove and recoup the low-volume payments.

We understand that in some instances, MACs may be discontinuing LVPA payments to a facility in the payment year for which the facility is eligible for the adjustment. However, the established policy is such that, if an ESRD facility meets the LVPA eligibility criteria in § 413.232, it is entitled to the payment adjustment for the entire payment year. Because there may be some inconsistent application of this policy, we are taking this opportunity to make this aspect of the LVPA policy clear in the regulation text.

We propose to revise § 413.232 by adding paragraph (h) to specify that, if an ESRD facility provides an attestation

in accordance with § 413.232(e) for the third eligibility year, the MAC verifies the as-filed cost report. If the MAC determines an ESRD facility meets the definition of a low-volume facility, CMS adjusts the low-volume facility’s base rate for the entire payment year. However, if the MAC determines an ESRD facility does not meet the definition of a low-volume facility, the MAC reprocesses claims and recoups low volume adjustments paid during the payment year.

C. Proposed Transitional Add-On Payment Adjustment for New and Innovative Equipment and Supplies for CY 2021 Payment

1. Background

As we discussed in section II.B.2.a in the CY 2020 ESRD PPS final rule, we finalized the establishment of a transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES) to support ESRD facilities in the uptake of certain new and innovative renal dialysis equipment and supplies under the ESRD PPS. Under our current regulation at § 413.236(b), we will provide the TPNIES to an ESRD facility for furnishing a covered equipment or supply only if the item: (1) Has been designated by CMS as a renal dialysis service under § 413.171, (2) is new, meaning it is granted marketing authorization by FDA on or after January 1, 2020, (3) is commercially available by January 1 of the particular calendar year, meaning the year in which the payment adjustment would take effect; (4) has a Healthcare Common Procedure Coding System (HCPCS) application submitted in accordance with the official Level II HCPCS coding procedures by September 1 of the particular calendar year; (5) is innovative, meaning it meets the criteria specified in § 412.87(b)(1) of this chapter and related guidance; and (6) is not a capital-related asset that an ESRD facility has an economic interest in through ownership (regardless of the manner in which it was acquired). Specifically, the equipment or supply must represent an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries.

Under the first criterion, as reflected in the CY 2020 ESRD PPS final rule, renal dialysis equipment and supplies will be considered “new” if FDA grants them marketing authorization on or after January 1, 2020. By including FDA marketing authorizations on or after January 1, 2020, we intended to support

ESRD facility use and beneficiary access to the latest technological improvements to renal dialysis equipment and supplies. We note in section II.B.2.b of this proposed rule, we are proposing to refine the newness criteria (year in which the product was approved) and establish that an equipment or supply is considered “new” within 3 years beginning on the date of FDA marketing authorization for that equipment or supply. For capital-related assets that are dialysis machines when used in the home setting, the 3 years would begin from the date of FDA marketing authorization for home use.

We stated in the CY 2020 ESRD PPS proposed rule that, for new and innovative equipment and supplies, we believed the IPPS SCI criteria and the process used to evaluate SCI under the IPPS could be used for identifying new and innovative equipment and supplies worthy of additional payment under the ESRD PPS. We noted that under the IPPS, CMS has been assessing new technologies for many years to assure that the additional new technology add-on payments to hospitals are made only for truly innovative and transformative products, and we stated that CMS is proposing to adopt the IPPS SCI criteria under the ESRD PPS for the same reason. We explained that we wanted to ensure that the add-on payment adjustments made under the ESRD PPS are limited to new equipment and supplies that are truly innovative. In addition, since renal dialysis services are routinely furnished to hospital inpatients and outpatients, we stated that we believed the same SCI criteria should be used to assess whether a new renal dialysis equipment or supply warrants additional payment under Medicare.

We finalized the adoption of IPPS’s SCI criteria specified in § 412.87(b)(1), including modifications finalized in future IPPS final rules, to determine when a new and innovative renal dialysis equipment or supply is eligible for the TPNIES under the ESRD PPS. That is, we would adopt IPPS’s SCI criteria in § 412.87(b)(1) and any supporting policy around these criteria as discussed in IPPS preamble language. We stated that we believed that by incorporating the IPPS SCI criteria for new and innovative renal dialysis equipment under the ESRD PPS, we would be consistent with IPPS and innovators would have standard criteria to meet for both settings. We also proposed to establish a process modeled after IPPS’s process of determining if a new medical service or technology meets the SCI criteria specified in § 412.87. That is, we proposed that CMS

¹⁵ Document Drafting Handbook, chapter 2, section 2.10, page 2-18: <https://www.archives.gov/files/federal-register/write/handbook/ddh.pdf>.

would use a similar process to determine whether the renal dialysis equipment or supply meets the eligibility criteria proposed in newly added § 413.236(b). Similar to how we evaluate whether a new renal dialysis drug or biological product is eligible for the TDAPA, as discussed in the CY 2016 ESRD PPS final rule (80 FR 69019), we would need to determine whether the renal dialysis equipment and supply meets our eligibility criteria for the TPNIES.

Specifically, under § 413.236(b)(5) we evaluate SCI for purposes of the TPNIES under the ESRD PPS based on the IPPS SCI criteria (see § 412.87(b)(1)). We note that in section II.B.2.a of this proposed rule we provide a detailed discussion of the SCI criteria. In addition, in section II.B.2.b of this proposed rule we are proposing to revise § 413.236(b)(5) to remove “and related guidance” to reflect that all related SCI guidance has now been incorporated into § 412.87(b)(1).

As we discuss in section II.B.2.a, in the CY 2020 ESRD PPS final rule (84 FR 60681 through 60698), we established in § 413.236(c) a process for our announcement of TPNIES determinations and a deadline for consideration of new renal dialysis equipment or supply applications under the ESRD PPS. CMS will consider whether a new renal dialysis equipment or supply meets the eligibility criteria specified in § 413.236(b). Then, after consideration of public comments we will announce the results in the **Federal Register** as part of our annual ESRD PPS final rule. We noted we would only consider a complete application received by February 1 prior to the particular calendar year. FDA marketing authorization for the equipment or supply must occur by September 1 prior to the particular calendar year. We note in section II.B.2.b of this proposed rule we are proposing to revise § 413.236(c) to replace “September 1” with “the HCPCS Level II code application deadline for Coding Cycle 2 for DMEPOS items and services as specified in the HCPCS Level II coding guidance on the CMS website” to reflect that FDA marketing authorization for the new and innovative equipment or supply must accompany the HCPCS application prior to the particular calendar year in order for the item to qualify for the TPNIES in the next calendar year.

2. CY 2021 Applications for the TPNIES

We received two applications for the TPNIES for CY 2021. A discussion of these applications is presented below.

a. Theranova 400 Dialyzer and Theranova 500 Dialyzer

(1) Baxter Healthcare Corporation (Baxter) Application

Baxter submitted an application for the Theranova 400 Dialyzer/Theranova 500 Dialyzer. The 400 and 500 denote differences in surface area. The applicant stated that Theranova represents an SCI over currently available hemodialysis (HD) therapies for the treatment of renal failure. The applicant stated that Theranova is a new class of hollow-fiber, single-use dialyzer intended to treat renal failure by HD. The applicant stated that it features an innovative 3-layer membrane structure that offers a higher permeability than high-flux dialyzers, with improved removal of large proteins up to 45 kilodaltons (kDa) while selectively maintaining essential proteins such as albumin.^{16 17 18} The applicant stated that Theranova has the potential to transform in-center HD by allowing Medicare beneficiaries with renal failure to benefit from expanded hemodialysis (HDx). HDx is defined as a process of blood purification that includes the clearance of small uremic toxins through large middle molecule (LMM) (categorized as uremic solute whose molecular size is 25kDa up to 60 kDa) toxins without the need for an external infusion of replacement fluid. For purposes of the application, HDx is collectively referred to in the application as “Theranova”. The applicant asserted that the Theranova dialyzer integrates with existing HD machines that an ESRD facility already owns and replaces other dialyzers.

The applicant described the Theranova membrane as unique and stated it allows for the removal of an expanded range of solutes, creating a filtration profile closer to a natural kidney. The applicant described the membrane structure as being divided into three distinct layers: A fingerlike porous outer layer, a sponge-like intermediate layer, and a very thin inner layer (skin). By reducing the inner diameter of the membrane, internal filtration is increased, allowing for enhanced clearance of LMMs through

¹⁶ Boschetti-de-Fierro, A., et al., “MCO Membranes: Enhanced Selectivity in High-Flux Cases,” *www.nature.com/Scientific Reports*, [5:18448]DOI: 10.1038/srep18448.

¹⁷ Krause, B., et al., “Highly selective membranes for Blood purification,” Gambro Dialysatoren GmbH, Hechingen/Germany, Presentation abstract March 26, 2015.

¹⁸ Zweigart, C., et al., “Medium cut-off membranes—closer to the natural kidney removal function,” *Int. J Artif Organs*, 2017, 40(7), pp. 328–334. DOI: 10.5301/ujao.5000603.

additional convective transport.¹⁹ The Theranova dialyzer enables the efficient removal of uremic toxins (up to 45 kDa).^{20 21} The applicant included an adapted figure from a book titled, “Modelling and Control of Dialysis Systems”²² to compare removal of toxins by Theranova to the kidney and to other dialysis therapies, such as low flux dialyzers (LF), high flux dialyzers (HFD) and hemodiafiltration (HDF). The applicant’s adapted figure showed the following: LF, HFD, HDF and HDx remove urea (60 Daltons (Da)), phosphate (96 Da), Parathyroid hormone (9,500 Da); HFD, HDF and HDx remove Beta 2 microglobulin (12 kDa), cystatin C (13 kDa), Myoglobin (17 kDa), and, kappa free-light-chains (23 kDa); HDF and HDx remove complement factor D (24 kDa), Interleukin (IL)-6 (25 kDa), alpha 1 microglobulin (33 kDa); and, HDx removes Chitinase-3-like protein 1 (40 kDa), lambda free-light-chains (45 kDa) and albumin (67 kDa).

The applicant stated that compared with low-flux HD, high-flux HD, and HDF, the Theranova dialyzer filtration profile is more similar to that of a natural kidney, as shown *in vitro*^{23 24} giving it expanded clearance of uremic toxins.

The applicant asserted that the design of the Theranova dialyzer allows for use on any HD machine, made by any manufacturer, by merely changing the dialyzer. The applicant stated that the membrane is compatible with standard fluid quality and does not require any additional fluid quality control measure.

Theranova received approval for Investigational Device Exemption (IDE) protocol from the FDA, on August 31, 2017 and then received approval for coverage on September 13, 2017. The Class II investigational device exemption received the code

¹⁹ Lorenzin, A., et al., “Quantification of Internal Filtration in Hollow Fiber Hemodialyzers with Medium Cut-Off Membrane,” *Blood Purif*, 2018, 46, pp. 196–204.

²⁰ Boschetti-de-Fierro, A., et al., “MCO Membranes: Enhanced Selectivity in High-Flux Cases,” *www.nature.com/Scientific Reports*, [5:18448] DOI: 10.1038/srep18448.

²¹ Boschetti-de-Fierro, A., et al., “MCO Dialyzers: Enhanced Selectivity High-Flux,” Gambro Dialysatoren GmbH, Research and Development, Hechingen, Germany, Poster No. SAT-481 (Baxter).

²² Azar, A.T. and Canaud, B., “Chapter 8: Hemodialysis System,” *Modeling and Control of Dialysis Systems*, 2013, pp. 99–106, SCI 404 Berlin, Springer-Verlag, Berlin, Heidelberg. ISBN: 978–3642274572.

²³ Krause, B., et al., “Highly selective membranes for Blood purification,” Gambro Dialysatoren GmbH, Hechingen/Germany, Presentation abstract March 26, 2015.

²⁴ Boschetti-de-Fierro, A., et al., “MCO Membranes: Enhanced Selectivity in High-Flux Cases,” *www.nature.com/Scientific Reports*, [5:18448] DOI: 10.1038/srep18448.

G170157.²⁵ The FDA requested a 6-month clinical study to validate efficacy of large toxin removal and safety. According to the applicant, safety is defined in part by albumin loss. The applicant stated that it is seeking authorization through the FDA's De Novo pathway and marketing authorization this year for the May 2020 cycle. The applicant stated that it plans to submit a HCPCS application to CMS in June 2020.

The applicant noted that it has not submitted an application for pass-through payments under the Medicare Outpatient Prospective Payment System (OPPS) or the NTAP program under the Medicare IPPS for the Theranova 400 Dialyzer/Theranova 500 Dialyzer.

The applicant stated that it expects Theranova to be commercially available immediately after receiving marketing authorization and will provide proof of commercial availability.

With regard to demonstrating the requirements for SCI, the applicant asserted that Theranova represents an SCI in outcomes for Medicare beneficiaries over currently available HD therapies treating renal failure. The applicant noted that ESRD patients on current HD therapies suffer unsatisfactorily high mortality and morbidity from cardiovascular disease and infections.²⁶

In addition, the applicant stated that the HDx enabled by Theranova effectively targets the removal of LMM uremic toxins (25 kDa to 60 kDa), which are linked to the development of inflammation, cardiovascular disease, and other comorbidities in dialysis patients. The applicant stated that this results in improved clinical outcomes, relative to current dialyzers in four clinical categories. First, a decreased rate of subsequent therapeutic interventions, including fewer infections, reduced hospitalization duration, and reduced medication usage. Specifically, the applicant stated that patients treated with HDx therapy have decreased infections. A prospective cross-over study found an

average of seven episodes of infection for patients treated with HDx versus 18 for high flux HD (p=0.003).²⁷ The applicant also stated that patients receiving HDx therapy with Theranova had hospital stays averaging 4.4 days versus 5.9 days for patients receiving traditional HD (p=0.0001) along with lower hospitalization rates (71 percent versus 77 percent (p=0.69)).²⁸ The U.S. IDE Randomized Controlled Trial (NCT03257410) of 172 patients, although not powered for all-cause hospitalization events, showed a 49 percent decreased number of hospitalization events in the Theranova arm (18 events) as compared to the control arm (37 events).²⁹ With regard to improved medication usage, the applicant stated that patients receiving HDx therapy had reduced medication usage. The applicant cited three studies that showed a significant decrease in erythropoietin stimulating agents (ESA) usage.^{30 31 32} One study also found a substantial reduction in the need for iron usage.^{33 34} Two studies saw an improvement in EPO resistance index (ERI) and one study showed a statistically significant decrease in phosphate binder (calcium carbonate) usage.^{35 36}

The second clinical improvement category listed by the applicant is a more rapid beneficial resolution of the disease process treatment. The applicant cited a 2019 publication which noted that the average recovery time after dialysis is reduced with HDx therapy,

with the median self-reported recovery time at 120 minutes, 60 min., 60 min., and 105 min. at 3,6,9, and 12 months compared to a baseline 240 min. (p<0.01 for 6, 9, and 12-month ratings; N=110).³⁷

The third category of improved clinical outcomes listed by the applicant is reduced inflammation in patients receiving HDx Therapy with Theranova. The applicant referenced a 2018 review article, which notes that chronic inflammation in ESRD patients is associated with the build-up of known uremic toxins spanning the molecular size spectrum from 12kDa to 45kDa such as beta-2-microglobulin, soluble tumor necrosis factor (TNF), Receptor 2, IL-1, Prolactin, IL-18, IL-6, Hyaluronic Acid, TNF-a, Soluble TNF Receptor 1, Pentraxin-3, and Advanced Glycation End-Products. The same article notes the following: (1) LMM (25 kDa to 60 kDa) have been associated with inflammation, cardiovascular events and other dialysis-related comorbidities; (2) current dialytic therapies, though efficient in removing small solutes, have limited capability in removing LMM; (3) current dialyzer design, limited by membrane permeability, does not provide long-lasting, effective reduction of the full spectrum of small molecular uremic toxins (<500 Da), conventional middle molecular uremic toxins (500 Da to <25 kDa) and large middle molecular uremic toxins (25 kDa to 60kDa), even when their usage is enhanced with convective transport; and (4) a broad spectrum of uremic toxins are not effectively treated by conventional HD nor HDF which is not readily utilized in the U.S.³⁸ The applicant asserted that for the first time, HDx enabled by Theranova results in the superior removal of the aggregate of small, conventional middle and large middle molecular uremic toxins.³⁹ The applicant asserted that Theranova, in effectively targeting the spectrum of uremic toxins, that this spectrum encompasses the totality of these inflammation-modulating molecules.

³⁷ Bolton, S., et al., "Dialysis symptom burden and recovery time in expanded hemodialysis," Manuscript submitted.

³⁸ Wolley, M., et al., "Exploring the Clinical Relevance of Providing Increased Removal of Large Middle Molecules," *Clin. J Am Soc Nephrol*, 2018, 13, pp.805-813.

³⁹ Kirsch AH, Lyko R, Nilsson LG., et al., Performance of hemodialysis with novel medium cut-off dialyzers. *Nephrol Dial Transplant*, 2017; 32: 165-172.

²⁵ Available on p. 49828 at: <https://www.federalregister.gov/documents/2017/10/27/2017-23447/medicare-and-medicaid-programs-quarterly-listing-of-program-issuances-july-through-september-2017>.

²⁶ United States Renal Data System. 2018 USRDS annual data report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2018.

²⁷ Cozzolino, C., et al., "Effects of a medium cut-off (Theranova) dialyzer on haemodialysis patients: a prospective, cross-over study," *Clinical Kidney Journal*, 2019, pp. 1-8. Doi 10.1093/ckj/sfz155.

²⁸ Sanabria, R.M., et al., "Expanded Hemodialysis and its effects on hospitalizations and medication usage," Submitted for publication.

²⁹ Weiner, D.E., et al., 2019, "Efficacy and Safety of Expanded Hemodialysis with the Theranova 400 Dialyzer: A Randomized Control Trial," Abstract at ASN meeting, FR-PO 488.

³⁰ Gallo, M., "The Real-Life Study on Expanded Hemodialysis (HDx): 9 Months Experience of a Single Hemodialysis Unit," *Nephrology Dialysis Transplantation*, 34, Issue Supplement_1, June 2019, g1z106.FP539, <https://doi.org/10.1093/ndt/gfz106.FP539>.

³¹ Sanabria, R.M., et al., *Ibid*.

³² Lim, J-H., et al., "Novel Medium Cut-Off Dialyzer Improves Erythropoietin Stimulating Agent Resistance in Maintenance Hemodialysis Patients: A Randomized Controlled Trial," Manuscript submitted for publication.

³³ Sanabria, R.M., et al., *Ibid*.

³⁴ Lim, J-H., et al., *Ibid*.

³⁵ Sanabria, R.M., et al., *Ibid*.

³⁶ Lim, J-H., et al., *Ibid*.

The applicant also asserted that when analyzing the full set of studies utilizing Theranova dialyzers, the collective evidence shows consistent improvement in these inflammatory marker levels. Of 14 measurements of inflammation across four studies,^{40 41 42 43 71} percent (10 of 14) showed statistically significant improvement in the inflammatory marker. For the remaining 29 percent of the measured inflammatory markers, all showed improvement in the inflammatory profile but were not statistically significant. In most of the situations where statistically significant results were not achieved, the applicant asserted, the studies were underpowered to demonstrate statistically significant change of the particular marker.

The applicant stated that studies have demonstrated stable albumin levels,^{44 45} and a reduction of endothelial dysfunction and Albumin and C-Reactive Protein (CRP) levels.^{46 47 48} In addition, the applicant specifically described a single cohort study (N=41) showing a significant decrease in serum levels for urea, β_2m , kappa and lambda free light chain at 3 months. At 3 and 6 months, there was a substantial decrease in serum CRP levels. Also, blood assay demonstrated a decline in

the production of IL-6.⁴⁹ In a 40-participant cross-over prospective study, HDx with Theranova versus high flux HD demonstrated both a higher reduction ratio and a decrease in serum levels for lambda free light chains.^{50 51 52}

The applicant also noted that, in addition to IL-6, a well-recognized biological marker of inflammation, there is also a broader spectrum of uremic toxins associated with inflammation. The applicant listed references for elevated levels of IL-6 leading to the following: hepcidin production with decreased iron availability;⁵³ increased endothelial damage;^{54 55} increased CRP and decreased albumin production.⁵⁶ The applicant attested that with the use of Theranova, patients present clinically with the opposite of each of the above listed concerns, suggesting that chronic inflammation mediated by IL-6 is reduced by treatment with Theranova. However, the applicant submitted a reference which concluded that when compared to HD using high flux membrane, HD using a medium cut-off (MCO) membrane may be not inferior in albumin loss.⁵⁷

An additional prospective cross-over study (N=20) showed reduced levels of IL-6 (6.4561.57 pg/ml vs. 9.4862.15 pg/ml) in patients treated with HDx.⁵⁸ The

applicant included findings from their U.S. IDE Study in the TPNIES application. Although the IL-6 level was not a primary endpoint of the U.S. IDE Study (NCT03257410), nor was the study sufficiently powered to statistically prove a change in IL-6 level, the analysis of the U.S. IDE Study (NCT03257410), comparing Theranova to HD with Elisio 17H, indicates a trend for difference in the pre- to post-dialysis change in plasma IL-6 level, favoring Theranova (p=0.07 and p=0.08 at 4 weeks and 24 weeks, respectively). The pre-dialysis level of IL-6 shows a positive trend for Theranova (p=0.2).⁵⁹ The applicant stated that the accumulation of IL-6 and lambda free light chains may contribute to the chronic inflammation state of ESRD patients, increasing the risk of chronic vascular disease and bacterial infections, respectively. The applicant noted that the company is exploring options to assess the impact of the reduction of these solutes via HDx in ongoing studies.

Finally, the last category of improved clinical outcomes listed by the applicant is enhanced quality of life across many different measures, including, but not limited to, decreased recovery time, decreased restless leg syndrome, and reduced pruritus. The applicant stated that there was decreased symptom burden, citing a study of patients who switched to HDx with Theranova in a multicenter 6-month observational study (N=992), who had statistically significant improvements in measures of symptoms of kidney disease, effects of kidney disease, and the burden of kidney disease.⁶⁰ The applicant also stated that there was improved reported mental health component and statistically significant reduced Restless Leg Syndrome diagnosis.^{61 62 63 64}

⁵⁹ Weiner, D.E., et al., 2019 "Efficacy and Safety of Expanded Hemodialysis with the Theranova 400 Dialyzer: A Randomized Control Trial," Abstract at ASN meeting, FR-PO 488.

⁶⁰ Alarcon, J.C., et al., "Real World Evidence on the Impact of Expanded Hemodialysis (HDx) Therapy on Patient Reported Outcomes (PROs): COREXH Registry," Manuscript submitted for Publication.

⁶¹ Alarcon, J.C., Manuscript submitted for publication, Ibid.

⁶² Gernone, G., et al., "Mid-term Evaluation of the New Medium Cut-Off Filter (Theranova) on Removal Efficiency and Quality of Life," *Nephrology Dialysis Transplantation*, 2018, ERA EDTA Scientific Congress Abstract, SP 489, doi.10.1093/ndt/gfy104.

⁶³ Florens, N and Juillard, L., "Expanded haemodialysis: news from the field," *Nephrol Dial Transplant*, 2018, 33, pp. iii48-iii52.

⁶⁴ Bunch, A., et al., "Long-Term Effects of Expanded Hemodialysis (HDx) on Clinical and Laboratory Parameters in a Large Cohort of Dialysis

⁴⁰ Belmouaz, M., et al., "Comparison of the Removal of Uremic Toxins with Medium Cut-Off and High Flux Dialyzers: A Randomized Clinical Trial," *Nephrol Dial Transplant*, 2020, 35, pp. 328-335.

⁴¹ Kharbanda, K., et al., "A Randomised Study Investigating the Effect of Medium Cut-Off Haemodialysis on Markers of Vascular Health Compared with On-Line Haemodiafiltration (MoDal Study)," Poster presented at the American Society of Nephrology, 2019.

⁴² Cozzolino, M., "Effects of Medium Cut-Off (Theranova) Dialyzer on Hemodialysis Patients: A Prospective Cross-Over Study [Abstract]," *J Am Soc Nephrol*, 29, 2018, pp. 616-617.

⁴³ Cantaluppi, V., et al., "Removal of Large Middle Molecules on Expanded Hemodialysis (HDx): A Multicenter Observational Study of 6 Months Follow-Up," *J Am Soc Nephrol*, 29, 2018, Poster TH-PO 357.

⁴⁴ Krishnasamy, R., et al., "Trial evaluating mid cut-off value membrane clearance of albumin and light chains in hemodialysis patients (REMOVAL-HD): a safety and efficacy study," 2018, ASN 2018 Kidney Week Abstract TH-P0353.

⁴⁵ Bunch, A., et al., "Long-Term Effects of Expanded Hemodialysis (HDx) on Clinical and Laboratory Parameters in a Large Cohort of Dialysis Patients," 2018, ASN 2018 Kidney Week Abstract FR-P0766.

⁴⁶ Kharbanda, k., et al. 2019, Ibid.

⁴⁷ Cantaluppi, V., et al., Ibid.

⁴⁸ Cantaluppi, V., et al., "Removal of Large-Middle Molecules, Inhibition of Neutrophil Activation and Modulation of Inflammation-Related Endothelial Dysfunction During Expanded Hemodialysis (HDx)," June 2019, *Nephrol Dial Transplantation*, 34, Issue Supplement_1, gzf096.FO048, <https://doi.org/10.1093/ndt/gzf096.FO048>.

⁴⁹ Cantaluppi, V., et al., Ibid.

⁵⁰ Belmouaz, M., et al., "Comparison of the Removal of Uremic Toxins with Medium Cut-Off and High Flux Dialyzers: A Randomized Clinical Trial," *J Am Soc Nephrol*, 2018, 29, Poster TH-PO348.

⁵¹ Belmouaz M, et al., "Comparison of hemodialysis with medium cut-off dialyzer and on-line hemodiafiltration on the removal of small and middle-sized molecules," *Clin Nephrol*, Jan 2018, 89 (2018)(1):50-56.

⁵² Belmouaz, M., et al., "Comparison of the Removal of Uremic Toxins with Medium Cut-Off and High-Flux Dialyzers: A Randomized Clinical Trial," *Nephrol Dial Transplant*, 2020, 35, pp. 328-335.

⁵³ Caramelo, C., et al., "Anemia: Pathophysiology, pathogenesis, treatment, incognate," *Rev Esp Cardiol*, 2007, 60, pp. 848-60.

⁵⁴ Kharbanda, K., et al., "A randomized study investigating the effect of medium cut off haemodialysis on markers of vascular health compared with on-line hemodiafiltration (MoDal Study)," 2019, Presented at the Scientific Congress American Society of Nephrology, 2019.

⁵⁵ Cozzolino, C., et al., "Effects of a medium cut-off (Theranova) dialyzer on haemodialysis patients: a prospective, cross-over study," *Clinical Kidney Journal*, 2019, pp. 1-8. Doi 10.1093/ckj/sfz155.

⁵⁶ Gillerot, G., et al. "Genetic and Clinical Factors Influence the Baseline Permeability of the Peritoneal Membrane," *Kidney Int*. 2005, 67, pp. 2477-2487.

⁵⁷ Jung, J.H., et al., "A 6-Month Study on the Efficacy of Hemodialysis Therapy Using Dialyzers with Medium Cut-Off Membranes in Asian Patients with End-Stage Renal Disease," *Nephrol Dial Transplant*, June 2019, 84, Issue Supplement, gzf103.SP487, <https://doi.org/10.1093/ndt/gzf103.SP487>.

⁵⁸ Cozzolino, C., et al., 2019, Ibid.

Regarding improved physical functioning and decreased pruritis, the applicant submitted an article reporting the results of a randomized control trial (N=50), where Theranova resulted in improved results for physical functioning and physical role, and the mean scores of mean pruritis distribution and frequency of scratching during sleep were significantly lower with Theranova.⁶⁵ In another study (single cohort, N=14), Theranova was associated with statistically significant improvement in the physical and mental component quality of life measures.⁶⁶ The applicant also submitted a case report of a HD patient with pruritis who responded to the initiation of HDx using a MCO dialysis membrane.⁶⁷

(2) CMS TPNIES Work Group Analysis

(a) Summary of Current Equipment or Supply by the CMS TPNIES Work Group

The following discussion was part of the content of the CMS TPNIES Work Group evaluative meetings.

Patients with ESRD requiring dialysis are at high risk of mortality due to the presence of uremic toxins.⁶⁸ However, identifying the putative uremic toxin (or toxins) has proven challenging; the European Uremic Toxin Work Group previously identified at least 90 compounds that are retained in patients undergoing dialysis.⁶⁹ Current HD technology relies on diffusion of toxins across a semi-permeable membrane to allow for the removal of small-sized (<500 Da) water-soluble molecules. While HD is generally able to remove water-soluble small toxins (<500 Da), HD has limited ability to clear protein bound solutes, those that are sequestered, or LMM solutes (>500 Da).^{70 71 72} The accumulation of uremic

toxins with higher molecular weight is associated with immunodeficiency, inflammation, protein-wasting, and cardiovascular complications. For instance, solutes such as Beta-2 microglobulin (11.8 kDa)^{73 74} are associated with increased mortality.⁷⁵ Protein-bound solutes such as indoxyl sulfate and p-cresol sulfate also appear to be poorly dialyzable and are associated with the uremic syndrome and cardiovascular disease.⁷⁶

While dialysis can eliminate the immediate risk of death from uremia, it does not replace functioning kidneys. Patients receiving adequate dialysis do not completely recover from the uremic syndrome, indicating that other uremic toxins may not fully be cleared.^{77 78} Compared to the general population, patients with ESRD who receive dialysis are at an increased risk of death, commonly suffer from uremic symptoms such as itching, restless legs, and malnutrition, and are at increased infection risk. Conventional dialysis is effective in removing small molecules, but is less effective in removing larger molecules, sequestered molecules, and protein-bound toxins. Accumulation of middle molecule and protein-bound toxins may contribute to adverse outcomes among patients receiving dialysis⁷⁹ and may explain why even a

transport" *Clin Kidney J.*, Dec. 2018, 15;12 (3), pp. 447–455.

⁷¹ García-Prieto, A., et al., "Evaluation of the efficacy of a medium cut-off dialyser and comparison with other high-flux dialysers in conventional haemodialysis and online haemodiafiltration." *Clin Kidney J.*, Oct. 2018, 11(5):742–746.

⁷² Dobre, M., et al., "Searching for Uremic Toxins" *Clinical Journal of American Society of Nephrology.* February 2013, 8 (2) 322–327.

⁷³ Belmouaz, M., et al., "Comparison of the Removal of Uremic Toxins with Medium Cut-Off and High-Flux Dialyzers: A Randomized Clinical Trial," *J Am Soc Nephrol.*, 29, 2018, Poster TH-PO348.

⁷⁴ Belmouaz, M., et al., "Comparison of hemodialysis with medium cut-off dialyzer and on-line hemodiafiltration on the removal of small and middle-sized molecules," *Clin Nephrol.* Jan 2018, 89 (2018)(1):50–56.

⁷⁵ Cordeiro, I., et al., "High-Flux versus High-Retention-Onset Membranes: In vivo Small and Middle Molecules Kinetics in Convective Dialysis Modalities," *Blood Purification*, Jul 2019, 30:1–8.

⁷⁶ Vanholder, R., et al., "Protein-bound uremic solutes: The forgotten toxin," *Kidney International.* Feb 2001, 59 (78), S266–S270.

⁷⁷ Tanaka H, Sirich TL, Plummer NS, Weaver DS, Meyer TW. An Enlarged Profile of Uremic Solutes. *PLoS One.* 2015; 10(8): e0135657.

⁷⁸ Sirich, T.L., et al., "The Frequent Hemodialysis Network Trial Group. Limited reduction in uremic solute concentrations with increased dialysis frequency and time in the Frequent Hemodialysis Network Daily Trial." *Kidney Int.* May 2017, 91 (5): 1186–1192. doi:10.1016/j.kint.2016.11.002. Epub 2017 Jan 12.

⁷⁹ Clark, W.R., et al., "Uremic Toxins and their Relation to Dialysis Efficacy." *Blood Purif.*, 2019,48(4), pp.299–314. Epub 2019 Sep 27.

small amount of "residual" kidney function is strongly associated with increased survival^{80 81} and higher quality of life.^{82 83}

Innovations in dialysis care include the development of technologies that might remove potential toxins resistant to clearance using current devices. One technology called HDF removes larger molecules by combining convection with diffusion. Convection relies on pressure gradients across the dialyzer membrane, leading to more effective removal of middle to large molecules from the blood. Substantial fluid losses with convection, must be replaced via infusion of typically ultrapure water and dialysis fluids.⁸⁴ This newer technology was later supplemented by online HDF, which enables dialysis providers with ultrapure water systems to generate replacement fluid solution. Although HDF has been associated with improvements to survival in retrospective, observational studies,⁸⁵ randomized controlled trials have been less consistent.^{86 87 88 89} Online HDF has become more widely used in Europe,

⁸⁰ Obi, Y., et al., "Residual Kidney Function Decline and Mortality in Incident Hemodialysis Patients," *J Am Soc Nephrol.*, Dec. 2016, 27(12), pp. 3758–3768. Epub 2016 May 11.

⁸¹ Wang, A.Y. and Lai, K.N. "The importance of residual renal function in dialysis patients." *Kidney Int.*, May, 2006, 69(10), pp. 1726–32.

⁸² Dobre, M., et al., "Searching for Uremic Toxins" *Clinical Journal of American Society of Nephrology.* February 2013, 8 (2) 322–327.

⁸³ Bargman, J.M., et al., "CANUSA Peritoneal Dialysis Study Group. Relative contribution of residual renal function and peritoneal clearance to adequacy of dialysis: a reanalysis of the CANUSA Study," *J Am Soc Nephrol.*, Oct. 2001, 12(10), pp. 2158–62.

⁸⁴ Zweigart, C., et al., "Medium cut-off membranes—closer to the natural kidney removal function." *Int. J Artif Organs.* 2017, 40(7), pp. 328–334. DOI: 10.5301/ujao.5000603.

⁸⁵ García-Prieto, A., et al., "Evaluation of the efficacy of a medium cut-off dialyser and comparison with other high-flux dialysers in conventional haemodialysis and online haemodiafiltration." *Clin Kidney J.*, Oct. 2018, 11(5):742–746.

⁸⁶ Grooteman, M.P., et al.; "CONTRAST Investigators. Effect of online hemodiafiltration on all-cause mortality and cardiovascular outcomes." *J Am Soc Nephrol.*, June 2012, 23(6), pp.1087–1096.

⁸⁷ Maduell, F., et al., "ESHOL Study Group. High-efficiency postdilution online hemodiafiltration reduces all-cause mortality in hemodialysis patients" *J Am Soc Nephrol.*, Feb 2013, 24(3), pp. 487–497. doi: 10.1681/ASN.2012080875. Epub 2013 Feb 14. Erratum in: *J Am Soc Nephrol.* 2014 May; 25(5):1130.

⁸⁸ Morena, M., et al., "FRENCHIE Study Investigators. Treatment tolerance and patient-reported outcomes favor online hemodiafiltration compared to high-flux hemodialysis in the elderly." *Kidney Int.*, June 2017, 91(6):1495–1509.

⁸⁹ Ok, E., et al., "Online Haemodiafiltration Study. Mortality and cardiovascular events in online haemodiafiltration (OL-HDF) compared with high-flux dialysis: results from the Turkish OL-HDF Study." *Nephrol Dial Transplant.* Jan 2013, 28(1), pp. 192–202.

Patients" ASN 2018 Kidney Week Abstract FR-P0766.

⁶⁵ Lim, J-H., et al. "Novel medium cut off dialyzer improves erythropoietin stimulating agent resistance in maintenance hemodialysis: a randomized controlled trial," Submitted for publication.

⁶⁶ Gernone, G., et al., "Mid-term Evaluation of the New Medium Cut-Off Filter (Theranova) on Removal Efficiency and Quality of Life," *Nephrology Dialysis Transplantation*, 2018, ERA EDTA Scientific Congress Abstract, SP 489, doi.10.1093/ndt/gfy104.

⁶⁷ Penny, J., et al. "Pruritis: Is there a salty truth?" Submitted for publication.

⁶⁸ Boschetti-de-Fierro, A., et al., "MCO Membranes: Enhanced Selectivity in High-Flux Cases," *www.nature.com/Scientific Reports*, [5:18448] DOI: 10.1038/srep18448.

⁶⁹ Vanholder R, et al., European Uremic Toxin Work Group (EUTox). Review on uremic toxins: Classification, concentration, and interindividual variability. *Kidney Int.* 2003 May;63 (5):1934–43.

⁷⁰ Macías N., et al., "Middle molecule elimination in expanded haemodialysis: only convective

but it not commonly used in the U.S. due to costs associated with the need for ultrapure water.⁹⁰

Newer dialysis membranes aimed at improved middle molecule clearance are an active area of research.⁹¹ High flux membranes with larger pore sizes can remove larger molecules, including inflammatory cytokines and immunoglobulin light chains but at the cost of albumin loss.⁹² This is significant because low albumin levels are associated with higher mortality rates in patients with ESRD.⁹³

In addition to potential risks associated with efforts to remove larger molecules during dialysis (such as the loss of albumin and immunoglobulins), benefits of improved middle molecule clearance have not been demonstrated in large, randomized-controlled trials. In 2002, a large multicenter randomized controlled trial (HEMO) compared patients receiving maintenance dialysis via high-flux versus low-flux dialyzer membranes. There was no difference in the primary endpoint (death from all causes) or in secondary endpoints (hospitalizations for cardiac cause or death, and hospitalizations for infection or death) between the two groups. In rhabdomyolysis, myoglobin clearance has been demonstrated with large pore dialyzers and HDF, but clinical benefit remains largely unproven.⁹⁴ Similarly, HDF has historically garnered much attention in sepsis due to its ability to efficiently clear inflammatory cytokines like IL-6, but numerous studies have shown no mortality benefit in sepsis with possible downsides in the form of shortened filter life.⁹⁵ No trials have examined the potential benefit of removing larger quantities of middle molecules than is typically achieved from high-flux membranes.

The clearance of protein-bound and sequestered molecules remains a technical challenge and may explain why HDF and other technologies aimed at improved middle-molecule clearance have not significantly changed clinical

outcomes.⁹⁶ Theoretically, intensive long-duration dialysis should improve the clearance of these difficult to remove substances.⁹⁷ In practice, large randomized trials have not shown any difference in the level of substances like indoxyl sulfate and p-cresol sulfate.^{98,99} Improving clearance of these molecules could improve clinical outcomes in patients without residual renal function and would be a boon to the dismal outcomes faced by patients undergoing dialysis.

(b) Assessment of Substantial Similarity to Currently Available Equipment or Supplies

With regard to the criterion as to whether Theranova uses the same or a similar mechanism of action to achieve a therapeutic outcome, the CMS TPNIES Work Group believes that this product slightly modifies existing HD technology. A MCO membrane was designed for use in HD (but not HFD or HDF) modes. These modifications include the removal of larger molecules and increased convection compared to existing HD. As to whether the new use of the technology involves treatment of the same or similar type of disease and the same or similar patient population, the CMS TPNIES Work Group notes that Theranova treats similar patients, specifically, patients with ESRD.

(c) Preliminary Assessment of SCI (see §§ 413.236(b)(5) and 412.87(b)(1))

With regard to the SCI criteria, we note that Theranova is a treatment modality and does not offer the ability to diagnose a medical condition as discussed in § 412.87(b)(1)(ii)(B). We note that Theranova does not offer a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments. The patients who are eligible for this treatment would also be eligible for HD, HDF, or online HDF. The CMS TPNIES Work Group carefully

analyzed the evidence submitted as to whether Theranova significantly improves the treatment and clinical outcomes of Medicare beneficiaries relative to renal dialysis services previously available as demonstrated by the totality of the circumstances. Below, we have summarized the clinical evidence for claims of SCI, along with the references submitted by the applicant.

There is significant literature on the topic of MCO membranes and high retention onset dialyzers. To evaluate this specific technology, the CMS TPNIES Work Group performed a literature search for published articles using the Theranova dialyzer and reviewed all articles submitted by the applicant. They are categorized according to an estimated degree of peer review. Summaries are also provided beneath each citation with disclosures also noted. On the studies with more clinically significant measures, there is more annotation added.

(d) Clinical Evidence for Claims of SCI

Below is a list of references for SCI based on evidence beginning with the highest form of evidence, peer-reviewed journals. We summarize the studies grouped by listings with the most rigorous review to those with the least rigorous review, specifically, those published in Peer-Reviewed Journals, then Review Articles and Editorials, to Posters and Abstracts, including submitted manuscripts, and ending with Incomplete Manuscripts.

Published in Peer-Reviewed Journals

- Belmouaz M, et al.¹⁰⁰ is a retrospective analysis of 10 patients treated with online HDF and then switched to MCO dialysis over 1 year. The authors evaluated three dialysis sessions per patient and noted that there were not significant differences between the two methods in clearance of urea, creatinine, β_2 -microglobulin, and myoglobin. The authors received funding support by Baxter.

- Belmouaz M, et al.¹⁰¹ is a cross-over prospective study performed in France. It included 40 patients randomly assigned to receive either 3 months of medium cut-off hemodialysis (MCO–

⁹⁰ Vanholder, R., et al., “Protein-bound uremic solutes: The forgotten toxin,” *Kidney International*. Feb 2001, 59 (78), S266–S270.

⁹⁷ Sirich, T.L., et al., “The Frequent Hemodialysis Network Trial Group. Limited reduction in uremic solute concentrations with increased dialysis frequency and time in the Frequent Hemodialysis Network Daily Trial.” *Kidney Int*, May 2017, 91 (5): 1186–1192. doi:10.1016/j.kint.2016.11.002. Epub 2017 Jan 12.

⁹⁸ Kalim, S., et al., “Extended Duration Nocturnal Hemodialysis and Changes in Plasma Metabolite Profiles,” *Clin J Am Soc Nephrol*, Mar 7, 2018, 13(3), pp.436–444.

⁹⁹ Sirich, T.L., et al., “The Frequent Hemodialysis Network Trial Group. Limited reduction in uremic solute concentrations with increased dialysis frequency and time in the Frequent Hemodialysis Network Daily Trial.” *Kidney Int*, May 2017, 91 (5): 1186–1192. doi:10.1016/j.kint.2016.11.002. Epub 2017 Jan 12.

⁹⁰ Zweigart, C., 2017. Ibid.

⁹¹ Zweigart, C., 2017. Ibid.

⁹² Krause, B., et al., “Highly selective membranes for Blood purification,” Gambio Dialysatoren GmbH, Hechingen/Germany, Presentation abstract March 26, 2015.

⁹³ Zweigart, C., et al., “Medium cut-off membranes—closer to the natural kidney removal function,” *Int. J Artif Organs*, 2017, 40(7), pp. 328–334. DOI: 10.5301/ujao.5000603.

⁹⁴ Amyot, S.L., et al., “Myoglobin clearance and removal during continuous venovenous hemofiltration,” *Intensive Care Medicine*, 1999 (25), PP. 1169–1172.

⁹⁵ Friedrich J.O., et al., “Hemofiltration compared to hemodialysis for acute kidney injury: systematic review and meta-analysis,” *Critical Care*, Aug 6, 2012 (16): R146.

¹⁰⁰ Belmouaz M, Diolez J, Bauwens M, Duthe F, Ecotiere L, Desport E, Bridoux F. Comparison of hemodialysis with medium cut-off dialyzer and online HDF on the removal of small and middle-sized molecules. *Clin Nephrol*. 2018 Jan;89 (2018)(1):50–56.

¹⁰¹ Belmouaz M, Bauwens M, Hauet T, Bossard V, Jamet P, Joly F, Chikhi E, Joffrion S, Gand E, Bridoux F. Comparison of the removal of uremic toxins with medium cut-off and high-flux dialyzers: A randomized clinical trial. *Nephrol Dial Transplant*. 2020;35:328–335.

HD) followed by 3 months of high-flux HD (HF-HD), or vice versa. The primary endpoint was myoglobin reduction ratio (RR) after 3 months of MCO-HD. Secondary endpoints were the effect of MCO-HD on other middle-weight toxins and protein-bound toxins, and on parameters of nutrition, inflammation, anemia, and oxidative stress. Compared with HF-HD, MCO-HD provides higher myoglobin and other middle molecules RR and is associated with moderate hypoalbuminemia. The authors noted that the potential benefits of this strategy on long-term clinical outcomes deserve further evaluation. This study was supported by Baxter.

- Boschetti-de-Fierro A, et al.¹⁰² is a report on *in vitro* testing of four prototypes for MCO membranes as compared to high-flux, high cut-off membranes, and a rat glomerular membrane model. Sieving characteristics were evaluated before and after blood contact. Authors note that increasing pore sizes often results in loss of albumin but controlling the pore size diameter and variance results in enhanced selection for middle sized proteins. A protein layer also forms along the synthetic membrane, further restricting the loss of albumin. All authors were employed by Gambro Dialysatoren, which is part of Baxter International Inc.

- Cordeiro ISF, et al.¹⁰³ is a prospective crossover trial of 16 patients undergoing HF-HD and switched to online hemodiafiltration (oHDF) and high retention onset (HRO) HD for 4 weeks. Molarity concentrations were lowered to greater extent in oHDF and HRO-HD.

- Cozzolino M, et al.¹⁰⁴ is an Italian prospective, open-label, cross-over study in 20 patients which compared the Theranova 400 HDx membrane to conventional HD, showing a non-significant trend of lower IL-1B and IL-6 levels with HDx. Although infections were statistically more likely in the HD population, the definition of infection was vague, and most of them appeared to be with respiratory tract and fever of unknown origin. Because culture evidence was not required, the risk of

bias in the categorization of infection is high (for example, upper respiratory tract infections inappropriately treated with antibiotics). The HDx had a non-significant trend towards fewer hospitalizations. Potential risks from HDx include an allergic reaction to polysulphone and lower serum albumin levels. The small sample size, single center disease, and short follow-up mean that the results, while promising, require substantial corroborating evidence in the form of a multi-center, blinded randomized controlled trial. The study was supported by an unrestricted grant from Baxter.

- García-Prieto A, et al.¹⁰⁵ is a crossover study of 18 HD patients who received online HDF for one week, then conventional HD the second week, and the use of a MCO membrane for the third week. Authors collected RR and albumin losses and noted that MCO membranes were similar in efficacy as oHDF. Both online and MCO methods had greater reduction of middle molecules. The study was conducted in Spain and authors did not declare any conflicts of interest.

- Gillerot G, et al.¹⁰⁶ is a research paper submitted by the applicant in which the investigators tested the role of IL-6 gene expression on 156 peritoneal dialysis (PD) patients and its putative role in inflammation. They tested a homogeneous population of 152 from Belgium and the North of France. The investigators believe their findings substantiate the critical role played by IL-6 in the peritoneal membrane and support the hypothesis that underlying mechanisms (regulation of IL-6 gene expression) could regulate systemic and local inflammation in association with comorbidity and uremia. However, they note that confirmation of this hypothesis will require well-designed, adequately powered studies, in different populations and different settings. This study was focused on PD and the Theranova membrane is used in HD, so extrapolation of the IL-6 data to that modality is questionable. These studies were supported by Baxter Belgium.

- Lorenzin A, et al.¹⁰⁷ is a performed mathematical modeling, and through it, the authors calculated that the HRO membranes allowed for internal filtration and high convective volumes.

- Lorenzin A, et al.¹⁰⁸ is a paper in which the authors used semi-empirical methods to estimate convective volumes for Theranova 400 and Theranova 500 under standard 4-hour HD conditions. Using their “most complex” mathematical model that incorporated gradients and blood changes along the dialyzer length, authors estimated internal filtration rates of 300ml/min and 400 ml/min for both hemodialyzers.

- Lorenzin A, et al.¹⁰⁹ is an *in vitro* test of Theranova 400 and 500 at zero net ultrafiltration. Albumin macro-aggregates were labeled with Technetium-99m (99mTc) to assess cross filtration through the length of the filter. Using a gamma camera, local cross filtration and internal filtration were calculated. Authors noted that the MCO membrane allowed for clearance of medium-large molecular weight solutes (~11 KDa) and retention of more albumin without requiring special equipment. The authors had no disclosures.

- Macías N, et al.¹¹⁰ is a prospective study of 14 patients on maintenance oHDF. Patients underwent a midweek dialysis session with the Theranova-500 machine under their usual dialysis conditions. Researchers measured the presence of uremic toxins at various molecular weights pre-dialysis, and post-dialysis. Pressures at the inlet and outlet of dialyzer compartments were also measured to estimate direct filtration and back filtration volumes. Researchers used semi-empirical methods to determine that diffusive clearance was more prominent than convective transport (which requires higher volumes). No funding or financial contribution was supplied. Membranes, monitors, and laboratory

¹⁰² Boschetti-de-Fierro A, Voigt M, Storr M, Krause B. MCO Membranes: Enhanced Selectivity in High-Flux Class. *Sci. Rep.* 5, 18448; doi: 10.1038/srep18448 (2015).

¹⁰³ Cordeiro ISF, Cordeiro L, Wagner CS, et al. High-Flux versus High-Retention-Onset Membranes: *In vivo* Small and Middle Molecules Kinetics in Convective Dialysis Modalities. *Blood Purification.* 2019 Jul 30:1-8.

¹⁰⁴ Cozzolino M, Magagnoli L, Ciceri P, Conte F, Galassi A. Effects of a medium cut-off (Theranova) dialyser on haemodialysis patients: A prospective, cross-over study. *Clinical Kidney Journal.* 2019, 1-8.

¹⁰⁵ García-Prieto A, Vega A, Linares T, Abad S, Macías N, Aragoncillo I, Torres E, Hernández A, Barbieri D, Luño J. Evaluation of the efficacy of a medium cut-off dialyser and comparison with other high-flux dialyzers in conventional haemodialysis and online haemodiafiltration. *Clin Kidney J.* 2018 Oct;11(5):742-746.

¹⁰⁶ Gillerot G, Goffin E, Michel C, Evenepoel P, Van Biesen W, Tintillier M, Stenvinkel P, Heimbürger O, Lindholm B, Nordfors L, Robert A, Devuyst O. Genetic and Clinical Factors Influence the Baseline Permeability of the Peritoneal Membrane. *Kid Int.* 2005; 76: 2477-2487.

¹⁰⁷ Lorenzin A, Neri M, Clark WR, et al. Ronco C (ed): *Expanded Hemodialysis—Innovative Clinical Approach in Dialysis.* Contrib Nephrol. Basel, Karger, 2017, vol 191, pp 127-141.

¹⁰⁸ Lorenzin A, Neri M, Clark WR, Garzotto F, Brendolan A, Nalesso F, Marchionna N, Zanella M, Sartori M, Fiore GB, Ronco C. Modeling of Internal Filtration in Theranova Hemodialyzers. *Contrib Nephrol.* 2017;191:127-141.

¹⁰⁹ Lorenzin A, Neri M, Lupi A, Todesco M, Santimaria M, Alghisi A, Brendolan A, Ronco C. Quantification of Internal Filtration in Hollow Fiber Hemodialyzers with Medium Cut-Off Membrane. *Blood Purif.* 2018;46(3):196-204.

¹¹⁰ Macías N, Vega A, Abad S, Aragoncillo I, García-Prieto AM, Santos A, Torres E, Luño J. Middle molecule elimination in expanded haemodialysis: Only convective transport? *Clin Kidney J.* 2018 Dec 15;12(3):447-455.

tests were those routinely used in the dialysis unit.

- Reque J, et al.¹¹¹ is a prospective study of eight patients who either underwent oHDF or underwent HDx with TheraNova 500 for 24 sessions. After a 1-week washout with HF-HD, all patients crossed over to the alternative method. Laboratory values were obtained before and after each session, specifically of urea, creatinine, phosphorous, beta2-microglobulin, myoglobin, and prolactin. The urea and beta2-microglobulin reduction ratios were the same but HDx demonstrated higher RR of myoglobin (60 percent compared to 35 percent in HDF). The authors had no disclosures.

Review Articles/Editorials

This is the second grouping in the list of evidence for SCI from most compelling to least compelling. We summarize the studies the applicant provided as follows:

- Caramelo C, et al.¹¹² is an article that reviews the clinical and pathophysiological characteristics of anemia in this context. Particular emphasis has been placed on cellular and molecular regulatory mechanisms, and their implications for treatment. The applicant referenced the review article's language on hepcidin, because it is considered the homeostatic regulator of iron in its intestinal absorption, its recycling by macrophages and its mobilization from liver stores. Its transcription is markedly induced in inflammatory processes, especially by cytokines like IL-6.

- Florens N, et al.¹¹³ is a review article included by the applicant in their application. It summarizes feedback from the first routine use of HDx therapy under real-life conditions in European facilities. The authors reported no adverse event after 5,191 HDx treatments, and opined that patients suffering from itching, restless legs syndrome, persistent asthenia or malnourishment could benefit from HDx therapy. While they discuss here the promising applications in which HDx could be valuable (myeloma, rhabdomyolysis or cardiovascular diseases), the message is mitigated by

¹¹¹ Reque J, Pérez Alba A, Panizo N, Sánchez-Canel JJ, Pascual MJ, Pons Prades R. Is Expanded Hemodialysis an Option to Online Hemodiafiltration for Small- and Middle-Sized Molecules Clearance? *Blood Purif.* 2019;47(1-3):126-131.

¹¹² Caramelo C, Just S, Gil P. Anemia in Heart Failure: Pathophysiology, Pathogenesis, Treatment and Incognitae. *Rev Esp Cardiol.* 2007; 60(8): 848-860.

¹¹³ Florens N, Juillard L. "Expanded Haemodialysis: News from the Field," *Nephrol Dial Transplant*, 2018; 33: iii48-iii52.

reminding why and how prudence should be taken in the design of future HDx studies, particularly with poor de-aeration of the filter in automatic mode and manual intervention required to prime the membrane. Some patients requiring more anti-coagulation using the TheraNova membrane, and patients being aware of the use of the TheraNova device because of lack of logo removal. The authors note that although promising, the clinical evidence is incomplete. Both authors received a grant Investigator Initiated research for the evaluation of HDx in clinical practice and one performed occasional lectures for Baxter.

- Wolley M, et al.¹¹⁴ is a clinical review article that recognizes that advances in dialysis technology do not always improve patient outcomes, and it reviews the clinical relevance regarding the removal of LMMs, particularly those involved in chronic inflammation, atherosclerosis, structural heart disease, and secondary immunodeficiency. The authors note that single-center safety and efficacy studies have identified that use of these membranes in maintenance dialysis populations is associated with limited loss of albumin and increased clearance of large middle molecules. When the review was published in 2018, the authors noted that larger, robustly conducted, multicenter studies were evaluating these findings. They concluded that after completion of these safety and efficacy studies, the perceived clinical benefits of providing clearance of LMMs must be assessed in rigorously conducted, randomized clinical studies. One of the authors received research funding from Baxter and participated on advisory boards and speaker bureaus for Baxter.

- Zweigart C, et al.¹¹⁵ is an editorial review submitted by the applicant on MCOs, which was generally favorable with regard to high quality and good performance. All of the authors are employees of the Gambro Dialysatoren GmbH, Hechingen (Germany) or Gambro Lundia AG. Gambro AB (including all direct and indirect subsidiaries) is now part of Baxter International Inc.

Posters and Abstracts

This is the third grouping in the list of evidence for SCI from most compelling to least compelling. We

¹¹⁴ Wolley M, Jardin M, Hutchinson, C. "Exploring the Clinical Relevance of Providing Increased Removal of Large Middle Molecules," *Clin J Am Soc Nephrol* 2018;13: 805-813.

¹¹⁵ Zweigart C, Boschetti-de-Fierro A, Hulko M, Nilsson L-G, Beck W, Storr M, Krause B. Medium Cut-Off Membranes—Closer to the Natural Kidney Removal Function. *Int J Artif Organs.* 2017; 40(7): 328-334.

summarize the poster sessions and abstracts, including submitted manuscripts which the applicant provided as follows:

- Belmouaz M, et al.¹¹⁶ is a randomized open label crossover study in which 46 patients underwent MCO-HD and HF-H). MCO-HD had higher medium RRs of myoglobin and beta-2 microglobulin and increased albumin loss compared to HF-HD. The authors received funding support by Baxter.

- Boschetti-de-Fierro A, et al.¹¹⁷ is a poster in which the investigators assessed the performance of the MCO devices in simulated HD and HDF treatments. The applicant's submission of the material presented in this poster was incomplete regarding date and location of the poster session. This study was funded by Baxter.

- Kharbanda K, et al.¹¹⁸ is a randomized study funded by Baxter Healthcare and the National Institute for Health Research which compared HDF with HDx and suggested an improved recovery time with HDx. The study showed lower levels of endothelial cell microvesicles in HDx. However, the study did not have comparable baseline recovery times (for example, 41 percent with <2 hours with HDx versus 35 percent with HDF) and the authors performed a per-protocol rather than an intention to treat analysis, exacerbating bias in the study.

- Kirsch AH, et al.¹¹⁹ is a poster that summarizes a two pilot randomized controlled prospective open-label crossover studies, in which 39 HD patients underwent treatment with MCO membranes, a HFD, and HDF. Authors concluded that MCO-HD removed middle molecules (free light chain) more effectively than high-flux and high-volume HDF. However, the authors noted that there are several limitations of the study. First, compared to the control dialyzers used, the experimental membranes used were different, less tight membranes. Second, the study

¹¹⁶ Belmouaz M, Bauwens M, Bouteau I, Thiery A, Ecotiere L, Bridoux F. Comparison of the Removal of Uremic Toxins with Medium Cut-Off and High-Flux Dialyzers: A Randomized Clinical Trial. *TH-PO348*, 2018.

¹¹⁷ Boschetti-de-Fierro A, Voigt M, Huiko M, Krause B. MCO Dialyzers: Enhanced Selectivity in High-Flux. Gambro Dialysatoren GmbH, Research and Development, Hechingen, Germany, Poster No. SAT-481 (Baxter).

¹¹⁸ Kharbanda K, Herring A, Wilkinson F, Alexander Y, Mitra S. A Randomised Study Investigating the Effect of Medium Cut-Off Haemodialysis on Markers of Vascular Health Compared with On-Line Haemodiafiltration (MoDal Study). Manchester Metropolitan University. 2019

¹¹⁹ Kirsch AH, Lyko R, Nilsson LG., et al. Performance of hemodialysis with novel medium cut-off dialyzers. *Nephrol Dial Transplant* 2017; 32: 165-172.

design was confined to only one single treatment with each dialyzer for each patient and the study did not examine the long term effects of such membranes on serum levels of middle molecules and albumin. The authors conclude that future studies should assess whether the performance of MCO-HD improves clinical outcomes. The study was conducted in Germany and funded by Baxter, and the conflicts of interest statement in the paper lists three of the ten authors as employees of Baxter.

- Bunch, A, et al.¹²⁰ is a multicenter prospective study in prevalent HD patients, older than 18 years old; enrolled from September 1 to November 30, 2017, and converted to HDx using Theranova 400. The investigators found an initial small decrease in serum albumin level, which stabilized and was within the normal range per their Bogata, Columbia laboratory references. Although Table 1 and Table 2 were cited in the abstract, both were missing. Dialysis performance adequacy (Kt/V) was achieved. No clinically significant differences in laboratory values at 6 months with November 30 of 2017, and converted to HDx using Theranova 400 (3 sessions per week, 4 hours per session, same heparin dose). The lead author has been listed as the medical director of Renal Therapy Services, owned by Baxter, in Bogota, Columbia.

- Cantaluppi V, et al.¹²¹ is a multicentric observational study of 6 months follow-up. American Society of Nephrology (ASN) Week, 2018, Abstract, Thu-PO357. This multicenter (Italy) study evaluated 41 HD patients comparing standard HD molecular levels versus HDx and found a significant decrease in urea, beta-2-microglobulin, and free light chains. The study did not evaluate clinical outcomes.

- Cantaluppi V, et al.¹²² is an abstract submitted by the applicant reporting on a study where 41 HD patients (age 67,6±13,4) in standard high flux HD

were shifted to HDx using Theranova 400 (1.7 m2, Baxter). Each patient was studied at baseline HD (T0), 3 months (T3) and 6 months (T6) after HDx, after which they were evaluated the following pre-dialysis parameters: Urea, Creatinine, Phosphate, Beta2-microglobulin, Myoglobin, Free Light Chains, Hemoglobin, Albumin and CRP. For in vitro studies, T0 and T6 plasma were used to evaluate neutrophil activation (ROS generation, apoptosis, adhesion) and endothelial dysfunction/senescence. The investigators concluded that HDx therapy provided high removal of different LMMS, leading to a significant reduction of molecules involved in uremia-associated inflammation and organ dysfunction (in particular Free Light Chains kappa and lambda). Long-term studies with a larger sample size are needed to evaluate the clinical impact of HDx.

- Cozzolino, M.¹²³ is an abstract of a pilot study with 20 prevalent HD patients studied for six months in two dialysis treatments: One MCO (Theranova) dialyzer and one high-flux dialyzer. The author claims the pilot study shows the Theranova dialyzer has a good tolerance profile and reduces the cumulative number of infections in HD patients. The study was funded by an unrestricted grant from Baxter.

- Gallo M.¹²⁴ is a single cohort study in Italy which compared HDx to baseline HD treatments in 15 patients and showed no difference in uremic toxins, though there was a change in ESA dose.

- Gernone G, et al.¹²⁵ is a single cohort study in Italy which investigated 14 patients using Theranova with baseline HD and showed no statistical change in outcomes, clearance, or quality of life.

- Jung JH, et al.¹²⁶ is a study that was questionably designed since they chose young, well-nourished patients at the

start of the study, which made it difficult to analyze the comparison of the two groups at various points in time. This observational study of 42 Korean patients comparing HD to HDx showed no comparative difference between the two groups in any markers.

- Krishnasamy R, and Hutchinson C.¹²⁷ is an abstract submitted by the applicant from this single-arm, multicenter study with 92 Australian/New Zealand patients. The study examined the safety and efficacy and patient-centered outcomes of MCO dialyzer use in chronic HD patients over 6 months. The investigators concluded that there was a small but acceptable reduction in serum albumin in regular HD using the MCO dialyzer. However, the figures were not included in the abstract sent by the applicant for review by the CMS TPNIES Work Group. The investigator noted that future randomized controlled trials should assess the impact of the MCO dialyzer on clinical and long-term patient-centered outcomes.

- Krause B, et al.¹²⁸ is a description of membrane manufacturing utilizing hollow fiber technology.

- Weiner DE, et al.¹²⁹ included two items for this U.S. based study at a large academic medical center. The first was the ASN 2019 Scientific Congress abstract and the second was a copy of the poster session at the ASN annual meeting in 2019. This open label randomized controlled trial in 172 patients who underwent 24 weeks of Theranova 400 MCO dialyzer compared to a high flux dialyzer showed a potential decrease in hospitalizations with HDx, but the authors did not produce statistical tests of significance. While this was a randomized control trial (RCT), covariates were not well-balanced, including substantially more patients with diabetes in the conventional HD arm. The study showed lower lambda free light chains in HDx compared to high flux HD. Albumin levels were maintained in both. The presenters concluded that larger studies of longer duration are needed to assess if better larger molecule clearance is associated with

¹²³ "Effects of Medium Cut-Off (Theranova) Dialyzer on Hemodialysis Patients: A Prospective Cross-Over Study [Abstract]." *J Am Soc Nephrol*, 29, 2018, pp. 616–617.

¹²⁴ Gallo M. The Real-Life study on expanded hemodialysis (HDx): 9 months experience of a single hemodialysis unit. *Nephrol Dial Transplantation and Transplantation*, June 2019, ERA EDTA Abstract. FP539.

¹²⁵ Gernone G, Montemurro M, Capurso D, Colucci G., Dell'Anna D, Deltomaso F, LaRosa R, La Volpe M, Partipilo F., Pepe V, Ripa E. Mid-term evaluation of the new medium cut-off filter (Theranova) on removal efficiency and quality of life. *Nephrology and Transplantation*, Abstract. SP489.

¹²⁶ Jung JH, Song JH, Ahn S-H. A 6-month study on the efficacy of hemodialysis therapy using dialyzers with medium cut-off membranes in Asian patients with end-stage renal disease. *Nephrol Dial Transplantation*, June 2019, 84 Issues Supplement-1, gzf103.SP487, <https://doi.org/10.1093/ndt/gfz103.SP487>.

¹²⁷ Krishnasamy R, and Hutchinson C. Trial Evaluating Mid Cut-Off Value Membrane Clearance of Albumin and Light Chains in Hemodialysis Patients (REMOVAL-HD): A Safety and Efficacy Study. Oct. 2018 ASN Scientific Congress Abstract TH-PO363.

¹²⁸ Krause B, Boschetti-de-Fierro A, Dutczak S, Zweigart C. Highly Selective Membranes for Blood Purification. Jahrestreffen der Fachgruppen "Fluidverfahrenstechnik" und "Membrantechnik" 26 Mar 2015.

¹²⁹ Weiner DE, Falzon L, Beck W, Xiao M, Tran H, Bernardo AA. Efficacy and Safety of Expanded Hemodialysis Enabled by a Medium Cut-Off Membrane: A Randomized Control Trial. FR-PO488, ASN 2019.

¹²⁰ Bunch A., Nilsson L, Vesga J, Ardila F, Zuniga E, Alarcon J. "Long-Term Effects of Expanded Hemodialysis (HDx) on Clinical and Laboratory Parameters in a Large Cohort of Dialysis Patients" ASN 2018 Kidney Week Abstract FR-P0766.

¹²¹ Cantaluppi V, Donati G, Lacquaniti A, Cosa F, Gernone G, Marengo M, Teatini U. Removal of large-middle molecules on expanded hemodialysis (HDx): A multicentric observational study of 6 months follow-up. ASN Week, 2018, Abstract, Thu-PO357.

¹²² Cantaluppi V, Marengo M, Alessandro Q, Berto M, Donati G, Antonio L, Cosa F, Gernone G, Teatini U, Migliori M, Panichi V. Removal of Large-Middle Molecules, Inhibition of Neutrophil Activation and Modulation of Inflammation-Related Endothelial Dysfunction During Expanded Hemodialysis (HDx), *Nephrol Dial Transplantation*, June 2019, 34, Issue Supplement 1, gzf096.FO048, <https://doi.org/10.1093/ndt/gfz096.FO048>.

improvements in clinical outcomes, including vascular disease, quality of life, and mortality. The authors received commercial support from Baxter.

- Alarcon J, et al.¹³⁰ describes a study over 12 months in which 992 patients from 12 renal clinics were followed after switching from high-flux HD to HDx. The authors assessed many patient quality of life outcomes using the short form kidney disease quality of life (KDQoL-SF36), dialysis symptom index (DSI) and prevalence of restless leg syndrome (RLS) and found modest reductions in DSI severity scores, increases in KDQoL-SF36 scores in some domains (but unchanged in the mental and physical domains), and reduced prevalence of restless leg syndrome. Unfortunately, the authors did not provide a control group. Also, the authors performed a large number of statistical tests without adjustment, further increasing the risk of Type 1 error. The study was supported by Renal Therapy Services-Columbia, owned by Baxter. Five of the eight authors are employees of Renal Therapy Services. One author is a full-time employee of Baxter and has a patent pending for RLS medication.

- Ariza J, et al.¹³¹ is a manuscript that was provided by the applicant. Cost estimates were extrapolated using an observational design, which suggested lower hospital days (but not hospitalizations) and lower medication use in the HDx. However, the lack of randomization makes this study difficult to evaluate. Furthermore, the authors did not show any difference in costs between HDx and HD. The study was funded by Baxter.

- Penny JD, et al.¹³² is a manuscript in submission that was included by the applicant. It is a single case-study of a HD patient with pruritis and extreme levels of tissue sodium. Both responded to HDx therapy. The authors acknowledge that further robust clinical exploration is required.

- Sanabria RM, et al.¹³³ is manuscript provided by the applicant and has not

been published. The observational study followed 81 patients receiving high-flux HD for 1 year who subsequently switched to HDx for 1 year. While there was a significant reduction in number of hospital days (but no change in hospitalization rate) and medication use, findings were limited by the lack of a control group. The shortening of hospital stays could be attributed to a systematic change in admission practice patterns, rather than HDx. Furthermore, Kt/V was higher in the HDx group, but the authors did not standardize dialysis dosing, making it difficult to attribute effects to HDx or to other causes of increased dialysis adequacy. Hemoglobin levels, albumin, hsCRP were not statistically different in the two arms. All investigators are employees of RTS Ltd, Columbia, an affiliate of Baxter Healthcare. The study was supported by Renal Therapy Services-Columbia, an independent entity owned by Baxter International, Inc.

Incomplete Manuscripts

This is the fourth and final grouping in the list of evidence for SCI from most compelling to least compelling. We summarize the incomplete manuscripts which the applicant provided as follows:

- Bolton S, et al.¹³⁴ is a manuscript provided by the applicant and is unfinished. It describes a crossover study of patients previously treated with high-flux HD and switched to Theranova. Patient reported outcome measures (PROMs) suggested decreased self-reported dialysis recovery time and symptom burden, especially at 6 months. However, regression to the mean appeared common, and there was no control group.

- Lim J, et al.¹³⁵ is a manuscript provided by the applicant, reporting a randomized trial comparing MCO to high-flux HD, with 50 patients undergoing 12 weeks of treatment in Korea. The study was small, and the authors performed a large number of statistical tests comparing quality-of-life outcomes, with only a couple statistically significant. Without adjusting p-values for the number of statistical test, the risk for Type 1 error is large and not unexpected. A second

trial suggested lower medication doses, but again results were statistically significant only for a few of the parameters of interest. The study is small and requires replication at additional centers to confirm results.

- Lim J-H, et al.¹³⁶ is a manuscript provided by the applicant, reporting a randomized trial comparing MCO to high-flux HD, with 50 patients undergoing 12 weeks of treatment in Korea. Its purpose was to evaluate the effects of ESA resistance of HD using a MCO dialyzer. The number of registered patients was small and the study duration not long enough to assess definite results. Also, the study was not blinded to clinicians, which may have affected the ESA and iron supplementation prescriptions. Additional studies need to be performed to assess clinical outcomes.

(e) Comments by the Members of the CMS TPNIES Work Group

The CMS TPNIES Work Group consists of CMS Medical Officers, senior staff, a senior technical adviser, a biomedical engineer and contracted physicians, including nephrologists. All materials sent by the applicant were reviewed by the members of the CMS TPNIES Work Group. The members of the CMS TPNIES Work Group voiced the specific concerns regarding the evidence submitted for proof of eligibility via the SCI criteria. While Theranova represents a unique technology, the CMS TPNIES Work Group noted that the current evidence supporting SCI is lacking but that other evidence may be forthcoming during the comment period. It is too early to tell if the patient-recorded outcomes, such as fewer cardiovascular events, are significant because of the small numbers in the studies. Specifically, a study for infection was cited with an N=20; another had an N=10. Also, the definition of the infection was vague. Although hospitalization rates are discussed in the articles, the cause of the hospitalization was unknown. Patient lab results should be correlated with patient-reported results. In the submitted articles, the studies are all open-label and observational, with tenuous findings; there should be larger studies focused on the U.S. dialysis population's patient health outcomes; the patients need to be blinded in these studies.

¹³⁰ Alarcon J, Bunch A, Ardila F, Zuniga E, Vesga J, Rivera A, Sanchez R, Sanabria M. Real world evidence on the impact of expanded hemodialysis (HDx) therapy on Patient Reported Outcomes (PROs): CPREXH Registry (in submission).

¹³¹ Ariza J., Walton SM, Sanabria M, Vega J, Suarez A, Rivera A. An Initial Evaluation of the Potential Cost Impact and Cost Effectiveness of Expanded Hemodialysis (in submission).

¹³² Penny JD, Salerno F, Akbari A, McIntyre, C. "Pruritis-Is There a Salty Truth?" (in submission). The applicant included a manuscript in submission.

¹³³ Sanabria RM, Vesga JI, Ariza J, Sanchez R, Suarez A, Bernardo A, Rivera A. Expanded Hemodialysis and its effects on hospitalization and medication usage: An exploratory study. (in submission).

¹³⁴ Bolton S, Gair S, Matthews M, Stewart L, McCullagh N, A 1-year routine assessment of patient-reported symptom burden after implementing expanded hemodialysis, 2019. (in process).

¹³⁵ Lim J, Park Y, Yook J, Choi S, Jung H, Choi J, Park S, Kim C, Kim Y, Cho J. Randomized controlled trial of medium cut-off versus high-flux dialyzers on quality-of-life outcomes in maintenance hemodialysis patients. (in submission).

¹³⁶ Lim J-H, Yook J-M, Choi S-Y, Jung H-Y, Choi, J-Y, Park S-H, Kim C-D, Kim Y-L, Cho H-H. Novel Medium Cut-Off Dialyzer Improves Erythropoiesis Stimulating Agent Resistance in Maintenance Hemodialysis Patients: A Randomized Control Trial. (in submission).

The background information provided by the applicant and researched by the group is conflicting. This may be due to the variation in the location of the studies, including Colombia, France, Belgium, England, Ireland, Australia, New Zealand, and Korea. One of the CMS TPNIES Work Group members suggested a meta-analysis be done, along with the heterogeneity of dialysis care in those countries as compared to the care received by the Medicare population in the U.S.

At this time, while HDx appears to be a promising technology, the CMS TPNIES Work Group has concerns that the current state of evidence insufficiently demonstrates SCI in Medicare patients undergoing dialysis, but that additional evidence may be forthcoming in the comment period does not believe that the current state of evidence sufficiently demonstrates SCI in Medicare patients undergoing dialysis. In general, the dialyzer appears to have improved middle molecule clearance. While observational studies show an association between high levels of middle molecules and poor outcomes, these correlations do not prove causation. For instance, a growing body of evidence suggests that protein-bound solutes such as indoxyl sulfate and p-cresol sulfate could be responsible for the uremic syndrome. Conventional HD, HDF, and HDx do not effectively clear protein-bound toxins.

A summary of the current body of evidence is as follows:

- Theranova more effectively removes middle molecules compared to conventional dialysis with high-flux membranes. These include molecules that have varying degrees of plausible toxicity (for example, beta 2 microglobulin to cytokines to endothelial proteins). Because nephrologists have not identified the putative uremic toxin, it is not certain that clearance of these toxins will lead to improved clinical outcomes.

- Although small before and after studies suggest potential clinical benefits from MCO dialyzer membranes compared with conventional HD via high-flux membranes, such as reduced infection, improved itching and restless legs, and shorter recovery time from dialysis, these studies are mostly observational, small in nature, with a high potential for bias. A large, multi-center trial would be necessary to prove substantial benefit from HDx over conventional HD.

- Several small studies suggest that MCO dialyzer membranes are comparable to HDF in removal of middle molecules, but online HDF is not generally available in the U.S.

Furthermore, online HDF has not consistently shown to improve health outcomes relative to conventional HD with high-flux membranes.

- There may be increased removal of albumin with MCO membranes compared to conventional high-flux dialysis, which could have negative health consequences.

- A large randomized controlled clinical trial examining the effects of removing larger molecules did not demonstrate clinical benefits from removing larger molecules, although it did not examine newer technologies which are more effective. This negative study provides reason to be somewhat skeptical about the benefits of HDx over HD.

- Following the FDA-requested 6-month clinical study to validate efficacy of large toxin removal and safety, the applicant stated that it anticipates FDA marketing approval in May 2020. However, we note that, per the application, safety is defined in part by albumin loss. At this time we do not believe the clinical trials included safety and efficacy studies for the large middle molecules the applicant asserts to be the cause of inflammation. Therefore, the perceived clinical benefits of providing clearance of those large middle molecules were not assessed in rigorously conducted, randomized clinical studies.

In summary, while HDx is a promising new technology, there is insufficient evidence at this time to demonstrate a clear clinical benefit for Medicare dialysis patients. However, additional evidence may be forthcoming in the comment period. Therefore, we are inviting public comment as to whether Theranova meets the TPNIES SCI criteria.

b. Tablo® Cartridge for the Tablo Hemodialysis System

(1) Outset Medical Application

For CY 2021, Outset Medical submitted an application for the TPNIES for the Tablo® Cartridge for use with the Tablo® Hemodialysis System. The applicant stated that the Tablo® Cartridge is intended to substantially improve the treatment of Medicare beneficiaries with ESRD by removing barriers to home dialysis.

The applicant noted that the Tablo® Cartridge is necessary to operate the Tablo® Hemodialysis System for use in home. The cartridge is comprised of a pre-strung blood tubing set and series of sensor-receptors mounted to a user-friendly organizer, and together these are referred to as the Cartridge. The blood tubing set comprises a blood

pump tubing segment that interfaces with a peristaltic (blood) pump mounted on the inner front panel of the Tablo® console and arterial and venous lines that connect to the corresponding lines on the patient. Additional components to the cartridge include consumable supplies: Bicarbonate and acid concentrate jugs and straws, and an adapter for disinfectant use.

The applicant stated that the blood tubing set is primarily comprised of one arterial line and one venous line and is enhanced with a recirculating adaptor, a bifurcated saline line, a pressure transducer protector, a drip chamber with clot filter, and an arterial pressure pod.

According to the applicant, in addition to the blood lines, there is an integrated saline line that enables automatic priming as well as monitored delivery of saline boluses during treatment. There is also an infusion line and two infusion ports (arterial and venous) for manual delivery of medicine, anticlotting agents, and blood sampling.

In describing what the Tablo® Cartridge does, the applicant states that it was designed with features to seamlessly integrate with sensors on the front panel of the console (for example, air sensing, arterial and venous pressure sensing) and to reduce touch points during priming and blood return (for example, recirculating adaptor and bifurcated saline line) to minimize contamination. The blood pump draws blood from the patient into the blood tubing set and passes the blood through a dialyzer before returning the treated blood to the patient.

The applicant specifically stated that the Tablo® Hemodialysis System includes the Tablo® Cartridge. In its entirety, it has been specifically designed for patient-driven self-care using an iterative human factors process, with key design objectives being to facilitate learning and to minimize device training time.¹³⁷ Human factors studies performed in a laboratory setting have demonstrated that patients can accurately learn and manage the Tablo® Hemodialysis System after a brief training period.^{138 139} A recent prospective,

¹³⁷ Alvarez, Luis, et al. "Clinical Experience with a New Hemodialysis System Designed for In-Center Self-Care Hemodialysis." *Self-Care*, vol. 8, no. 3, 2017, pp. 12–18. *Self-Care* vol. 8, no. 3, 2017, pp. 12–18

¹³⁸ Wilcox, Stephen B., et al. "Results of Human Factors Testing in a Novel Hemodialysis System Designed for Ease of Patient Use." *Hemodialysis International*, vol. 20, no. 4, 16 May 2016, pp. 643–649. doi:10.1111/hdi.12430

¹³⁹ Alvarez, Luis, et al. "Tablet-Based Training for In-Center Self Dialysis -A Pilot Study." *Journal of*

multicenter, open-label, crossover trial comparing in-center and in-home HD using Tablo® Hemodialysis System further supports the clinical efficacy, safety, and ease of use of the system.¹⁴⁰

The applicant stated that the Tablo® Hemodialysis System is the first and only all-in-one technology and includes a number of features that make it new and different from current standard of home dialysis care. These unique features include (1) A single-use Tablo® Cartridge with user-friendly pre-strung blood, saline, and infusion tubing and an integrated blood pressure monitor that interfaces with the console to enable automated features such as air removal, priming, and blood return which minimize user errors, save time and streamline the user experience;¹⁴¹ (2) on demand water and dialysate production using a standard tap water source, eliminating the need for time-consuming advance water preparation, bagged dialysate or dialysate batching;¹⁴² (3) a consumer-centric touchscreen interface that guides users with step-by-step instructions including non-technical language, animation, and color-coded parts, to enable easier training, faster set-up and simpler management including clear alarm explanations and resolution instructions;¹⁴³ and (4) electronic data capture and automatic wireless transmission to eliminate the need for manual record keeping by the patient, care partner, or nurse.¹⁴⁴

The applicant asserted, both in the written application and at an in-person meeting with CMS, that the observational studies with the Tablo® Hemodialysis System were able to achieve CMS adequacy targeted on three times per week dialysis at an average treatment time of less than 4 hours. Tablo® has demonstrated the ability to treat to adequacy targets within the Medicare standard reimbursement of three treatments per week.

The applicant has not submitted an application for pass-through payments under the Medicare OPPS or the NTAP program under the Medicare IPPS for

the American Society of Nephrology, vol. 27, no. Abstract Edition, Nov. 2016, p. 895A.

¹⁴⁰ Plumb, Troy et al. "Safety and efficacy of the Tablo hemodialysis system for in-center and home hemodialysis." Hemodialysis International, Online, 2019. DOI:10.1111/hdi.12795.

¹⁴¹ Outset Medical, "Safety Reference Guide." DOC-0004336 Rev 04, 2019.

¹⁴² Outset Medical, "Tablo Preconfigured System White Paper." DOC-0004252 Rev 01, 2019.

¹⁴³ Alvarez, Luis, et al. "Tablet-Based Training for In-Center Self Dialysis - A Pilot Study." Journal of the American Society of Nephrology, vol. 27, no. Abstract Edition, Nov. 2016, p. 895A.

¹⁴⁴ Outset Medical, "Tablo Information Security Design White Paper." DOC-0003639 Rev 03, 2019.

the Tablo Hemodialysis System, including the Tablo® Cartridge.

This application for TPNIES is only for the Tablo® Cartridge and its components for use in the home, which the applicant stated that it intended to begin marketing in March 2020 following FDA clearance of the Tablo® Hemodialysis System for home use. On March 31, 2020, Outset Medical received FDA clearance to market the device for use in the home, and CMS received a copy of this letter.

The applicant submitted a Premarket Notification 510(k) for marketing clearance of Tablo®. Previous 510(k) authorizations for the Tablo® Hemodialysis System and Tablo® Cartridge were for hospital and outpatient clinic use only. The applicant could not use or market the Tablo® Cartridge in the home setting until the Tablo® Hemodialysis System was granted marketing authorization by the FDA (note: Table Hemodialysis System and cartridge was granted FDA market authorization in November 2016). While the cartridge was previously cleared through a separate 510k and was not necessary to include in the submission for marketing clearance for home use, the Tablo® Hemodialysis System cannot be operated without the Tablo® Cartridge. According to the applicant, the cartridge was included in the use instructions for the home approval.

The applicant noted that the Tablo® Cartridge is not currently available for marketing in the home setting. As explained above, the applicant intended to begin marketing in the home setting in March 2020, after the FDA clears the Tablo® Hemodialysis System for marketing for home use. The applicant expected the first shipments of the Tablo® Cartridge for use in the home to occur March 2020. However, it is our understanding that to-date, the first patient to start training is scheduled to begin June 1, 2020.

The applicant does have an IDE to study the Tablo® Hemodialysis System's safety and efficacy for use in the home, which has been completed as of the filing of the TPNIES application. The applicant stated that the IDE would be closed once marketing authorization for the use of the Tablo® Hemodialysis System in the home is approved. The IDE study reference number is G140098. The Tablo® Cartridge is assigned a Class II device category.

The applicant stated that it would submit a HCPCS application for the Tablo® Cartridge in advance of the September 1, 2020 deadline.

The applicant identified and described how the new and innovative

renal dialysis equipment or supply meets the criteria for SCI over existing renal dialysis services. The applicant states the Tablo® Cartridge is necessary to operate the Tablo® Hemodialysis System and therefore enables the system to deliver the treatments that meet CMS's SCI criteria.

The applicant states that the Tablo® Hemodialysis System enables a treatment option for a patient population unresponsive to, or ineligible or, currently available treatments. As supporting background material, the applicant notes that home HD is a highly underutilized treatment for ESRD patients. Currently 90 percent of patients receive HD in a clinic. Fewer than 2 percent have HD treatment at home. Contributing to this low penetration rate is also a high dropout rate with the incumbent home devices of 25 percent and 35 percent at 12 and 24 months, respectively.¹⁴⁵ The barriers to home dialysis adoption and retention have been well studied and include: (1) Treatment burden for patients and care partner fatigue; (2) technical challenges operating HD machine; (3) space, home modifications, and supplies management; (4) patients not wanting medical equipment in the home; and (5) safety concerns.¹⁴⁶ The applicant asserts that Tablo® is the first new home HD system in over 15 years, designed to address many of the above-mentioned barriers that currently result in patients resigning themselves to in-center care and/or stopping home modalities due to the associated burden of self-managed therapy. Among other things, the objective of this order is for 80 percent of ESRD patients starting kidney replacement therapy (KRT) with a transplant or home dialysis by 2025.¹⁴⁸ The applicant states that this goal will require a multi-faceted solution, inclusive of less burdensome technology, to address the key barriers to home dialysis.

The applicant believes that the Tablo® Hemodialysis System has the potential to significantly increase home dialysis.

¹⁴⁵ Sehasi, Rebecca et al. Factors Associated With Discontinuation of Home Hemodialysis, American Journal of Kidney Disease, Volume 67, Issue 4, 2016, Pages 629-637.

¹⁴⁶ Seshasai, R.K., et al. The home hemodialysis patient experience: A qualitative assessment of modality use and discontinuation. Hemodialysis International, 23: 139-150, 2019. doi:10.1111/hdi.12713.

¹⁴⁷ Chan, Christopher T. et al. Exploring Barriers and Potential Solutions in Home Dialysis: An NKF-KDOQI Conference Outcomes Report, Mar 2019, American Journal of Kidney Diseases, Volume 73, Issue 3, 363-371.

¹⁴⁸ U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, Advancing American Kidney Health, July 10, 2019.

The applicant conducted an IDE study for the primary purpose of evaluating the safety and efficacy of Tablo® Hemodialysis System use in the home setting. The applicant stated that the results from the IDE study demonstrate the following: (1) Patients will opt for home dialysis if the Tablo® Hemodialysis System is available; (2) patients have confidence in the safety and efficacy of the Tablo® Hemodialysis System; (3) the unique features of the Tablo® Cartridge as part of the Tablo® Hemodialysis System simplify set-up and use; and (4) the wireless transmission of data feature is reassuring to patients because it relieves patients of the burden of recording and fear that the patient may forget to document some aspect of treatment. The applicant claims that the IDE study results show that these key features will facilitate growth and ongoing use of the Tablo® Hemodialysis System in the home setting.

During the course of the study, with an average treatment time of 3.4 hours, twenty-eight out of thirty patients completed all phases of the trial and no patient dropouts occurred during the in-home phase. There is only one other mobile HD machine on the market. Its IDE, based on six times per week therapy at an average treatment duration of 2.8 hours, showed a higher drop-out rate (19 percent vs Tablo's® 7 percent) and lower adherence to treatment at home (89 percent vs Tablo's® 99 percent).^{149 150}

The applicant asserts that the Tablo® Hemodialysis System significantly reduces training time for both patients and their caregivers, improving training completion and reducing patient technique failure and care partner burden. The applicant state that the cartridge element of the Tablo® Hemodialysis System removes many of the manual steps and minimizes both set up time, and the need to make difficult connections, which requires training to avoid contamination. In human factors testing submitted to the FDA, the use of the cartridge resulted in 90 percent of the users being able to set up Tablo® in under 10 minutes.¹⁵¹ The

¹⁴⁹ Kraus, M., et al., A comparison of center-based vs. home-based daily hemodialysis for patients with end-stage renal disease. *Hemodialysis International*, 11: 468–477 2007 doi:10.1111/j.1542–4758.2007.00229.x.

¹⁵⁰ Plumb, T.J., Alvarez, et al. Safety and efficacy of the Tablo hemodialysis system for in-center and home hemodialysis. *Hemodialysis International* 2019l. doi:10.1111/hdi.12795.

¹⁵¹ Alvarez, Luis, et al. "Clinical Experience with a New Hemodialysis System Designed for In-Center Self-Care Hemodialysis." *Self-Care*, vol.8, no. 3, 2017, pp. 12–18. *Self-Care* vol. 8, no. 3, 2017, pp.12–18.

applicant stated that the Tablo® Hemodialysis System home IDE data demonstrates that on average it takes 3.5 training sessions to learn the Tablo® Hemodialysis System compared to 14.5 sessions on the device that is the current standard of care for home HD.¹⁵² The applicant asserts that reduced training time increases likelihood of successful completion, reduces patient technique failure, and decreases caregiver burden. The applicant notes the following: (1) The graphical user interface guides users through the treatment and eliminates the need for memorization and mental math; (2) sensors and automation eliminate multiple manual steps in treatment set-up; and (3) contextual alarms instantly alert patients to any issues with their treatment and provide video and text direction on how to resolve them. This is in comparison to numerical alarm codes with the incumbent device that requires reference to the user manual or memorization with no video guidance available.

The applicant states that the Tablo® Hemodialysis System significantly reduces set up and treatment time reducing treatment burden, improving retention at home, and reducing the need for and involvement of a care partner. The applicant noted that data from Outset Medical's Tablo® Hemodialysis System home IDE trial showed that a patient could set up the Tablo® Hemodialysis System in 9.2 minutes.¹⁵³ With the average number of treatments of 3.6 per week for an average duration of 3.4 hours,¹⁵⁴ a Tablo® Hemodialysis System user treating 4 times per week can expect to spend approximately 14 hours a week preparing for and conducting treatments, versus 40 hours a week on the incumbent device for patients who batch solutions.^{155 156} The applicant states that this significant reduction in setup and treatment time is a result of

¹⁵² Chahal, Yaadveer, Decreased Time to Independence with the Tablo Hemodialysis System: A Subset Analysis of the Tablo Home Clinical Trial, Abstract accepted for the National Kidney Foundation Spring Clinical Meeting 2020.

¹⁵³ Outset Medical subset analysis of Home IDE Trial data on set up time for Tablo Cartridge and concentrates.

¹⁵⁴ Plumb, T.J., Alvarez, et al. Safety and efficacy of the Tablo hemodialysis system for in-center and home hemodialysis. *Hemodialysis International*, 2019l. doi:10.1111/hdi.12795.

¹⁵⁵ NxStage Medical, Transitional Dialysis Care Operational Guidance, June 2019, <https://www.nxstage.com/wpcontent/uploads/2019/06/APM2548-Rev-B-TDC-Operational-Guidance.pdf>.

¹⁵⁶ Kraus, M., et al., A comparison of center-based vs. home-based daily hemodialysis for patients with end-stage renal disease. *Hemodialysis International*, 11: 468–477 2007 doi:10.1111/j.1542–4758.2007.00229.x.

software and workflow improvements incorporated in the Tablo® Hemodialysis System and its cartridge, many of which were driven by patient feedback. Reducing overall treatment burden improves modality retention at home on behalf of the patient and limits the care partner burden by reducing the need for their active involvement in treatment.

The applicant states that the cartridge portion of the Tablo® Hemodialysis System is pre-strung and requires only two connections to operate as compared to other systems that require stringing, hanging, snapping, and tapping multiple lines. In the home IDE time set up of dialysate concentrates, the Tablo® Cartridge took less than 12 minutes on average. With an average time of 8 minutes, an uninterrupted patient can initiate therapy in as little as 20 minutes.¹⁵⁷ This is a significant improvement in the standard of care, which can take approximately 45 minutes.¹⁵⁸ The applicant asserts that the Tablo® Hemodialysis System's automatic and integrated sensors and automated degassing and priming also make the machine easier to use and quicker to set up and get to treatment.

The applicant states that the Tablo® Hemodialysis System is the only system with a fully integrated water treatment system that allows for real-time water purification and dialysate produced on demand with no need to batch solutions or hang bags of dialysate. In addition, the applicant noted that it requires only a standard, grounded electrical outlet and Environmental Protection Agency quality tap water to operate, obviating the need to store bags of dialysate in the home, significantly reducing the number of supplies patients need to receive each month.

The applicant notes that the Tablo® Hemodialysis System reduces patient/care partner burden and technique failure. Specifically, the applicant stated that automation of processes such as prime and rinse back reduces the overall number of treatment related steps. In addition, the applicant says that the Tablo® Hemodialysis System's easy to use touchscreen interface walks users through each step of setup, treatment, and take down; the treatment information displays data that patients most wanted to see. The applicant asserts that this automation and patient-centric design reduces technique failure as evidence by results from the IDE study, which demonstrated a significant

¹⁵⁷ Outset Medical subset analysis of Home IDE Trial data on set up time for Tablo Cartridge and concentrates.

¹⁵⁸ Informal interviews with NxStage patients.

increase in treatment adherence and high rate of study completion compared to the current standard.

The applicant further states that the Tablo® Hemodialysis System eliminates documentation burden and reduces reporting errors, and that it is the only HD system with 2-way wireless transmission delivering HIPAA compliant data to the healthcare provider without any need for additional equipment. This frees patients from the need to manually document treatment data by hand or on a separate tablet and ensures higher data accuracy.

The 28 patients who entered the home phase of the Tablo® Hemodialysis System home IDE answered weekly if they needed help with treatment over the prior seven days. The applicant stated that by the end of the study, 216 of 224 possible responses were obtained. The care partner burden rating for prior in-home patients who were previously dialyzing on the incumbent device decreased from 3.1 to 2.4 on Tablo®. Among prior in-home patients, 69 percent of patients reported needing help from a trained individual with their prior device with 46 percent of respondents stating the help needed was device related, 15 percent related to cannulation alone, and 8 percent reported other. By contrast, while on Tablo®, only 38 percent of patients reported needing help with treatment—only 22 percent needed help related to use of Tablo® while 16 percent needed help related to cannulation. The applicant asserts that this data underscores a significant decrease in patients needing assistance with treatment at home.

The applicant states that Tablo® Hemodialysis System's unique features increase patient safety and satisfaction. The applicant notes that Tablo® Hemodialysis System's integrated, 2-way wireless connection provides clinicians with the ability to monitor patients in real time without any separate equipment necessary. The applicant asserts that the Tablo® Hemodialysis System is the only HD technology with this function, which allows for early identification and intervention by a patient's healthcare team as a key safety feature. At 34 inches tall, Tablo® Hemodialysis System user interface matches the height of a user while seated in a standard dialysis chair allowing patients to directly, and quickly engage with the integrated touch screen to view progress of the treatment, resolve alarms, and adjust certain functions to tailor the treatment to his or her needs. As an example, a patient with limited mobility

can reach the interactive touch screen to adjust the flow rate if they feel cramping coming on. The IDE generated data that demonstrated how the technology enabled more rapid resolution of alarms. During the home arm of the study, patients were able to resolve alarms on the Tablo® Hemodialysis System in 5 seconds.¹⁵⁹ The applicant asserts that rapid resolution of alarms and enhanced communication improve safety by facilitating rapid correction of any treatment related events, limiting treatment interruptions and improving communication between the patient and provider.

Once approved for home use, the applicant states that the Tablo® Hemodialysis System will provide a simpler, easier to use system that is likely to increase the number of people who are able to receive and remain on dialysis at home by addressing many of the well-documented, key barriers to home dialysis reported in peer-reviewed literature.

In addressing the way in which the Tablo® Hemodialysis System with its cartridge significantly improves clinical outcomes relative to the renal dialysis services previously available, the applicant focused on hospitalization and quality of life. The applicant stated that the Tablo® Hemodialysis System's 2-way wireless connection allows for real-time intervention to prevent hospitalizations. The applicant stated that during the Tablo® Hemodialysis System home IDE, the patients using the Tablo® Hemodialysis System had an all cause admission rate of 426 per 1,000 patient years. In the general dialysis population, the all cause admission rate is 1688 per 1,000 patient years and for patients who do PD, the hospitalization rate is 1460 per 1,000 patient years, highlighting that the Tablo® Hemodialysis System may significantly reduce hospitalizations and lower cost of care.¹⁶⁰ The applicant states that Tablo® Hemodialysis System's integrated, 2-way wireless connection provides clinicians the ability to monitor patients in real time without any separate equipment necessary, and is the only equipment with this embedded functionality which allows for earlier identification and intervention by a patient's healthcare

¹⁵⁹ Wilcox, Stephen B. et al., Results of human factors testing in a novel hemodialysis system designed for ease of patient use, *Hemodialysis International* 2016; 20:643–649.

¹⁶⁰ United States Renal Data System. 2019 USRDS annual data report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2019, Executive Summary Reference Table G2.

team and could prevent unnecessary hospitalizations for dialysis related events or missed treatments.

The applicant stated that the Tablo® Hemodialysis System can effectively deliver adequacy with 3–4 treatments per week, potentially reducing Medicare expenditures on additional dialysis treatments per week. The applicant said that among home HD patients, Medicare payment for dialysis treatments was highly variable across different regions at 3.5 to 5.7 per week.¹⁶¹ In the IDE for the Tablo® Hemodialysis System, the applicant asserted that there was effectively delivered adequacy with 4 treatments per week with an average session length of 3.4 hours, resulting in an average weekly treatment duration of ~13.6 hours. An average weekly standard Kt/V of 2.8 was achieved and 94 percent of patients achieved an ultrafiltration rate within 10 percent of the prescribed value.¹⁶² The applicant noted that a previous study of Tablo® Hemodialysis System used in the clinic showed achievement of a spKt/V of 1.2 based on 3 treatments per week including for patients over 90kg. While the frequency of how often patients should receive dialysis is a clinical decision that should be made between the physician and the patient, the Tablo® Hemodialysis System is the only mobile HD system with clinical data showing achievement of adequacy standards and ultrafiltration endpoints for 3 and 4 treatments per week regardless of the size of the patient.^{163 164} The applicant concludes that in this way, the Tablo® Hemodialysis System has the potential to reduce Medicare expenditures on the billing of additional dialysis treatments.

The applicant states that Tablo® Hemodialysis System's ability to deliver adequacy on fewer treatments per week may also reduce vascular access complications due to frequent cannulation.¹⁶⁵

¹⁶¹ Wilk, Adam S. et al., Persistent Variation in Medicare Payment Authorization for Home Hemodialysis Treatments Health services research vol. 53,2 (2018): 649–670.

¹⁶² Plumb, T.J., Alvarez, et al. Safety and efficacy of the Tablo hemodialysis system for in-center and home hemodialysis. *Hemodialysis International*, 2019. doi:10.1111/hdi.12795.

¹⁶³ Alvarez, Luis et al. Urea Clearance Results in Patients Dialyzed Thrice Weekly Using a Dialysate Flow of 300 mL/min, clinical abstract, presented March 2019, Annual Dialysis Conference, Dallas, TX.

¹⁶⁴ Alvarez, Luis and Chertow, Glenn, Real World In-Center Urea Clearance Experience with a Novel Hemodialysis System, clinical abstract, presented March 2019, Annual Dialysis Conference, Dallas, TX.

¹⁶⁵ Agency for Healthcare Quality and Research, End Stage Renal Disease in the Medicare

The applicant submitted several examples in four topics to demonstrate how the Tablo® Hemodialysis System improves the quality of life. The applicant noted that patients value having a high-quality daily life, ability to live well, and feeling empowered to control their outcomes over mortality.¹⁶⁶ The applicant asserted that the use of the Tablo® Hemodialysis System at home allows patients to have an improved quality of life and control over their outcomes.

The first topic of improved quality of life focused on sleep and reduction in fatigue. The applicant noted that kidney patients participating in an international research collaborative to identify outcome measures most important to them ranked fatigue/energy as their top priority.¹⁶⁷ The applicant reported that patients in the IDE who were on home HD with an incumbent device experienced a 14 percent improvement in waking up feeling rested while on the Tablo® Hemodialysis System. Additionally, 22 percent fewer patients reported having trouble staying asleep, and 15 percent fewer patients reported waking up several times during the night while on the Tablo® Hemodialysis System.¹⁶⁸ The applicant asserted that this data shows that the Tablo® Hemodialysis System is able to make a clinically significant improvement in the quality of life indicator most valued by dialysis patients.

The second topic of improved quality of life discussed by the applicant was improvement in the patients' experience of hypotensive events. The applicant submitted that investigators report that a drop in blood pressure was also ranked in the top 10 of symptoms rated by patients that impact their quality of life.¹⁶⁹ The applicant reported that a total of 12 (40.0 percent) and 8 (26.7 percent) subjects reported hypotensive events during the Tablo® Hemodialysis System treatments during the In-Center

and In-Home treatment periods, respectively, compared to 27 (90.0 percent) subjects reporting hypotensive events at baseline on another HD machine. All patients who reported hypotensive events while on dialysis in the study had also reported hypotension in their baseline history.¹⁷⁰

The third topic of improved quality of life was that fewer patients reported feeling cold. The applicant reported that a total of 15 (50.0 percent) subjects during the in-center treatment period and 12 (40.0 percent) subjects during the In-Home treatment period reported feeling cold while dialyzing on the Tablo® Hemodialysis System compared to 28 (93.3 percent) subjects who reported feeling cold at baseline while dialyzing on another dialysis machine. The applicant asserted that the Tablo® Hemodialysis System's design results in tight control of dialysate temperature and allows patients to easily and accurately adjust temperature through the graphical user interface.¹⁷¹

The fourth topic of improved quality of life was patient preference for the Tablo® Hemodialysis System. The applicant stated that the Kidney Health Initiative (KHI), a public private partnership between the FDA and the American Society of Nephrology, Renal Replacement Therapy (RRT) Roadmap prioritizes patient-centered innovation, which includes dialysis equipment that is more portable, removes barriers to home dialysis and improves patients ease of use to increase opportunities for self-care. The RRT, which was developed in conjunction with patients, also prioritizes patient centered outcomes and technology that reduces disruption in social and family life.¹⁷² The applicant reported that among prior home HD users in the IDE trial, 85 percent reported they preferred the Tablo® Hemodialysis System to their current equipment.¹⁷³ Patients also rated Tablo® as easier to set-up, treat, and take down. Ease of use ratings comparing the patient's prior device to Tablo® were as follows: Set up—3.5 to

4.5, Treatment—3.3 to 4.6, Take Down—3.8 to 4.6.¹⁷⁴

In summary, the applicant submitted that the Tablo® Hemodialysis System has the potential to significantly expand the number of patients who are able to receive home HD and persist on the therapy. The applicant stated that it is an innovative HD system that removes most of the device-related key barriers, reduces dialysis-related symptoms, is mobile and easy to use, and therefore minimizes dialysis-related disruptions in patients' lives.

(2) CMS TPNIES Work Group

(a) Summary of current technology by CMS TPNIES Work Group

Patients with ESRD who are not able to receive a kidney transplant must undergo maintenance dialysis therapy. Patients can receive dialysis 3–4 days a week at an in-center HD facility, or they can administer dialysis themselves at home. Due to the reliance on outpatient dialysis units, numbers of patients utilizing home dialysis in the U.S. have remained low. In 2017, only 10.8 percent of US dialysis patients received home-based therapies.¹⁷⁵ Patients and caregivers cite concerns with self-cannulation, fears of needle disconnect and complications.¹⁷⁶ Home dialysis use is lower than many other rich countries.¹⁷⁷

Most patients administering dialysis at home use PD. However, home HD has more recently re-emerged as an alternative way for patients to dialyze at home. Home HD may offer many of the advantages observed with peritoneal dialysis, such as increased flexibility and quality-of-life benefits. However, adoption of home HD has been limited, with approximately only 1 percent of ESRD patients utilizing this modality.¹⁷⁸

Observational studies do not indicate significant differences in survival when comparing home dialysis to in-center dialysis.¹⁷⁹ Yet, there are some potential

Population: Frequency and Duration of Hemodialysis and Quality of Life Assessment, Draft Technology Assessment, Agency for Healthcare Quality and Research November 22, 2019.

¹⁶⁶ Urquhart-Secord, Rachel et al Patient and Caregiver Priorities for Outcomes in Hemodialysis: An International Nominal Group Technique Study American Journal of Kidney Diseases, Sept. 2016, Volume 68, Issue 3, 444–454.

¹⁶⁷ Ibid.

¹⁶⁸ Plumb, T.J., Alvarez, L., Ross, D.L., Lee, J.J., Mulhern, J.G., Bell, J.L., Abra, G., Prichard, S.S., Chertow, G.M. and Aragon, M.A. (2019), Safety and efficacy of the Tablo hemodialysis system for in-center and home hemodialysis. Hemodialysis International. doi:10.1111/hdi.12795.

¹⁶⁹ Urquhart-Secord, Rachel et al. Patient and Caregiver Priorities for Outcomes in Hemodialysis: An International Nominal Group Technique Study American Journal of Kidney Diseases, Sept. 2016, Volume 68, Issue 3, 444–454.

¹⁷⁰ Outset Medical Data from Home IDE Trial, pg 33 of clinical report submitted to the Food and Drug Administration, data table 43, 2019.

¹⁷¹ Ibid.

¹⁷² Kidney Health Initiative, Technology Roadmap for Innovative Approaches to Renal Replacement Therapy, prepared by the Next Group, October 2018, https://www.asnonline.org/gblast/files/KHI_RRT_Roadmap1.0_FINAL_102318_web.pdf.

¹⁷³ Chahal, Yaadveer, Patient Device Preference for Home Hemodialysis: A Subset Analysis of the Tablo Home IDE Trial, Abstract Accepted by the National Kidney Foundation Spring Clinical Meeting 2020.

¹⁷⁴ Outset Medical Data from Home IDE Trial, pg 33 of clinical report submitted to the Food and Drug Administration, data table 43, 2019.

¹⁷⁵ United States Renal Data System (USRDS). 2019 Annual Data Report: Reference Tables. <https://www.usrds.org/reference.aspx>. Last Access Date Feb 20, 2020.

¹⁷⁶ Young BA, Chan C, Blagg C, Lockridge R, Golper T, Finkelstein F, Shaffer R, Mehrotra R; ASN Dialysis Advisory Group. How to overcome barriers and establish a successful home HD program. Clin J Am Soc Nephrol. 2012 Dec;7(12):2023–32. doi: 10.2215/CJN.07080712. Epub 2012 Oct 4.

¹⁷⁷ Wilkie M. Home dialysis—an international perspective. NDT Plus. 2011 Dec;4(Suppl 3):iii4–iii6.

¹⁷⁸ Mailloux LU, Blagg CR, Berns JS (ed.) Home Hemodialysis. Uptodate. Nov 18, 2016.

¹⁷⁹ Chiu YW, Jiwakanon S, Lukowsky L, Duong U, Kalantar-Zadeh K, Mehrotra R. An update on the comparisons of mortality outcomes of hemodialysis

benefits to home-based dialysis. Prior analyses have noted that home-based dialysis affords greater patient flexibility, improved quality of life,¹⁸⁰ increased likelihood of employment,¹⁸¹ and improved cost.¹⁸² However, regarding cost comparisons, it is important to note that many cost analyses of home-based dialysis include estimates from peritoneal dialysis. The machines for HD are costly and there may be higher rates of infection from self-cannulation, which could offset any savings. Since such a small percentage of patients receive home-based HD, it is challenging to know actual cost without pooling it with peritoneal dialysis estimates. Regardless, due to an executive order issued in 2019, economic incentives for home dialysis (both peritoneal and home HD) were increased with the goal of expanding its use.¹⁸³

(b) Description of New Technology by the CMS TPNIES Work Group

The first personal HD system on the market was called the Akysis personal HD (Akysis Ph.D.) system. It created its own ultrapure dialysate and was FDA cleared in 2002. It later underwent recall in 2006 due to marketing inconsistencies with system design.¹⁸⁴ Eventually, the manufacturer shut down operations after difficulties in securing financing.¹⁸⁵ In addition to these issues, it was a large machine that required significant patient utility resources and specialized maintenance.¹⁸⁶ Around this time, development of the Allient dialysis system began, which utilizes a

and peritoneal dialysis patients. *Semin Nephrol.* 2011;31:152–158.

¹⁸⁰Rubin HR, Fink NE, Plantinga LC, Sadler JH, Klinger AS, Powe NR. Patient ratings of dialysis care with peritoneal dialysis vs hemodialysis. *JAMA.* 2004;291:697–703.

¹⁸¹Muehrer RJ, Schatell D, Witten B, Gangnon R, Becker BN, Hofmann RM. Factors affecting employment at initiation of dialysis. *Clin J Am Soc Nephrol.* 2011 Mar;6(3):489–96.

¹⁸²Berger A, Edelsberg J, Inglese GW, Bhattacharyya SK, Oster G. Cost comparison of peritoneal dialysis versus hemodialysis in end-stage renal disease. *American Journal of Managed Care.* 2009;15:509–518.

¹⁸³The White House. Executive Order on Advancing American Kidney Health. July 10, 2019. <https://www.whitehouse.gov/presidential-actions/executive-order-advancing-american-kidney-health/>. Last Access Date Feb 18, 2020.

¹⁸⁴Food and Drug Administration. Class 2 Device Recall Akysis Ph.D. Personal Hemodialysis System. Medical Devices Database. June 2006. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/cfm?id=46686>.

¹⁸⁵Modern Healthcare. Dialysis machine firm Akysis shuts down. Feb 21, 2007. <https://www.modernhealthcare.com/article/20070221/NEWS/70221010/dialysis-machine-firm-akysis-shuts-down>. Last Access Date Feb 18, 2020.

¹⁸⁶Mailloux LU, Blagg CR, Berns JS (ed.) *Home Hemodialysis*. Uptodate. Nov 18, 2016.

sorbent column to regenerate dialysate from tap water.¹⁸⁷ It is still in development for potential home based therapy.

Several home dialysis machines are currently available. Recently, the NxStage® System One dialysis machine was FDA approved for 510(k) premarket status in August 2017.¹⁸⁸ It has a smaller profile than the Akysis machine but requires 4 to 6 large bags of ultrapure dialysate and comes with home storage requirements. The NxStage® PureFlow SL was subsequently developed for use with the NxStage® System One. It allows patients to prepare dialysate from tap water with a reduced need to store dialysate bags. The NxStage® system advertises an easier experience learning how to administer home dialysis. Within this arena, the Tablo® Hemodialysis System has recently emerged and been approved for use in hospitals and outpatient settings. The Tablo® Hemodialysis System is most comparable to NxStage System One combined with NxStage® PureFlow, in that it may be easier to use than conventional home dialysis machines and can be used from a tap water source. The applicant is currently pursuing approval for use of cartridges for the Tablo® Hemodialysis System in the home setting. While this application centers on reimbursement of the Tablo® Cartridge, this cartridge is only compatible with the Tablo® Hemodialysis System. The cartridge is made up of a rigid “Organizer” which mounts the necessary tubing to allow for greater ease in set-up. This self-contained and single-use cartridge houses both the arterial and venous lines, an adaptor to connect the lines, a saline line, and an infusion line. There is also a pressure transducer protector, venous drip chamber with clot filter, and an arterial pressure pod. The applicant noted that the cartridge simplifies connection to the Tablo® Hemodialysis System and reduces set-up time. It would seem that this cartridge would be most useful in the home-setting, since hospital and clinic settings would normally have trained personnel to assist with set-up. Although separate from the Tablo® Cartridge, the Tablo® Hemodialysis System also performs real-time water

¹⁸⁷Ash SR. The Allient dialysis system. *Semin Dial.* 2004 Mar-Apr;17(2):164–6.

¹⁸⁸Food and Drug Administration. Traditional Section 510(k) Premarket Notification Letter, Number K171331. August 24, 2017. https://www.accessdata.fda.gov/cdrh_docs/pdf17/K171331.pdf.

purification on demand dialysate production.

A significant challenge to increasing the use of home dialysis includes burn out (or technique failure) and return to in-center HD. According to one recent observational study, approximately 25 percent of patients who initiate home HD return to in-center HD within the first year.¹⁸⁹ A good measure of a home-based system’s success would be in its ability to allow patients to remain on the therapy long-term. Failure to maintain home HD, and low use of home HD, may be a result of anxiety and unease that many patients have about performing the treatment themselves (or with the help of care takers).^{190 191 192} This includes fear of self-cannulation in order to access the blood for dialysis and a lack of self-efficacy in performing the therapy. By simplifying the process of setting up dialysis tubing, offered by the Tablo® Hemodialysis System cartridge, some patients may be able to successfully perform home HD.

(c) Approvals

The applicant has not previously submitted applications for pass-through or add-on payments. The applicant has received 510(k) marketing clearance for the machine to be used in hospital and outpatient clinic use only. As such, the applicant is pursuing FDA authorization for use in the home setting for February 2020. The Tablo® Hemodialysis System cartridge received FDA marketing approval in December, 2019 and the Tablo® Hemodialysis System received FDA marketing authorization for home setting in March 2020. The applicant noted that upon approval, the company plans to ship that same month. The technology had an investigational device exemption for use in the home and which closed after approval of marketing authorization. It is assigned as a Class II device category.

¹⁸⁹Seshasai RK, Mitra N, Chaknos CM, Li J, Wirtalla C, Negoianu D, Glickman JD, Dember LM. Factors Associated With Discontinuation of Home Hemodialysis. *Am J Kidney Dis.* 2016 Apr;67(4):629–37.

¹⁹⁰Cafazzo JA, Leonard K, Easty AC, Rossos PG, Chan CT. Patient-perceived barriers to the adoption of Nocturnal Home Hemodialysis. *Clin J Am Soc Nephrol.* 2009;4:784–789.

¹⁹¹Suri RS, Larive B, Garg AX, et al. Burden on caregivers as perceived by hemodialysis patients in the frequent Hemodialysis network (FHN) trials. *Nephrol Dial Transplant.* 2011;26:2316–2322.

¹⁹²Zhang AH, Bargman JM, Lok CE, et al. Dialysis modality choices among chronic kidney disease patients: Identifying the gaps to support patients on home-based therapies. *Int Urol Nephrol.* 2010;42:759–764

(d) Assessment of Substantial Similarity to Currently Available Technology

The NxStage® One is the only home-based HD system that is FDA has approved at this time. The Tablo® Hemodialysis System differs from the NxStage® in that dialysate is produced on demand whereas the NxStage® requires that patients batch dialysate or use pre-filled concentrate with the PureFlow. The Tablo® Hemodialysis System also includes a cartridge (which is the portion being evaluated for TPNIES) designed to facilitate the connection of tubing in the appropriate configuration.

This product treats similar patients, notably patients with ESRD requiring HD.

(e) Assessment of SCI (see §§ 413.236(b)(5) and 412.87(b)(1))

The Tablo® Hemodialysis System is a treatment modality, not a diagnostic tool. With regard to the question as to whether this new renal dialysis equipment offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments, we note that patients who are eligible for this treatment would currently be eligible for in-center HD, home HD with currently available treatments, and possibly PD.

(f) Clinical Evidence for Claims of SCI

The applicant included an annotated bibliography in its application. Many of the articles describe the features of the HD system: straightforward and relatively efficient set-up and training, presence of safety features, water purification system, and wireless communication. In terms of clinical outcomes and improvements, the referenced authors have presented or published data on safety, clearance and treatment times, hypotensive events and cold symptoms, and patient preference. As these are arguably more important considerations, we are focusing on the evidence with those claims of clinical improvement or patient reported outcomes.

Below is a list of references for SCI based on evidence published from several sources. We summarize the studies grouped by listings with the most rigorous review to those with the least rigorous review, specifically, Trials Published in Peer-Reviewed Journals, then Posters and Abstracts, and ending with Unpublished Data.

Trials Published in Peer-Reviewed Journals

- Plumb TJ, et al.¹⁹³ describes the IDE study, which was a prospective, multicenter, open-label crossover trial evaluating in-center versus in-home use of the Tablo® Hemodialysis System. Thirty patients underwent a run-in period, 8 weeks of in-center therapy (4 treatments a week), then a 4-week transition period, and finally an 8-week in-home treatment (4 times a week). Authors evaluated efficacy in effective removal of uremic toxins, as measured by a weekly standard Kt/Vurea ≥ 2.1 and a secondary endpoint of delivered ultrafiltration within 10 percent of prescribed. Twenty-eight out of 30 patients completed the study. One patient died from cardiac arrest and the authors felt it was unrelated to the treatments. Another patient withdrew prior to starting in-home HD. There were primary outcomes, secondary outcomes, adverse event rates, alarms per treatment, and alarm response times between the two groups. Patients demonstrated high adherence rates of 96 percent, and 99 percent for the in-center and in-home groups, respectively. There is bias from the open-label study and this is a small study conducted over a short period of 12 weeks total, 4 weeks of in-home dialysis. Long-term and larger studies would be helpful to capture any safety signals. Some authors serve as Chief Medical Officer or consultants for Outset Medical.

- Kraus M, et al.¹⁹⁴ is a study involving the comparator technology known as NxStage® System, which is a portable HD unit. This was a prospective, open-label, crossover study comparing in-center HD versus home HD in 32 patients over 18 weeks total. The primary endpoint was delivery of 90 percent prescribed fluid volume, which was achieved in similar fashion and >90 percent in both groups. There were statistically significant differences in adverse events, which favored the home HD group. The applicant included this study to demonstrate similar evidence as well as compare time spent in performing the home sessions. Treatment durations were slightly shorter than what was noted in the IDE study above (mean 2.8 hours for

¹⁹³ Plumb TJ, Alvarez L, Ross DL, Lee JJ, Mulhern JG, Bell JL, Abra G, Prichard SS, Chertow GM, Aragon MA. Safety and efficacy of the Tablo hemodialysis system for in-center and home hemodialysis. *Hemodial Int.* 2020 Jan;24(1):22–28. doi: 10.1111/hdi.12795. Epub 2019 Nov 7.

¹⁹⁴ Kraus M, Burkart J, Hegeman R, Solomon R, Coplon N, Moran J, A comparison of center-based vs. home-based daily hemodialysis for patients with end-stage renal disease. *Hemodialysis International*, 11: 468–477, (2007).

NxStage® versus mean 3.4 hours with Tablo® Hemodialysis System). This study was supported by NxStage® Medical Inc.

Posters/Abstracts

- Alvarez, Luis et al.¹⁹⁵ is a retrospective study, 29 patients underwent HD with the Tablo® Hemodialysis System at a lower flow rate than what is used in conventional in-center HD. Average treatment times were slightly higher in the Tablo® Hemodialysis System group compared to those using non-Tablo® systems. After patient weight stratification at 90 kg, authors felt that both groups achieved similar weight changes (extrapolated from pre and post weights), as well as Kt/Vurea change. This research was funded by Outset Medical, Inc.

- Alvarez, Luis et al.¹⁹⁶ utilized lower flow rates of 300 ml/min, and evaluated patients as they transitioned to in-center but self-directed HD with Tablo® Hemodialysis System. Patients underwent 3 times a week treatment and data was collected over a 3-month period. Based on urea samples and calculated Kt/Vurea, authors concluded that this treatment resulted in adequate clearance.

- Chahal, Yaadveer¹⁹⁷ is a study that focused on the patient experience through surveys and compared the patient's responses to prior in-home and in-center experiences. As part of the IDE study, 13 participants provided survey responses to compare their experience with the Tablo® Hemodialysis System to their prior experience with in-home dialysis. Of those 13 participants, 85.6 percent found this system easier to use. While this is promising, the true test of superiority in this realm would be rates of discontinuation at 1 year. Issues of self-cannulation and the burden of this responsibility still remain with this system. The primary study was undertaken by Outset Medical.

¹⁹⁵ Alvarez L, Spry L, Mulhern J, PPrichard S, Shallall C, Chertow G, Aragon, M, Urea Clearance Results in Patients Dialyzed Thrice Weekly Using a Dialysate Flow of 300 mL/min, clinical abstract, presented March 2019, Annual Dialysis Conference, Dallas, TX.

¹⁹⁶ Alvarez, Luis and Chertow, Glenn, Real World In-Center Urea Clearance Experience with a Novel Hemodialysis System, clinical abstract, presented March 2019, Annual Dialysis Conference, Dallas, TX.

¹⁹⁷ Chahal, Yaadveer. Patient Device Preference for Home Hemodialysis: A Subset Analysis of the Tablo Home IDE Trial, Abstract Accepted by the National Kidney Foundation Spring Clinical Meeting 2020.

Unpublished Data

• Outset Medical Data¹⁹⁸ is a limited section, in which the applicant submitted cold and hypotensive events while on in-center or in-home HD. From just raw numbers, there were lower percentages of either sign/symptom within the home dialysis group compared to in-center.

(g) Comments of the CMS TPNIES Work Group

Only the Tablo® Cartridge portion of the Tablo® Hemodialysis System is being evaluated in this application, but it is important to note that it can only be used with the Tablo® Hemodialysis System. Although there are changes to the Tablo® Hemodialysis System for home use, the cartridge portion remains unchanged from its original FDA approval. Therefore, the cartridge itself is not new. Also, it is unclear as to whether the Tablo® Hemodialysis System can be used in-center without the cartridge. As such, much of the evidence presented in this application is really about the system itself, such as ease of training, its various features, and less about the incremental benefit of using the cartridge. Additionally, the system itself may have its own risks and benefits which are not within the scope of this application, and peripherally and incompletely addressed with the provided materials. For example, a study should be conducted determining the number of patients who were back in the hospital for a dialysis-related condition.

To evaluate the cartridge, it would be helpful to have studies on whether there are any issues with the components of the cartridge (that is, any dialyzer reactions to tubing, any issues affecting clearance). Since the primary intent of the cartridge is to facilitate patient set-up at home, the most useful evidence would be in the form of larger studies of patient-reported outcomes, quality of life, analyses of patient/caregiver burnout, and sustained adherence (beyond 1 year) to the use of this home-based modality. If the applicant is claiming to improve the patients' quality of life, then it needs to be proven for patient-specific outcomes and with a risk-benefit analysis to the patient. In some of the references cited, the patient factors affecting home HD are self-cannulation, burdens to caregivers, and concerns for complications, yet the cartridge has not demonstrated improvements in addressing these issues.

The cartridge is a promising concept to encourage home HD but again, the evaluation of this technology is complicated by the need to also peripherally assess the system. There does not appear to be a need for this cartridge in the hospital or clinic setting as trained personnel should be able to assist with set-up. Within the larger policy context of FDA approval and the fact that TPNIES does not currently cover capital-related assets, the CMS TPNIES Work Group believes there are some irregularities and misalignments in the current application, and is concerned that the stand-alone cartridge cannot be evaluated for meeting the criteria for SCI.

We invite public comment as to whether the stand-alone cartridge of the Tablo® Hemodialysis System meets the SCI criteria for the TPNIES.

III. CY 2021 Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury (AKI)

A. Background

The Trade Preferences Extension Act of 2015 (TPEA) (Pub. L. 114–27) was enacted on June 29, 2015, and amended the Act to provide coverage and payment for dialysis furnished by an ESRD facility to an individual with acute kidney injury (AKI). Specifically, section 808(a) of the TPEA amended section 1861(s)(2)(F) of the Act to provide coverage for renal dialysis services furnished on or after January 1, 2017, by a renal dialysis facility or a provider of services paid under section 1881(b)(14) of the Act to an individual with AKI. Section 808(b) of the TPEA amended section 1834 of the Act by adding a subsection (r) to provide payment, beginning January 1, 2017, for renal dialysis services furnished by renal dialysis facilities or providers of services paid under section 1881(b)(14) of the Act to individuals with AKI at the ESRD PPS base rate, as adjusted by any applicable geographic adjustment applied under section 1881(b)(14)(D)(iv)(II) of the Act and adjusted (on a budget neutral basis for payments under section 1834(r) of the Act) by any other adjustment factor under section 1881(b)(14)(D) of the Act that the Secretary elects.

In the CY 2017 ESRD PPS final rule, we finalized several coverage and payment policies in order to implement subsection (r) of section 1834 of the Act and the amendments to section 1881(s)(2)(F) of the Act, including the payment rate for AKI dialysis (81 FR 77866 through 77872, and 77965). We interpret section 1834(r)(1) of the Act as requiring the amount of payment for

AKI dialysis services to be the base rate for renal dialysis services determined for a year under the ESRD PPS base rate as set forth in § 413.220, updated by the ESRD bundled market basket percentage increase factor minus a productivity adjustment as set forth in § 413.196(d)(1), adjusted for wages as set forth in § 413.231, and adjusted by any other amounts deemed appropriate by the Secretary under § 413.373. We codified this policy in § 413.372 (81 FR 77965).

B. Proposed Annual Payment Rate Update for CY 2021

1. CY 2021 AKI Dialysis Payment Rate

The payment rate for AKI dialysis is the ESRD PPS base rate determined for a year under section 1881(b)(14) of the Act, which is the finalized ESRD PPS base rate, including the applicable annual market basket payment update, geographic wage adjustments and any other discretionary adjustments, for such year. We note that ESRD facilities have the ability to bill Medicare for non-renal dialysis items and services and receive separate payment in addition to the payment rate for AKI dialysis.

As discussed in section II.B.4.d of this proposed rule, the CY 2021 proposed ESRD PPS base rate is \$255.59, which reflects the application of the proposed CY 2021 wage index budget-neutrality adjustment factor of .998652, a proposed addition to the ESRD PPS base rate to include calcimimetics, and the CY 2021 proposed ESRDB market basket increase of 2.2 percent reduced by the multifactor productivity adjustment of 0.4 percentage points, that is, 1.8 percent. Accordingly, we are proposing a CY 2021 per treatment payment rate of \$255.59 for renal dialysis services furnished by ESRD facilities to individuals with AKI. This payment rate is further adjusted by the wage index as discussed below.

2. Geographic Adjustment Factor

Under section 1834(r)(1) of the Act and § 413.372, the amount of payment for AKI dialysis services is the base rate for renal dialysis services determined for a year under section 1881(b)(14) of the Act (updated by the ESRD bundled market basket and multifactor productivity adjustment), as adjusted by any applicable geographic adjustment factor applied under section 1881(b)(14)(D)(iv)(II) of the Act. Accordingly, we apply the same wage index under § 413.231 that is used under the ESRD PPS and discussed in section II.B.4.b of this proposed rule. The AKI dialysis payment rate is adjusted by the wage index for a

¹⁹⁸ Outset Medical Data from Home IDE Trial, page 33 of clinical report submitted to the FDA, data Table 43, 2019.

particular ESRD facility in the same way that the ESRD PPS base rate is adjusted by the wage index for that facility (81 FR 77868). Specifically, we apply the wage index to the labor-related share of the ESRD PPS base rate that we utilize for AKI dialysis to compute the wage adjusted per-treatment AKI dialysis payment rate. As stated previously, we are proposing a CY 2021 AKI dialysis payment rate of \$255.59, adjusted by the ESRD facility's wage index.

IV. End-Stage Renal Disease Quality Incentive Program (ESRD QIP)

A. Background

For a detailed discussion of the End-Stage Renal Disease Quality Incentive Program's (ESRD QIP's) background and history, including a description of the Program's authorizing statute and the

policies that we have adopted in previous final rules, we refer readers to the following final rules:

- CY 2011 ESRD PPS final rule (75 FR 49030),
- CY 2012 ESRD PPS final rule (76 FR 628),
- CY 2012 ESRD PPS final rule (76 FR 70228),
- CY 2013 ESRD PPS final rule (77 FR 67450),
- CY 2014 ESRD PPS final rule (78 FR 72156),
- CY 2015 ESRD PPS final rule (79 FR 66120),
- CY 2016 ESRD PPS final rule (80 FR 68968),
- CY 2017 ESRD PPS final rule (81 FR 77834),
- CY 2018 ESRD PPS final rule (82 FR 50738),
- CY 2019 ESRD PPS final rule (83 FR 56922), and

- CY 2020 ESRD PPS final rule (84 FR 60713).

We have also codified many of our policies for the ESRD QIP at 42 CFR 413.177 and 413.178.

B. Proposed Updates to Requirements Beginning With the PY 2023 ESRD QIP

1. PY 2023 ESRD QIP Measure Set

Under our current policy, we retain all ESRD QIP measures from year to year unless we propose through rulemaking to remove them or otherwise provide notification of immediate removal if a measure raises potential safety issues (77 FR 67475). Accordingly, the PY 2023 ESRD QIP measure set will include the same 14 measures as the PY 2022 ESRD QIP measure set. These measures are described in Table 6.

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TABLE 6: PY 2023 ESRD QIP Measure Set

National Quality Forum (NQF) #	Measure Title and Description
0258	In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Administration, a clinical measure Measure assesses patients' self-reported experience of care through percentage of patient responses to multiple testing tools.
2496	Standardized Readmission Ratio (SRR), a clinical measure Ratio of the number of observed unplanned 30-day hospital readmissions to the number of expected unplanned 30-day readmissions.
Based on NQF #2979	Standardized Transfusion Ratio (STrR), a reporting measure Ratio of the number of observed eligible red blood cell transfusion events occurring in patients dialyzing at a facility to the number of eligible transfusions that would be expected.
N/A	(Kt/V) Dialysis Adequacy Comprehensive, a clinical measure A measure of dialysis adequacy where K is dialyzer clearance, t is dialysis time, and V is total body water volume. Percentage of all patient months for patients whose delivered dose of dialysis (either hemodialysis or peritoneal dialysis) met the specified threshold during the reporting period.
2977	Hemodialysis Vascular Access: Standardized Fistula Rate clinical measure Measures the use of an arteriovenous (AV) fistula as the sole means of vascular access as of the last hemodialysis treatment session of the month.
2978	Hemodialysis Vascular Access: Long-Term Catheter Rate clinical measure Measures the use of a catheter continuously for 3 months or longer as of the last hemodialysis treatment session of the month.
1454	Hypercalcemia, a clinical measure Proportion of patient-months with 3-month rolling average of total uncorrected serum or plasma calcium greater than 10.2 mg/dL.
1463	Standardized Hospitalization Ratio (SHR), a clinical measure Risk-adjusted SHR of the number of observed hospitalizations to the number of expected hospitalizations.
Based on NQF #0418	Clinical Depression Screening and Follow-Up, a reporting measure Facility reports in CROWNWeb one of six conditions for each qualifying patient treated during performance period.
N/A	Ultrafiltration Rate (UFR), a reporting measure* Number of months for which a facility reports elements required for ultrafiltration rates for each qualifying patient.
Based on NQF #1460	National Healthcare Safety Network (NHSN) Bloodstream Infection (BSI) in Hemodialysis Patients, a clinical measure. The Standardized Infection Ratio (SIR) of BSIs will be calculated among patients receiving hemodialysis at outpatient hemodialysis centers.
N/A	NHSN Dialysis Event reporting measure Number of months for which facility reports NHSN Dialysis Event data to the Centers for Disease Control and Prevention (CDC).
N/A	Percentage of Prevalent Patients Waitlisted (PPPW), a clinical measure Percentage of patients at each dialysis facility who were on the kidney or kidney-pancreas transplant waitlist averaged across patients prevalent on the last day of each month during the performance period.
2988	Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec), a reporting measure Percentage of patient-months for which medication reconciliation was performance and documented by an eligible professional

Note: We are proposing to update the scoring methodology used to calculate the Ultrafiltration Rate reporting measure so that facilities are scored based on the number of eligible patient-months, instead of facility-months.

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2. Estimated Performance Standards for the PY 2023 ESRD QIP

Section 1881(h)(4)(A) of the Social Security Act (the Act) requires the Secretary to establish performance standards with respect to the measures selected for the ESRD QIP for a performance period with respect to a year. The performance standards must

include levels of achievement and improvement, as required by section 1881(h)(4)(B) of the Act, and must be established prior to the beginning of the performance period for the year involved, as required by section 1881(h)(4)(C) of the Act. We refer readers to the CY 2013 ESRD PPS final rule (76 FR 70277) for a discussion of the achievement and improvement standards that we have established for

clinical measures used in the ESRD QIP. We recently codified definitions for the terms “achievement threshold,” “benchmark,” “improvement threshold,” and “performance standard” in our regulations at § 413.178(a)(1), (3), (7), and (12), respectively.

In the CY 2020 ESRD PPS final rule (84 FR 60728), we set the performance period for the PY 2023 ESRD QIP as CY 2021 and the baseline period as CY

2019. In this proposed rule, we are estimating the achievement thresholds, 50th percentiles of the national performance, and benchmarks for the

PY 2023 clinical measures in Table 7 using data from 2018. We intend to update these standards, using CY 2019

data, in the CY 2021 ESRD PPS final rule.
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TABLE 7: Estimated Performance Standards for the PY 2023 ESRD QIP Clinical Measures Using the Most Recently Available Data

Measure	Achievement Threshold (15 th Percentile of National Performance)*	Median (50 th Percentile of National Performance)*	Benchmark (90 th Percentile of National Performance)*
Vascular Access Type (VAT)			
Standardized Fistula Rate	53.72%	64.96%	77.31%
Catheter Rate	17.70%	10.50%	4.32%
Kt/V Comprehensive	93.56%	97.13%	99.24%
Hypercalcemia	1.77%	0.58% (0.59%)	0.00%
Standardized Readmission Ratio	1.268 (1.269)	0.998	0.629 (0.641)
Standardized Transfusion Ratio	1.675	0.830	0.173
NHSN BSI	1.365	0.604	0
Standardized Hospitalization Ratio	1.248	0.967 (0.976)	0.670 (0.677)
PPPW	8.12%	16.73%	33.90%
ICH CAHPS: Nephrologists' Communication and Caring	58.12%	67.89%	78.52% (78.35%)
ICH CAHPS: Quality of Dialysis Center Care and Operations	54.16 (53.87%)	62.47%	72.11%
ICH CAHPS: Providing Information to Patients	74.09%	80.48%	87.14%
ICH CAHPS: Overall Rating of Nephrologists	49.33% (47.92%)	62.22% (60.59%)	76.57% (75.16%)
ICH CAHPS: Overall Rating of Dialysis Center Staff	49.12% (48.59%)	63.04% (62.99%)	77.49%
ICH CAHPS: Overall Rating of the Dialysis Facility	53.98% (53.46%)	68.59%	83.03%
Note: If the PY 2023 final numerical value is worse than the PY 2022 finalized value, we will substitute the PY 2023 final numerical value for the PY 2022 finalized value. We have provided the PY 2023 finalized value as a reference in parentheses for clinical measures whose PY 2023 estimated value is worse than the PY 2022 finalized value.			

Data sources: VAT measures: 2018 CROWNWeb; SRR, SHR: 2018 Medicare claims; Kt/V: 2018 CROWNWeb; Hypercalcemia: 2018 CROWNWeb; NHSN: 2018 CDC; ICH CAHPS: CMS 2018; PPPW: 2018 CROWNWeb and 2018 OPTN.

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3. Proposed Update to the Scoring Methodology for the Ultrafiltration Rate Reporting Measure

In the CY 2017 ESRD PPS final rule, we adopted the Ultrafiltration Rate reporting measure under the authority of section 1881(h)(2)(B)(ii) of the Act (81

FR 77912). The measure assesses the number of months for which a facility reports all data elements required to calculate ultrafiltration rates (UFR) for each qualifying patient. It is based upon the NQF-endorsed Avoidance of Utilization of High Ultrafiltration Rate (>= 13 ml/kg/hr) (NQF #2701), which assesses the percentage of patient-

months for patients with a UFR greater than or equal to 13 ml/kg/hr.

In the CY 2017 ESRD PPS final rule (81 FR 77917), we also finalized a policy to score the Ultrafiltration Rate reporting measure using the following equation, beginning in PY 2020 (81 FR 77917):

$$\left(\frac{\# \text{ months successfully reporting data}}{\# \text{ eligible months}} \times 12 \right) - 2$$

In this proposed rule, we are proposing to replace the current Ultrafiltration Rate reporting measure

scoring equation with the following equation, beginning with PY 2023:

$$\left(\frac{\text{number of patient-months successfully reporting data}}{\text{number of eligible patient-months}} \times 12 \right) - 2$$

This proposal would modify the scoring methodology for the Ultrafiltration Rate reporting measure so that facilities would be scored based on the number of eligible patient-months, as opposed to facility-months. The facility-month scoring methodology requires facilities to report every data element necessary to calculate a UFR reporting rate for 100 percent of its eligible patients each month in order to receive any credit for successfully reporting the measure for that month. The facility-month scoring approach then counts the number of months in the performance period that the facility received credit for reporting over the course of the performance period. For example, under the facility-scoring methodology, if a facility has 10 eligible patients in January, the facility must report all required UFR data elements for each of those 10 patients in order to receive any credit for January reporting. If the facility only reports the required UFR data elements for 9 of those 10 patients, the facility receives a zero for January. Our concern with this approach is that there may be circumstances, such as when an eligible patient is hospitalized, when facilities cannot obtain UFR data for a single patient, and as a consequence, cannot receive any credit for the data it did report that month. When we finalized the Ultrafiltration Rate reporting measure in the CY 2017 ESRD PPS final rule, stakeholders raised their concern regarding this issue (81 FR 77914). At the time, we responded that because we defined the population for this reporting measure by assignment to a facility for a full month, the facility is still required to provide data even in cases where a patient may spend part of that month hospitalized since the data elements are products of ongoing dialysis treatment. We stated that since we do not restrict facilities from coordinating with hospitals to obtain relevant data, we

believed that such coordination is appropriate. However, our rationale for this was based on the reporting requirements prescribed by a facility-month definition. Furthermore, coordinating with hospitals to obtain relevant data continues to be a stakeholder concern in reporting UFR data. We believe that the proposed patient-month scoring methodology is more objective because it scores facilities based on the percentage of eligible patients across the entire performance period for which they report all UFR data elements. Thus, if a facility has 100 eligible patients in CY 2020 and reports all data elements necessary to calculate a UFR rate for 90 of them, the facility will receive a rounded score based on a 90 percent reporting rate. We believe that this methodology will give facilities more flexibility to receive credit for UFR reporting throughout the 12-month performance period.

The Ultrafiltration Rate reporting measure is intended to guard against risks associated with high ultrafiltration (that is, rapid fluid removal) rates for adult dialysis patients undergoing HD, because of indications that high ultrafiltration is an independent predictor of mortality. Faster ultrafiltration may lead to a number of health risks resulting from large volumes of fluid removed rapidly during each dialysis session, with deleterious consequences for the patient both in the short and longer term. The outcome of this reporting measure is the documentation of the ultrafiltration measurements, which ultimately contributes to the quality of the patient's ESRD treatment. We believe that calculating the measure rates using the patient-month scoring methodology better supports our goal of assessing performance on whether the facility is documenting UFR for its eligible

patients, which we believe will lead to better patient-level outcomes.

We also believe that this change is consistent with our plan to re-evaluate our reporting measures for opportunities to more closely align them with NQF measure specifications (see 84 FR 60724). We believe that this proposed change would make the Ultrafiltration Rate reporting measure more consistent with the NQF measure upon which it is based, Avoidance of Utilization of High Ultrafiltration Rate (≥ 13 ml/kg/hr) (NQF #2701), which reports results using a "patient-month" construction. Although we recognize that both the Anemia Management reporting measure and the Serum Phosphorus reporting measure are also calculated using a facility-month construction, we are not proposing to change the scoring methodology used for either of those measures because both measures are finalized for removal beginning with the PY 2021 ESRD QIP (83 FR 56986 through 56989). The proposed update to the UFR reporting measure scoring methodology will make the scoring methodology for that measure consistent with the scoring methodology we are using to calculate the Medication Reconciliation (MedRec) reporting measure (83 FR 57011). We also believe that the utilization of this patient-month scoring methodology for both the MedRec and the Ultrafiltration Rate reporting measures better reflects our intent to score facilities based on actions taken by the facility that impact patient experiences.

We seek comment on this proposal.

4. Eligibility Requirements for the PY 2023 ESRD QIP

Our current minimum eligibility requirements for scoring the ESRD QIP measures are described in Table 8. We are not proposing any changes to these eligibility requirements for the PY 2023 ESRD QIP in this proposed rule.

TABLE 8: Eligibility Requirements for Scoring on ESRD QIP Measures

Measure	Minimum data requirements	CCN open date	Small facility adjuster
Kt/V Comprehensive (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
VAT: Long-term Catheter Rate (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
VAT: Standardized Fistula Rate (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
Hypercalcemia (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
NHSN BSI (Clinical)	11 qualifying patients	Before October 1 prior to the performance period that applies to the program year.	11-25 qualifying patients
NHSN Dialysis Event (Reporting)	11 qualifying patients	N/A	11-25 qualifying patients
SRR (Clinical)	11 index discharges	N/A	11-41 index discharges
STrR (Reporting)	10 patient-years at risk	N/A	10-21 patient-years at risk
SHR (Clinical)	5 patient-years at risk	N/A	5-14 patient-years at risk
ICH CAHPS (Clinical)	Facilities with 30 or more survey-eligible patients during the calendar year preceding the performance period must submit survey results. Facilities will not receive a score if they do not obtain a total of at least 30 completed surveys during the performance period	Before October 1 prior to the performance period that applies to the program year.	N/A
Depression Screening and Follow-Up (Reporting)	11 qualifying patients	Before April 1 of the performance period that applies to the program year.	N/A
Ultrafiltration (Reporting)	11 qualifying patients	Before April 1 of the performance period that applies to the program year.	N/A
MedRec (Reporting)	11 qualifying patients	Before October 1 prior to the performance period that applies to the program year.	N/A
PPPW (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients

5. Clarification of the Timeline for Facilities To Make Changes To Their NHSN Bloodstream Infection (BSI) Clinical Measure and NHSN Dialysis Event Reporting Measure Data for Purposes of the ESRD QIP

Under our current policy for the NHSN BSI clinical measure and NHSN Dialysis Event reporting measure, facilities are required to submit monthly data on a quarterly basis, and each quarter's data is due 3 months after the end of the quarter (81 FR 77879 through 77881). For example, data collected by facilities between January 1 and March 31, 2021 is due to NHSN by June 30, 2021, data collected between April 1 and June 30, 2021 is due to NHSN by September 30, 2021, and data collected between July 1 and September 30, 2021 is due to NHSN by December 31, 2021. After each quarterly data submission deadline, the Centers for Disease

Control and Prevention (CDC) takes a snapshot of the facility's data for the quarter and creates a permanent data file. Each quarterly permanent data file is aggregated together to create the annual CMS ESRD QIP Final Compliance File, which the CDC transmits to CMS for purposes of determining whether the facility has met the reporting requirements for these measures. Facilities may make changes to their quarterly NHSN data for purposes of the ESRD QIP at any point up until the applicable quarterly submission data deadline.

We have become aware that the NHSN system does not prevent facilities from making changes to their data for purposes of CDC surveillance after the applicable ESRD QIP quarterly submission deadline has passed. However, we are clarifying that any changes that a facility makes to its data

after the ESRD QIP deadline that applies to those data will not be included in the quarterly permanent data file that the CDC generates for purposes of creating the annual CMS ESRD QIP Final Compliance File. Rather, as noted above, each quarterly permanent data file captures a snapshot of the facility's data as of the quarterly submission deadline, and that file cannot be updated for purposes of the ESRD QIP because of operational and timing issues.

6. Estimated Payment Reduction for the PY 2023 ESRD QIP

Under our current policy, a facility will not receive a payment reduction for a payment year in connection with its performance for the ESRD QIP if it achieves a total performance score (TPS) that is at or above the minimum TPS (mTPS) that we establish for the payment year. We have defined the

mTPS in our regulations at § 413.178(a)(8) as, with respect to a payment year, the TPS that an ESRD facility would receive if, during the baseline period it performed at the 50th percentile of national performance on all clinical measures and the median of national ESRD facility performance on all reporting measures.

Our current policy, which is codified at § 413.177 of our regulations, is also to implement the payment reductions on a

sliding scale using ranges that reflect payment reduction differentials of 0.5 percent for each 10 points that the facility's TPS falls below the minimum TPS (76 FR 634 through 635).

For PY 2023, we estimate based on available data that a facility must meet or exceed a mTPS of 57 in order to avoid a payment reduction. We note that the mTPS estimated in this proposed rule is based on data from CY 2018 instead of the PY 2023 baseline

period (CY 2019) because CY 2019 data are not yet available.

We refer readers to Table 7 for the estimated values of the 50th percentile of national performance for each clinical measure. Under our current policy, a facility that achieves a TPS below 57 would receive a payment reduction based on the TPS ranges indicated in Table 9.

TABLE 9: Payment Reduction Scale for PY 2023 Based on the Most Recently Available Data

<u>Total performance score</u>	<u>Reduction (%)</u>
100-57	0%
56-47	0.5%
46-37	1.0%
36-27	1.5%
26-0	2.0%

We intend to update the mTPS for PY 2023, as well as the payment reduction ranges for that payment year, in the CY 2021 ESRD PPS final rule.

7. Proposal To Reduce the Number of Records That a Facility Selected for NHSN Validation Must Submit

One of the critical elements of the ESRD QIP's success is ensuring that the data submitted to calculate measure scores and TPSs are accurate. The ESRD QIP currently includes two validation studies for this purpose: the Consolidated Renal Operations in a Web-Enabled Network (CROWNWeb) data validation study (OMB Control Number 0938-1289) and the NHSN validation study (OMB Control Number 0938-1340). In the CY 2019 ESRD PPS final rule, we adopted the CROWNWeb data validation study as a permanent feature of the Program (83 FR 57003). Under that policy, we will continue validating CROWNWeb data in PY 2023 and subsequent payment years, and we will deduct 10 points from a facility's TPS if it is selected for validation but does not submit the requested records.

We also adopted a methodology for the PY 2022 NHSN validation study, which targets facilities for NHSN validation by identifying facilities that are at risk for under-reporting. For additional information on this methodology, we refer readers to the CY

2018 ESRD PPS final rule (82 FR 50766 through 50767). In the CY 2020 ESRD PPS final rule, we finalized our proposal to continue using this methodology for the NHSN validation study for PY 2023 and subsequent years (84 FR 60727). In that rule, we concluded that to achieve the most reliable results for a payment year, we would need to review approximately 6,072 charts submitted by 303 facilities, and that this sample size would produce results with a 95 percent confidence level and a 1 percent margin of error. Based on those results and our desire to ensure that dialysis event data reported to the NHSN for purposes of the ESRD QIP are accurate, we finalized our proposal to continue use of this methodology in the PY 2023 NHSN validation study and for subsequent years.

Additionally, as we had previously finalized for CROWNWeb validation, we finalized our proposal to adopt NHSN validation as a permanent feature of the ESRD QIP with the methodology we first finalized for PY 2022 and are continuing for PY 2023 and subsequent years. We continue to believe that the purpose of our validation programs is to ensure the accuracy and completeness of data that are scored under the ESRD QIP, and we believe that validating NHSN data using this methodology achieves that goal.

In the CY 2019 ESRD PPS final rule, we finalized that a sample of 300 facilities will be selected for the NHSN validation study each year, and that each facility will be required to submit 20 patient records per quarter for each of the first two quarters of the calendar year (83 FR 57001), for a total of 40 records. In this proposed rule, we are proposing to change this requirement and allow facilities selected to participate in the NHSN validation study to submit a total of 20 patient records for the applicable calendar year. We are also proposing to allow facilities to submit patient records from any two quarters during the year, as long as all of the records are from no more than two quarters. For example, a facility could choose to submit 2 records from Q1 and 18 records from Q4, or 6 records from Q2 and 14 records from Q3, but it could not submit 4 records from Q1, 8 records from Q2, and 8 records from Q3.

We have concluded that this revised approach would reduce facility burden by decreasing the required number of patient records and allowing more flexibility for facilities to choose what records to submit, while continuing to maintain a sample size that is adequate for our validation analysis. In reaching this conclusion, we were informed by the CDC's recommendations. Based on the sample estimation analysis, the CDC recommended the following factors to

improve the precision of estimation of accuracy of dialysis events reported to NHSN: An expected 80 percent of dialysis events reporting accuracy from facilities and setting the precision of the NHSN validation study to a 95 percent confidence level and 1 percent margin of error, which would require a total of 6,072 chart reviews. Beginning with the CY 2017 and CY 2018 NHSN dialysis validation, we have gradually increased the number of facilities randomly selected for validation, as well as the number of charts for review, in order to achieve the 6,000 chart threshold necessary for an accurate review. Initially, 35 facilities were randomly selected and 10 charts per facility were reviewed. For CY 2019, 150 facilities were randomly selected and each facility submitted a total of 20 records, to achieve the total of 3,000 charts available for review. For CY 2020, the goal was to increase from 150 to 300 facilities, where each facility would submit a total of 20 records thereby achieving the total of 6,000 charts available for review, as we previously finalized (83 FR 57001). Because a total of 20 records would achieve the 6,000 chart threshold necessary for an accurate review, we concluded that we could reduce the sample size from 40 records to 20 records. We believe a total of 20 medical records across a 6-month validation study time frame for a calendar year, rather than 20 records per quarter, would provide a sufficiently accurate sample size.

We believe the reduction in patient records still provides an adequate sample size for the validation and reduces overall facility burden. A recent estimation analysis conducted by the CDC supports our belief that a review of 20 charts per facility across a specified validation timeline that are acquired by randomly selecting approximately 300 facilities would continue to meet the medical record selection criteria outlined in the NHSN Dialysis Validation methodology. This would meet the CDC's recommended sample estimate to achieve the 95 percent confidence level precision and 1 percent margin of error, while also reducing facility burden.

We seek comment on this proposal.

We are not proposing any changes to the CROWNWeb validation study methodology.

C. Proposals for the PY 2024 ESRD QIP

1. Continuing Measures for the PY 2024 ESRD QIP

Under our previously adopted policy, the PY 2023 ESRD QIP measure set will also be used for PY 2024.

2. Performance Period for the PY 2023 ESRD QIP and Subsequent Years

We continue to believe that 12-month performance and baseline periods provide us sufficiently reliable quality measure data for the ESRD QIP. In the CY 2020 ESRD PPS final rule, we finalized the performance and baseline periods for the PY 2023 ESRD QIP (84 FR 60728). We also finalized our proposal to adopt automatically a performance and baseline period for each year that is 1 year advanced from those specified for the previous payment year. For example, under this policy, we would automatically adopt CY 2022 as the performance period and CY 2020 as the baseline period for the PY 2024 ESRD QIP.

In this proposed rule, we are not proposing any changes to this policy.

3. Performance Standards for the PY 2024 ESRD QIP and Subsequent Years

Section 1881(h)(4)(A) of the Act requires the Secretary to establish performance standards with respect to the measures selected for the ESRD QIP for a performance period with respect to a year. The performance standards must include levels of achievement and improvement, as required by section 1881(h)(4)(B) of the Act, and must be established prior to the beginning of the performance period for the year involved, as required by section 1881(h)(4)(C) of the Act. We refer readers to the CY 2012 ESRD PPS final rule (76 FR 70277) for a discussion of the achievement and improvement standards that we have established for clinical measures used in the ESRD QIP. We recently codified definitions for the terms "achievement threshold," "benchmark," "improvement threshold," and "performance standard" in our regulations at § 413.178(a)(1), (3), (7), and (12), respectively.

a. Performance Standards for Clinical Measures in the PY 2024 ESRD QIP

At this time, we do not have the necessary data to assign numerical values to the achievement thresholds, benchmarks, and 50th percentiles of national performance for the clinical measures because we do not have CY 2020 data. We intend to publish these numerical values, using CY 2020 data, in the CY 2022 ESRD PPS final rule.

b. Performance Standards for the Reporting Measures in the PY 2024 ESRD QIP

In the CY 2019 ESRD PPS final rule, we finalized the continued use of existing performance standards for the Screening for Clinical Depression and Follow-Up reporting measure, the

Ultrafiltration Rate reporting measure, the NHSN Dialysis Event reporting measure, and the MedRec reporting measure (83 FR 57010 through 57011). We will continue use of these performance standards in PY 2024.

4. Scoring the PY 2024 ESRD QIP

a. Scoring Facility Performance on Clinical Measures

In the CY 2014 ESRD PPS final rule, we finalized policies for scoring performance on clinical measures based on achievement and improvement (78 FR 72215 through 72216). In the CY 2019 ESRD PPS final rule, we finalized a policy to continue use of this methodology for future payment years (83 FR 57011) and we codified these scoring policies at § 413.178(e).

We are not proposing to change our scoring policies in this proposed rule.

b. Scoring Facility Performance on Reporting Measures

Our policy for scoring performance on reporting measures is codified at § 413.178(e), and more information on our scoring policy for reporting measures can be found in the CY 2020 ESRD PPS final rule (84 FR 60728). We previously finalized policies for scoring performance on the NHSN Dialysis Event reporting measure in the CY 2018 ESRD PPS final rule (82 FR 50780 through 50781), as well as policies for scoring the Ultrafiltration Rate reporting measure, MedRec reporting measure, and Clinical Depression Screening and Follow-up reporting measure in the CY 2019 ESRD PPS final rule (83 FR 57011). We also previously finalized the scoring policy for the STRr reporting measure in the CY 2020 ESRD PPS final rule (84 FR 60721 through 60723). We refer the reader to section IV.B.3 of this proposed rule for proposed changes to the scoring methodology for the Ultrafiltration Rate reporting measure.

5. Weighting the Measure Domains and the TPS for PY 2024

Under our current policy, we assign the Patient & Family Engagement Measure Domain a weight of 15 percent of the TPS, the Care Coordination Measure Domain a weight of 30 percent of the TPS, the Clinical Care Measure Domain a weight of 40 percent of the TPS, and the Safety Measure domain a weight of 15 percent of the TPS.

In the CY 2019 ESRD PPS final rule, we finalized a policy to assign weights to individual measures and a policy to redistribute the weight of unscored measures (83 FR 57011 through 57012). In the CY 2020 ESRD PPS final rule, we finalized a policy to use the measure weights we finalized for PY 2022 for the

PY 2023 ESRD QIP and subsequent payment years, and also to use the PY 2022 measure weight redistribution policy for the PY 2023 ESRD QIP and subsequent payment years (84 FR 60728 through 60729). We are not proposing any updates to these policies. Under our current policy, a facility must be eligible to be scored on at least one measure in two of the four measures domains in order to be eligible to receive a TPS (83 FR 57012).

V. Collection of Information Requirements

A. Legislative Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection requirement should be approved by OMB, the Paperwork Reduction Act of 1995 (44 U.S.C. 3506(c)(2)(A)) requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

Using the following format describe the information collection requirements that are in each section.

B. Requirements in Regulation Text

In sections II.B.1 through II.B.3 and II.B.5 of this proposed rule, we are proposing changes to regulatory text for the ESRD PPS for CY 2021. However, the changes that are being proposed do not impose any new information collection requirements.

C. Additional Information Collection Requirements

This proposed rule does not impose any new information collection requirements in the regulation text, as specified above. However, there are changes in some currently approved information collections. The following

is a discussion of these information collections.

1. ESRD QIP—Wage Estimates

To derive wages estimates, we used data from the U.S. Bureau of Labor Statistics' May 2019 National Occupational Employment and Wage Estimates. In the CY 2016 ESRD PPS final rule (80 FR 69069), we stated that it was reasonable to assume that Medical Records and Health Information Technicians, who are responsible for organizing and managing health information data, are the individuals tasked with submitting measure data to CROWNWeb and NHSN, as well as compiling and submitting patient records for purpose of the data validation studies, rather than a Registered Nurse, whose duties are centered on providing and coordinating care for patients. The median hourly wage of a Medical Records and Health Information Technician is \$20.50 per hour.¹⁹⁹ Fringe benefit and overhead are calculated at 100 percent. Therefore, using these assumptions, we estimate an hourly labor cost of \$41.00 as the basis of the wage estimates for all collections of information calculations in the ESRD QIP. We have adjusted these employee hourly wage estimates by a factor of 100 percent to reflect current HHS department-wide guidance on estimating the cost of fringe benefits and overhead. These are necessarily rough adjustments, both because fringe benefits and overhead costs vary significantly from employer to employer and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative and we believe that these are reasonable estimation methods.

We used this updated wage estimate, along with updated facility and patient counts to re-estimate the total information collection burden in the ESRD QIP for PY 2023 that we discussed in the CY 2020 ESRD QIP final rule (84 FR 60787 through 60788) and to estimate the total information collection burden in the ESRD QIP for PY 2024. We provide the re-estimated information collection burden associated with the PY 2023 ESRD QIP and the newly estimated information collection burden associated with the PY 2024 ESRD QIP in sections IV.C.2 and IV.C.3 of this proposed rule.

¹⁹⁹ <https://www.bls.gov/oes/current/oes292098.htm>.

2. Estimated Burden Associated With the Data Validation Requirements for PY 2023 and PY 2024

In the CY 2020 ESRD PPS final rule, we finalized a policy to adopt the CROWNWeb data validation methodology that we previously adopted for the PY 2016 ESRD QIP as the methodology we would use to validate CROWNWeb data for all payment years, beginning with PY 2021 (83 FR 57001 through 57002). Under this methodology, 300 facilities are selected each year to submit 10 records to CMS, and we reimburse these facilities for the costs associated with copying and mailing the requested records. The burden associated with these validation requirements is the time and effort necessary to submit the requested records to a CMS contractor. In this proposed rule, we are updating these estimates using a newly available wage estimate of a Medical Records and Health Information Technician. We estimate that it will take each facility approximately 2.5 hours to comply with this requirement. If 300 facilities are asked to submit records, we estimate that the total combined annual burden for these facilities will be 750 hours (300 facilities × 2.5 hours). Since we anticipate that Medical Records and Health Information Technicians or similar administrative staff will submit these data, we estimate that the aggregate cost of the CROWNWeb data validation each year will be approximately \$30,750 (750 hours × \$41.00), or an annual total of approximately \$102.50 (\$30,750/300 facilities) per facility in the sample. The decrease in our burden estimate is due to using the median hourly wage instead of the mean hourly wage for Medical Records and Health Information Technicians or similar staff and is not the result of any policies proposed in this proposed rule. The burden associated with these requirements is captured in an information collection request (OMB control number 0938–1289).

In section IV.B.7 of this proposed rule, we proposed to reduce the number of records that a facility selected to participate in the NHSN data validation study must submit to a CMS contractor, beginning with PY 2023. Under the proposal, a facility would be required to submit records for 20 patients across any two quarters of the year, instead of 20 records for each of the first two quarters of the year. The burden associated with this proposal is the time and effort necessary to submit the requested records to a CMS contractor. Applying our proposal to reduce the

number of records required from each facility participating in the NHSN validation study, we estimate that it would take each facility approximately 5 hours to comply with this requirement. If 300 facilities are asked to submit records each year, we estimate that the total combined annual burden hours for these facilities per year would be 1,500 hours (300 facilities × 5 hours). Since we anticipate that Medical Records and Health Information Technicians or similar staff would submit these data, using the newly available wage estimate of a Medical Records and Health Information Technician, we estimate that the aggregate cost of the NHSN data validation each year would be approximately \$61,500 (1,500 hours × \$41), or a total of approximately \$205 (\$61,500/300 facilities) per facility in the sample. The reduction in our burden estimate is due to a reduction in the number of medical records collected and the utilization of the median hourly wage instead of the mean hourly wage. The burden associated with these requirements is captured in an information collection request (OMB control number 0938–1340).

3. CROWNWeb Reporting Requirements for PY 2023 and PY 2024

To determine the burden associated with the CROWNWeb reporting requirements, we look at the total number of patients nationally, the number of data elements per patient-year that the facility would be required to submit to CROWNWeb for each measure, the amount of time required for data entry, the estimated wage plus benefits applicable to the individuals within facilities who are most likely to be entering data into CROWNWeb, and the number of facilities submitting data to CROWNWeb. In the CY 2020 ESRD PPS final rule, we estimated that the burden associated CROWNWeb reporting requirements for the PY 2023 ESRD QIP was approximately \$211 million.

We are not proposing any changes that would affect the burden associated with CROWNWeb reporting requirements for PY 2023 or PY 2024. However, we have re-calculated the burden estimate for PY 2023 using updated estimates of the total number of dialysis facilities, the total number of patients nationally, and wages for Medical Records and Health Information Technicians or similar staff as well as a refined estimate of the number of hours needed to complete data entry for CROWNWeb reporting. In the CY 2020 ESRD PPS final rule, we estimated that the amount of time

required to submit measure data to CROWNWeb was 2.5 minutes per element and used a rounded estimate of 0.042 hours in our calculations. In this proposed rule, we did not use a rounded estimate of the time needed to complete data entry for CROWNWeb reporting. There are 229 data elements for 523,314 patients across 7,386 facilities. At 2.5 minutes per element, this yields approximately 676.05 hours per facility. Therefore, the PY 2023 burden is 4,993,288 hours (676.05 hours × 7,386 facilities). (Using the wage estimate of a Medical Records and Health Information Technician, we estimate that the PY 2023 total burden cost is \$205 million (4,993,288 hours × \$41). There is no net incremental burden change from PY 2023 to PY 2024 because we are not proposing to change the reporting requirements for PY 2024.

VI. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VII. Economic Analyses

A. Regulatory Impact Analysis

1. Introduction

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review, Executive Order 13563 on Improving Regulation and Regulatory Review, the Regulatory Flexibility Act (RFA) (Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), Executive Order 13132 on Federalism, the Congressional Review Act (5 U.S.C. 801 *et seq.*), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs.

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). 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). We estimate that this rulemaking is “economically significant” as measured by the \$100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a RIA that to the best of our ability presents the costs and benefits of the rulemaking.

We solicit comments on the regulatory impact analysis provided.

2. Statement of Need

a. ESRD PPS

This rule proposes a number of routine updates and several policy changes to the ESRD PPS for CY 2021. The proposed routine updates include the CY 2021 wage index values, the wage index budget-neutrality adjustment factor, and outlier payment threshold amounts. Failure to publish this proposed rule would result in ESRD facilities not receiving appropriate payments in CY 2021 for renal dialysis services furnished to ESRD beneficiaries.

b. AKI

This rule also proposes routine updates to the payment for renal dialysis services furnished by ESRD facilities to individuals with AKI. Failure to publish this proposed rule would result in ESRD facilities not receiving appropriate payments in CY 2021 for renal dialysis services furnished to patients with AKI in accordance with section 1834(r) of the Act.

c. ESRD QIP

This rule proposes to implement requirements for the ESRD QIP, including a proposal to modify the scoring methodology for the Ultrafiltration Rate reporting measure

beginning with the PY 2023 ESRD QIP and a proposal to update the reporting requirements for facilities selected for NHSN data validation. The rule also clarifies the review and correction timeline for the NHSN BSI clinical measure and NHSN Dialysis Event reporting measure.

3. Overall Impact

a. ESRD PPS

We estimate that the proposed revisions to the ESRD PPS would result in an increase of approximately \$190 million in payments to ESRD facilities in CY 2021, which includes the amount associated with updates to the outlier thresholds, payment rate update, updates to the wage index, the proposal to adopt the new OMB delineations with a transition period, and the proposal to include calcimimetics in the ESRD PPS base rate. These figures do not reflect estimated increases or decreases in expenditures based on our proposal to expand eligibility for the TPNIES to certain new and innovative home dialysis machines when used in the home. The fiscal impact of this proposal cannot be determined due to the uniqueness of each new and innovative home dialysis machine and its cost.

b. AKI

We estimate that the proposed updates to the AKI payment rate would result in an increase of approximately \$5 million in payments to ESRD facilities in CY 2021.

c. ESRD QIP

For PY 2023, we have re-estimated the costs associated with the information collection requirements under the ESRD QIP with updated estimates of the total number of dialysis facilities, the total number of patients nationally, wages for Medical Records and Health Information Technicians or similar staff, and a refined estimate of the number of hours needed to complete data entry for CROWNWeb reporting. We have made no changes to our methodology for calculating the annual burden associated with the information collection requirements for the CROWNWeb validation study and CROWNWeb reporting. We updated the

annual burden associated with the NHSN validation study to reflect our proposal to reduce the total number of records collected. This proposed update would reduce the collection of information requirements associated with the NHSN validation study by \$65,460 per year across the facilities selected for validation that year.

We also updated the payment reduction estimates using more recent data for the measures in the ESRD QIP measure set and applying our proposal to modify the scoring methodology for the Ultrafiltration Rate reporting measure beginning with the PY 2023 ESRD QIP. We estimate \$205 million in information collection burden, which includes the cost of complying with this rule, and an additional \$16 million in estimated payment reductions across all facilities for PY 2023.

For PY 2024, we estimate that the proposed revisions to the ESRD QIP would result in \$205 million in information collection burden and \$16 million in estimated payment reductions across all facilities impact of \$221 million as a result of the policies we have previously finalized and the policies we have proposed in this proposed rule.

4. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this proposed rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on last year's proposed rule will be the number of reviewers of this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed last year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we thought that the number of past commenters would be a fair estimate of the number of reviewers of this rule. We welcome any comments on the approach in estimating the number of entities which will review this proposed

rule. We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We seek comments on this assumption.

Using the wage information from the Bureau of Labor Statistics (BLS) for medical and health service managers (Code 11-9111), we estimate that the cost of reviewing this rule is \$109.36 per hour, including overhead and fringe benefits https://www.bls.gov/oes/current/oes_nat.htm. Assuming an average reading speed, we estimate that it would take approximately 6.25 hours for the staff to review half of this proposed rule. For each entity that reviews the rule, the estimated cost is \$683.50 (6.25 hours × \$109.36). Therefore, we estimate that the total cost of reviewing this regulation rounds to \$62,882. (\$683.50 × 92 reviewers).

B. Detailed Economic Analysis

1. CY 2021 End-Stage Renal Disease Prospective Payment System

a. Effects on ESRD Facilities

To understand the impact of the changes affecting payments to different categories of ESRD facilities, it is necessary to compare estimated payments in CY 2020 to estimated payments in CY 2021. To estimate the impact among various types of ESRD facilities, it is imperative that the estimates of payments in CY 2020 and CY 2021 contain similar inputs. Therefore, we simulated payments only for those ESRD facilities for which we are able to calculate both current payments and new payments.

For this proposed rule, we used CY 2019 data from the Part A and Part B Common Working Files as of April 3, 2020, as a basis for Medicare dialysis treatments and payments under the ESRD PPS. We updated the 2019 claims to 2020 and 2021 using various updates. The updates to the ESRD PPS base rate are described in section II.B.4.d of this proposed rule. Table 10 shows the impact of the estimated CY 2021 ESRD PPS payments compared to estimated payments to ESRD facilities in CY 2020.

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**TABLE 10: Impact of Proposed Changes in Payment to ESRD Facilities for CY 2021
Proposed Rule**

Facility Type	Number of Facilities (A)	Number of Treatments (in millions) (B)	Effect of 2021 Changes in Outlier Policy (C)	Effect of Changes in Wage Index Data (D)	Effect of CBSA change & 5% Cap Policy (E)	Effect of Bundling Calcimimetics into Base Rate (F)	Effect of Change for Payment Rate Update (G)	Effect of Total 2021 Proposed Changes (H)
All Facilities	7,610	44.8	0.3%	0.0%	0.0%	-0.6%	1.8%	1.6%
Type								
Freestanding	7,224	43.1	0.3%	0.0%	0.0%	-0.5%	1.8%	1.6%
Hospital based	386	1.8	0.6%	0.1%	0.1%	-2.9%	1.8%	-0.4%
Ownership Type								
Large dialysis organization	5,809	34.8	0.3%	0.0%	0.0%	0.3%	1.8%	2.4%
Regional chain	944	5.7	0.2%	0.0%	-0.1%	-3.9%	1.8%	-2.0%
Independent	534	2.9	0.3%	0.1%	0.3%	-2.5%	1.8%	0.0%
Hospital based ¹	299	1.3	0.6%	0.1%	0.2%	-2.5%	1.8%	0.1%
Unknown	24	0.0	0.6%	-0.7%	-0.1%	1.5%	1.8%	3.1%
Geographic Location^{2, 3}								
Rural	1,292	6.5	0.3%	0.1%	-1.2%	-0.5%	1.8%	0.6%
Urban	6,318	38.4	0.3%	0.0%	0.2%	-0.6%	1.8%	1.7%
Census Region								
East North Central	1,220	6.0	0.4%	0.0%	-0.1%	0.0%	1.8%	2.1%
East South Central	604	3.3	0.3%	0.0%	0.0%	-1.7%	1.8%	0.3%
Middle Atlantic	845	5.4	0.4%	0.4%	0.3%	-1.2%	1.8%	1.6%
Mountain	419	2.4	0.2%	-0.4%	-0.1%	0.9%	1.8%	2.5%
New England	201	1.4	0.3%	-0.8%	-0.1%	-0.2%	1.8%	1.0%
Pacific ⁴	907	6.4	0.3%	0.0%	0.1%	0.5%	1.8%	2.6%
Puerto Rico and Virgin Islands	52	0.3	0.2%	0.0%	-0.1%	0.2%	1.8%	2.1%
South Atlantic	1,746	10.7	0.4%	0.1%	0.0%	-1.3%	1.8%	0.8%
West North Central	514	2.3	0.4%	-0.3%	-0.1%	0.2%	1.8%	2.1%
West South Central	1,102	6.7	0.3%	0.1%	0.0%	-0.9%	1.8%	1.2%
Facility Size								
Less than 4,000 treatments	1,315	2.6	0.3%	0.0%	0.0%	0.6%	1.8%	2.7%
4,000 to 9,999 treatments	2,803	12.2	0.3%	0.0%	-0.1%	-0.5%	1.8%	1.6%
10,000 or more treatments	3,246	29.7	0.3%	0.0%	0.0%	-0.7%	1.8%	1.4%
Unknown	246	0.3	0.3%	-0.2%	0.1%	-0.1%	1.8%	1.9%
Percentage of Pediatric Patients								
Less than 2%	7,508	44.5	0.3%	0.0%	0.0%	-0.6%	1.8%	1.5%
Between 2% and 19%	36	0.3	0.3%	0.2%	-0.1%	-0.9%	1.8%	1.3%
Between 20% and 49%	13	0.0	0.3%	-0.1%	-0.1%	3.9%	1.8%	5.8%
More than 50%	53	0.0	0.2%	0.0%	-0.1%	4.5%	1.8%	6.5%

¹Includes hospital-based ESRD facilities not reported to have large dialysis organization or regional chain ownership.

²Facility counts for Urban/Rural uses 2021 CBSA delineation. Under 2020 and previous CBSA delineation, facility counts for urban and rural are 6,306 and 1,304 respectively. For payment percent change columns, appropriate definition of Urban/Rural is used for each step.

³The 1.17 percent drop in total payments among rural facilities (and increase in total payments among urban facilities) is mostly due facilities shifting from rural to urban status under new CBSA delineation. Controlling for old-CBSA urban/rural status, the change in payment is close to 0 percent.

⁴Includes ESRD facilities located in Guam, American Samoa, and the Northern Mariana Islands.

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Column A of the impact table indicates the number of ESRD facilities for each impact category and column B indicates the number of dialysis treatments (in millions). The overall effect of the proposed changes to the outlier payment policy described in section II.B.4.c of this proposed rule is shown in column C. For CY 2021, the impact on all ESRD facilities as a result of the changes to the outlier payment policy would be a 0.3 percent increase in estimated payments. All ESRD facilities are anticipated to experience a positive effect in their estimated CY 2021 payments as a result of the proposed outlier policy changes.

Column D shows the effect of the annual update to the wage index, as described in section II.B.4.b of this proposed rule. That is, this column reflects the update from the CY 2020 ESRD PPS wage index using CY 2020 OMB delineations with a basis of the FY 2021 pre-floor, pre-reclassified IPPS hospital wage index data in a budget neutral manner. The total impact of this change is 0.0 percent, however, there are distributional effects of the change among different categories of ESRD facilities. The categories of types of facilities in the impact table show changes in estimated payments ranging from a 0.8 percent decrease to a 0.4 percent increase due to the annual update to the ESRD PPS wage index.

Column E shows the effect of adopting the proposed new OMB delineations and the transition policy as described in sections II.B.4.b.(2) and II.B.4.b.(3), respectively, of this proposed rule. That is, the impact represented in this column reflects the change from using the CY 2020 OMB delineations and basing the CY 2021 ESRD PPS wage index on the FY 2021 pre-floor, pre-reclassified IPPS hospital wage index data to the new OMB delineations and a 5 percent cap on wage index decreases in CY 2021, in a budget neutral manner. The total impact of this change is 0.0 percent, however, there are distributional effects of the change among different categories of ESRD facilities. The categories of types of facilities in the impact table show changes in estimated payments ranging

from a 1.2 percent decrease to a 0.3 percent increase due to these proposals to the ESRD PPS wage index.

Column F shows the effect of the proposed addition to the ESRD PPS base rate to include calcimimetics as described in section II.B.1 of this proposed rule. That is, the impact represented in this column reflects the change, under the ESRD PPS, proposed for payment to ESRD facilities for furnishing calcimimetics. Beginning January 1, 2018, ESRD facilities received payment for calcimimetics under the TDAPA policy in § 413.234(c). Under our proposal, beginning January 1, 2021, we would modify the ESRD PPS base rate by adding \$12.06 to include calcimimetics and no longer pay for calcimimetics using the TDAPA. In addition, calcimimetics would become outlier eligible services under § 413.237. The categories of types of facilities in the impact table show changes in estimated payments ranging from a 3.9 percent decrease to a 4.5 percent increase due to this proposal.

Column G shows the effect of the proposed CY 2021 ESRD PPS payment rate update as described in section II.B.4.a of this proposed rule. The proposed ESRD PPS payment rate update is 1.8 percent, which reflects the proposed ESRDB market basket percentage increase factor for CY 2021 of 2.2 percent and the proposed MFP adjustment of 0.4 percent.

Column H reflects the overall impact, that is, the effects of the proposed outlier policy changes, the proposed updated wage index and transition policy, the payment rate update, and the proposed addition to the ESRD PPS base rate to include calcimimetics. We expect that overall ESRD facilities would experience a 1.6 percent increase in estimated payments in CY 2021. The categories of types of facilities in the impact table show impacts ranging from a 2.0 percent decrease to a 6.5 percent increase in their CY 2021 estimated payments.

b. Effects on Other Providers

Under the ESRD PPS, Medicare pays ESRD facilities a single bundled payment for renal dialysis services, which may have been separately paid to

other providers (for example, laboratories, durable medical equipment suppliers, and pharmacies) by Medicare prior to the implementation of the ESRD PPS. Therefore, in CY 2021, we estimate that the proposed ESRD PPS would have zero impact on these other providers.

c. Effects on the Medicare Program

We estimate that Medicare spending (total Medicare program payments) for ESRD facilities in CY 2021 would be approximately \$9.3 billion. This estimate takes into account a projected decrease in fee-for-service Medicare dialysis beneficiary enrollment of 8.6 percent in CY 2021.

d. Effects on Medicare Beneficiaries

Under the ESRD PPS, beneficiaries are responsible for paying 20 percent of the ESRD PPS payment amount. As a result of the projected 1.6 percent overall increase in the proposed CY 2021 ESRD PPS payment amounts, we estimate that there would be an increase in beneficiary co-insurance payments of 1.6 percent in CY 2021, which translates to approximately \$40 million.

e. Alternatives Considered

(1) Inclusion of Calcimimetics Into the ESRD PPS Bundled Payment

In section II.B.1 of this proposed rule, we propose that beginning January 1, 2021, we would modify the ESRD PPS base rate by adding \$12.06 to include calcimimetics and no longer pay for calcimimetics using the TDAPA. In addition, calcimimetics would become ESRD outlier services eligible for outlier payments under § 413.237. With regard to the methodology proposed to calculate the amount to be added the ESRD PPS base rate, we considered using the Medicare expenditures reflecting payments made for the calcimimetics in CYs 2018 and 2019, that is, approximately \$2.3 billion and dividing by total treatments furnished in both years to arrive at an amount of \$27.08. However, using the most recent calendar quarter of ASP data available to calculate the ASP-based values as the proxy rate incorporates the lower priced generic calcimimetics into the

calculation of the amount added for oral calcimimetics. We believe it is appropriate for the ESRD PPS base rate to reflect generic drug manufacturer ASP data since we believe that this aligns with how ESRD facilities would purchase and furnish the oral calcimimetics in the future.

(2) Expansion of the TPNIES to Capital-Related Assets That are Home Dialysis Machines When Used in the Home for a Single Patient

In section II.B.3 of this proposed rule, we propose to expand the TPNIES policy and allow capital-related assets that are home dialysis machines when used in the home for a single patient to be eligible for the add-on payment adjustment when used in the home. Then, consistent with the policies finalized last year for other renal dialysis equipment and supplies eligible for the TPNIES, we would pay 65 percent of the pre-adjusted per treatment amount for a period of 2 years. With regard to the duration of applying the TPNIES for capital-related assets that are home dialysis machines when used in the home for a single patient, we considered paying the TPNIES for 3 years. However, we believe that the proposal is consistent with the TDAPA and other Medicare fee-for-service add-on payment programs (for example, the IPPS NTAP), and supports innovation for dialysis in the home setting, the President's Executive Order on Advancing American Kidney Health, and current

HHS initiatives to support home dialysis, while taking into account the potential increase in ESRD PPS expenditures.

(3) CY 2021 ESRD PPS Wage index

In section II.B.4.b of this proposed rule, we propose to adopt the new OMB delineations with a transition policy. That is, we are proposing to adopt the OMB delineations based on the September 14, 2018 OMB Bulletin No. 18-04 and, to mitigate any potential negative impacts, we would apply a 5 percent cap on any decrease in an ESRD facility's wage index from the ESRD facility's wage index from the prior calendar year. This transition would be phased in over 2 years, such that the estimated reduction in an ESRD facility's wage index would be capped at 5 percent in CY 2021 and no cap would be applied to the reduction in the wage index for the second year, CY 2022. With regard to the transition policy, we considered doing a 2-year 50/50 blended wage index approach consistent with the adoption of OMB delineations in the CY 2015 ESRD PPS final rule (79 FR 66142). However, we determined that the proposed 5 percent cap on any decrease policy would be an appropriate transition for CY 2021 as it provides predictability in payment levels from CY 2020 to the upcoming CY 2021 and additional transparency because it is administratively simpler than the 50/50 blended approach.

2. Proposed Payment for Renal Dialysis Services Furnished to Individuals With AKI

a. Effects on ESRD Facilities

To understand the impact of the changes affecting payments to different categories of ESRD facilities for renal dialysis services furnished to individuals with AKI, it is necessary to compare estimated payments in CY 2020 to estimated payments in CY 2021. To estimate the impact among various types of ESRD facilities for renal dialysis services furnished to individuals with AKI, it is imperative that the estimates of payments in CY 2020 and CY 2021 contain similar inputs. Therefore, we simulated payments only for those ESRD facilities for which we are able to calculate both current payments and new payments.

For this proposed rule, we used CY 2019 data from the Part A and Part B Common Working Files as of April 3, 2020, as a basis for Medicare for renal dialysis services furnished to individuals with AKI. We updated the 2019 claims to 2020 and 2021 using various updates. The updates to the AKI payment amount are described in section III.B of this proposed rule. Table 11 shows the impact of the estimated CY 2021 payments for renal dialysis services furnished to individuals with AKI compared to estimated payments for renal dialysis services furnished to individuals with AKI in CY 2020.

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TABLE 11: Impact of Proposed Changes in Payment for Renal Dialysis Services Furnished to Individuals with AKI for CY 2021 Proposed Rule

Facility Type	Number of Facilities (A)	Number of Treatments (in thousands) (B)	Effect of All Wage Index Changes (C)	Effect of Bundling Calcimimetics in the Base Rate (D)	Effect of Changes in Payment Rate Update (E)	Effect of Total 2021 Proposed Changes (F)
All Facilities	5,064	284.9	-0.1%	5.0%	1.8%	6.9%
Type						
Freestanding	4,941	279.6	-0.1%	5.0%	1.8%	6.9%
Hospital based	123	5.3	0.0%	5.0%	1.8%	6.9%
Ownership Type						
Large dialysis organization	4,189	239.5	-0.1%	5.0%	1.8%	6.9%
Regional chain	583	29.2	-0.1%	5.0%	1.8%	6.8%
Independent	208	12.8	0.1%	5.0%	1.8%	7.0%
Hospital based ¹	77	3.3	0.2%	5.0%	1.8%	7.1%
Unknown	7	0.1	-0.9%	5.0%	1.8%	6.0%
Geographic Location²						
Rural	874	45.1	-0.2%	5.0%	1.8%	6.7%
Urban	4,190	239.8	0.0%	5.0%	1.8%	6.9%
Census Region						
East North Central	886	52.8	-0.1%	5.0%	1.8%	6.9%
East South Central	404	20.4	-0.2%	5.0%	1.8%	6.7%
Middle Atlantic	518	31.7	0.3%	5.0%	1.8%	7.3%
Mountain	291	16.8	-0.4%	5.0%	1.8%	6.5%
New England	157	8.3	-1.0%	5.0%	1.8%	5.9%
Pacific ³	596	43.4	0.0%	5.0%	1.8%	6.9%
Puerto Rico and Virgin Islands	2	0.0	-0.1%	5.0%	1.8%	6.8%
South Atlantic	1,190	66.0	0.0%	5.0%	1.8%	6.9%
West North Central	349	13.7	-0.5%	5.0%	1.8%	6.4%
West South Central	671	31.8	0.1%	5.0%	1.8%	7.0%
Facility Size						
Less than 4,000 treatments	652	27.7	-0.1%	5.0%	1.8%	6.8%
4,000 to 9,999 treatments	1,915	99.0	-0.1%	5.0%	1.8%	6.9%
10,000 or more treatments	2,398	154.7	-0.1%	5.0%	1.8%	6.9%
Unknown	99	3.4	0.0%	5.0%	1.8%	6.9%
Percentage of Pediatric Patients						
Less than 2%	5,064	284.9	-0.1%	5.0%	1.8%	6.9%
Between 2% and 19%	0	0.0	0.0%	0.0%	0.0%	0.0%
Between 20% and 49%	0	0.0	0.0%	0.0%	0.0%	0.0%
More than 50%	0	0.0	0.0%	0.0%	0.0%	0.0%

¹Includes hospital-based ESRD facilities not reported to have large dialysis organization or regional chain ownership.

²Facility counts for Urban/Rural uses 2021 CBSA delineation. Under 2020 and previous CBSA delineation, facility counts for urban and rural are 4,180 and 884 respectively. For payment percent change columns, appropriate definition of Urban/Rural is used for each step.

³Includes ESRD facilities located in Guam, American Samoa, and the Northern Mariana Islands

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Column A of the impact table indicates the number of ESRD facilities for each impact category and column B indicates the number of AKI dialysis treatments (in thousands).

Column C shows the effect of the proposed CY 2021 wage indices.

Column D shows the effect of the adjustment to the AKI dialysis payment rate that reciprocates the adjustment proposed to the ESRD PPS base rate for CY 2021, consistent with § 413.372. As discussed in section II.B.1 of this proposed rule, we propose to modify the ESRD PPS base rate by adding \$12.06 to include calcimimetics.

Column E shows the effect of the proposed CY 2021 ESRD PPS payment rate update. The proposed ESRD PPS payment rate update is 1.8 percent, which reflects the proposed ESRDB market basket percentage increase factor for CY 2021 of 2.2 percent and the proposed MFP adjustment of 0.4 percent.

Column F reflects the overall impact, that is, the effects of the updated wage index, the proposed addition to the ESRD PPS base rate, and the payment rate update. We expect that overall ESRD facilities would experience a 6.9 percent increase in estimated payments in CY 2021. The categories of types of facilities in the impact table show impacts ranging from an increase of 0.0 percent to 7.3 percent in their CY 2021 estimated payments.

b. Effects on Other Providers

Under section 1834(r) of the Act, as added by section 808(b) of TPEA, we propose to update the payment rate for renal dialysis services furnished by ESRD facilities to beneficiaries with AKI. The only two Medicare providers and suppliers authorized to provide these outpatient renal dialysis services are hospital outpatient departments and ESRD facilities. The decision about where the renal dialysis services are

furnished is made by the patient and his or her physician. Therefore, this proposal will have zero impact on other Medicare providers.

c. Effects on the Medicare Program

We estimate approximately \$56 million would be paid to ESRD facilities in CY 2021 as a result of AKI patients receiving renal dialysis services in the ESRD facility at the lower ESRD PPS base rate versus receiving those services only in the hospital outpatient setting and paid under the outpatient prospective payment system, where services were required to be administered prior to the TPEA.

d. Effects on Medicare Beneficiaries

Currently, beneficiaries have a 20 percent co-insurance obligation when they receive AKI dialysis in the hospital outpatient setting. When these services are furnished in an ESRD facility, the patients would continue to be responsible for a 20 percent co-insurance. Because the AKI dialysis payment rate paid to ESRD facilities is lower than the outpatient hospital PPS's payment amount, we would expect beneficiaries to pay less co-insurance when AKI dialysis is furnished by ESRD facilities.

e. Alternatives Considered

As we discussed in the CY 2017 ESRD PPS proposed rule (81 FR 42870), we considered adjusting the AKI payment rate by including the ESRD PPS case-mix adjustments, and other adjustments at section 1881(b)(14)(D) of the Act, as well as not paying separately for AKI specific drugs and laboratory tests. We ultimately determined that treatment for AKI is substantially different from treatment for ESRD and the case-mix adjustments applied to ESRD patients may not be applicable to AKI patients and as such, including those policies and adjustment would be inappropriate. We continue to monitor utilization and

trends of items and services furnished to individuals with AKI for purposes of refining the payment rate in the future. This monitoring would assist us in developing knowledgeable, data-driven proposals.

3. ESRD QIP

a. Effects of the PY 2023 ESRD QIP on ESRD Facilities

The ESRD QIP is intended to prevent possible reductions in the quality of ESRD dialysis facility services provided to beneficiaries. The general methodology that we are using to determine a facility's TPS is described in our regulations at § 413.178(e).

Any reductions in the ESRD PPS payments as a result of a facility's performance under the PY 2023 ESRD QIP would apply to the ESRD PPS payments made to the facility for services furnished in CY 2023, as codified in our regulations at § 413.177.

For the PY 2023 ESRD QIP, we estimate that, of the 7,386 dialysis facilities (including those not receiving a TPS) enrolled in Medicare, approximately 23.2 percent or 1,657 of the facilities that have sufficient data to calculate a TPS would receive a payment reduction for PY 2023. We are presenting an estimate for the PY 2023 ESRD QIP to update the estimated impact that was provided in the CY 2020 ESRD PPS final rule (84 FR 60797). If our proposal to update the scoring methodology for the Ultrafiltration Rate reporting measure is finalized, the total estimated payment reductions for all the 1,657 facilities expected to receive a payment reduction in PY 2023 would decrease from \$18,247,083.76 to approximately \$15,586,453.64. Facilities that do not receive a TPS do not receive a payment reduction.

Table 12 shows the overall estimated distribution of payment reductions resulting from the PY 2023 ESRD QIP.

TABLE 12: Estimated Distribution of PY 2023 ESRD QIP Payment Reductions

Payment Reduction	Number of Facilities	Percent of Facilities*
0.0%	5,490	76.82%
0.5%	1,215	17.00%
1.0%	336	4.70%
1.5%	65	0.91%
2.0%	41	0.57%

*239 facilities not scored due to insufficient data

To estimate whether a facility would receive a payment reduction for PY 2023, we scored each facility on achievement and improvement on several clinical measures we have previously finalized and for which there

were available data from CROWNWeb and Medicare claims. Payment reduction estimates are calculated using the most recent data available (specified in Table 13) in accordance with the policies proposed in this proposed rule.

Measures used for the simulation are shown in Table 13. These estimates also incorporate the proposed update to the scoring methodology for the Ultrafiltration Rate reporting measure.

TABLE 13: Data Used to Estimate PY 2023 ESRD QIP Payment Reductions

Measure	Period of time used to calculate achievement thresholds, 50th percentiles of the national performance, benchmarks, and improvement thresholds	Performance period
ICH CAHPS Survey	Jan 2017-Dec 2017	Jan 2018-Dec 2018
SRR	Jan 2017-Dec 2017	Jan 2018-Dec 2018
SHR	Jan 2017-Dec 2017	Jan 2018-Dec 2018
PPPW	Jan 2017-Dec 2017	Jan 2018-Dec 2018
Kt/V Dialysis Adequacy Comprehensive	Jan 2017-Dec 2017	Jan 2018-Dec 2018
VAT		
Standardized Fistula Ratio	Jan 2017-Dec 2017	Jan 2018-Dec 2018
% Catheter	Jan 2017-Dec 2017	Jan 2018-Dec 2018
Hypercalcemia	Jan 2017-Dec 2017	Jan 2018-Dec 2018

For all measures except SHR and SRR, clinical measures with less than 11 patients for a facility were not included in that facility's TPS. For SHR and STRR, facilities were required to have at least 5 patient-years at risk and 11 index discharges, respectively, in order to be included in the facility's TPS. Each facility's TPS was compared to an estimated mTPS and an estimated payment reduction table that were consistent with the proposals outlined in sections IV.B and IV.C of this proposed rule. Facility reporting measure scores were estimated using available data from CY 2017 and CY

2018. Facilities were required to have at least one measure in at least two domains to receive a TPS.

To estimate the total payment reductions in PY 2023 for each facility resulting from this proposed rule, we multiplied the total Medicare payments to the facility during the 1-year period between January 2018 and December 2018 by the facility's estimated payment reduction percentage expected under the ESRD QIP, yielding a total payment reduction amount for each facility.

Table 14 shows the estimated impact of the finalized ESRD QIP payment reductions to all ESRD facilities for PY

2023. The table also details the distribution of ESRD facilities by size (both among facilities considered to be small entities and by number of treatments per facility), geography (both rural and urban and by region), and by facility type (hospital based and freestanding facilities). Given that the performance period used for these calculations differs from the performance period we are using for the PY 2023 ESRD QIP, the actual impact of the PY 2023 ESRD QIP may vary significantly from the values provided here.

**TABLE 14: Estimated Impact of Proposed QIP Payment Reductions to ESRD Facilities for
PY 2023**

	Number of Facilities	Number of Treatments 2018 (in millions)	Number of Facilities with QIP Score	Number of Facilities Expected to Receive a Payment Reduction	Payment Reduction (percent change in total ESRD payments)
All Facilities	7,386	44.6	7,147	1,657	-0.15%
Facility Type:					
Freestanding	6,995	42.7	6,791	1,556	-0.15%
Hospital-based	391	1.9	356	101	-0.22%
Ownership Type:					
Large Dialysis	5,603	34.5	5,473	1,115	-0.12%
Regional Chain	927	5.7	897	241	-0.19%
Independent	512	2.9	488	216	-0.34%
Hospital-based (non-chain)	305	1.5	275	83	-0.24%
Unknown	39	0.0	14	2	-0.10%
Facility Size:					
Large Entities	6,530	40.2	6,370	1,356	-0.13%
Small Entities ¹	817	4.4	763	299	-0.30%
Unknown	39	0.0	14	2	-0.10%
Rural Status:					
1) Yes	1,285	6.5	1,239	138	-0.06%
2) No	6,101	38.2	5,908	1,519	-0.17%
Census Region:					
Northeast	1,004	6.9	974	213	-0.13%
Midwest	1,696	8.4	1,634	393	-0.16%
South	3,360	20.4	3,232	823	-0.16%
West	1,271	8.6	1,252	180	-0.08%
US Territories ²	55	0.4	55	48	-1.36%
Census Division:					
Unknown	8	0.1	8	2	-0.12%
East North Central	1,188	6.1	1,140	315	-0.19%
East South Central	587	3.3	578	131	-0.14%
Middle Atlantic	806	5.4	779	190	-0.15%
Mountain	409	2.3	404	52	-0.08%
New England	198	1.4	195	23	-0.06%
Pacific	862	6.3	848	128	-0.08%
South Atlantic	1,699	10.5	1,642	475	-0.19%
West North Central	508	2.2	494	78	-0.09%
West South Central	1,074	6.6	1,012	217	-0.13%
US Territories ²	47	0.3	47	46	-1.57%
Facility Size (# of total treatments)					
Less than 4,000 treatments	1,206	2.5	1,114	220	-0.15%
4,000-9,999 treatments	2,644	11.9	2,620	488	-0.11%
Over 10,000 treatments	3,159	29.8	3,149	882	-0.18%
Unknown	377	0.5	264	67	-0.22%

¹Small Entities include hospital-based and satellite facilities, and non-chain facilities based on DFC self-reported status.

²Includes American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and Virgin Islands.

b. Effects of the PY 2024 ESRD QIP on ESRD Facilities

For the PY 2024 ESRD QIP, we estimate that, of the 7,386 dialysis facilities (including those not receiving a TPS) enrolled in Medicare,

approximately 23.2 percent or 1,657 of the facilities that have sufficient data to calculate a TPS would receive a payment reduction for PY 2024. The total payment reductions for all the 1,657 facilities expected to receive a payment reduction is approximately

\$15,586,453.64. Facilities that do not receive a TPS do not receive a payment reduction.

Table 15 shows the overall estimated distribution of payment reductions resulting from the PY 2024 ESRD QIP.

TABLE 15: Estimated Distribution of PY 2024 ESRD QIP Payment Reductions

Payment Reduction	Number of Facilities	Percent of Facilities*
0.0%	5,490	76.82%
0.5%	1,215	17.00%
1.0%	336	4.70%
1.5%	65	0.91%
2.0%	41	0.57%

*239 facilities not scored due to insufficient data

To estimate whether a facility would receive a payment reduction in PY 2024, we scored each facility on achievement and improvement on several clinical measures we have previously finalized

and for which there were available data from CROWNWeb and Medicare claims. Payment reduction estimates were calculated using the most recent data available (specified in Table 15) in

accordance with the policies proposed in this proposed rule. Measures used for the simulation are shown in Table 16.

TABLE 16: Data Used to Estimate PY 2024 ESRD QIP Payment Reductions

Measure	Period of time used to calculate achievement thresholds, 50th percentiles of the national performance, benchmarks, and improvement thresholds	Performance period
ICH CAHPS Survey	Jan 2017-Dec 2017	Jan 2018-Dec 2018
SRR	Jan 2017-Dec 2017	Jan 2018-Dec 2018
SHR	Jan 2017-Dec 2017	Jan 2018-Dec 2018
PPPW	Jan 2017-Dec 2017	Jan 2018-Dec 2018
Kt/V Dialysis Adequacy Comprehensive	Jan 2017-Dec 2017	Jan 2018-Dec 2018
VAT		
Standardized Fistula Ratio	Jan 2017-Dec 2017	Jan 2018-Dec 2018
% Catheter	Jan 2017-Dec 2017	Jan 2018-Dec 2018
Hypercalcemia	Jan 2017-Dec 2017	Jan 2018-Dec 2018

For all measures except SHR, SRR, and STRR, measures with less than 11 patients for a facility were not included in that facility's TPS. For SHR and SRR, facilities were required to have at least 5 patient-years at risk and 11 index discharges, respectively, in order to be included in the facility's TPS. For the STRR reporting measure, facilities were required to have at least 10 patient-years at risk in order to be included in the facility's TPS. Each facility's TPS was compared to an estimated mTPS and an

estimated payment reduction table that incorporates the proposals outlined in section IV.B and IV.C of this proposed rule. Facility reporting measure scores were estimated using available data from CY 2018. Facilities were required to have at least one measure in at least two domains to receive a TPS.

To estimate the total payment reductions in PY 2024 for each facility resulting from this proposed rule, we multiplied the total Medicare payments to the facility during the 1-year period

between January 2018 and December 2018 by the facility's estimated payment reduction percentage expected under the ESRD QIP, yielding a total payment reduction amount for each facility.

Table 17 shows the estimated impact of the finalized ESRD QIP payment reductions to all ESRD facilities for PY 2024. The table details the distribution of ESRD facilities by size (both among facilities considered to be small entities and by number of treatments per facility), geography (both rural and

urban and by region), and by facility type (hospital based and freestanding facilities). Given that the performance

period used for these calculations differs from the performance period we are proposing to use for the PY 2024

ESRD QIP, the actual impact of the PY 2024 ESRD QIP may vary significantly from the values provided here.

TABLE 17: Estimated Impact of Proposed QIP Payment Reductions to ESRD Facilities for**PY 2024**

	Number of Facilities	Number of Treatments 2018 (in millions)	Number of Facilities with QIP Score	Number of Facilities Expected to Receive a Payment Reduction	Payment Reduction (percent change in total ESRD payments)
All Facilities	7,386	44.6	7,147	1,657	-0.15%
Facility Type:					
Freestanding	6,995	42.7	6,791	1,556	-0.15%
Hospital-based	391	1.9	356	101	-0.22%
Ownership Type:					
Large Dialysis	5,603	34.5	5,473	1,115	-0.12%
Regional Chain	927	5.7	897	241	-0.19%
Independent	512	2.9	488	216	-0.34%
Hospital-based (non-chain)	305	1.5	275	83	-0.24%
Unknown	39	0.0	14	2	-0.10%
Facility Size:					
Large Entities	6,530	40.2	6,370	1,356	-0.13%
Small Entities ¹	817	4.4	763	299	-0.30%
Unknown	39	0.0	14	2	-0.10%
Rural Status:					
1) Yes	1,285	6.5	1,239	138	-0.06%
2) No	6,101	38.2	5,908	1,519	-0.17%
Census Region:					
Northeast	1,004	6.9	974	213	-0.13%
Midwest	1,696	8.4	1,634	393	-0.16%
South	3,360	20.4	3,232	823	-0.16%
West	1,271	8.6	1,252	180	-0.08%
US Territories ²	55	0.4	55	48	-1.36%
Census Division:					
Unknown	8	0.1	8	2	-0.12%
East North Central	1,188	6.1	1,140	315	-0.19%
East South Central	587	3.3	578	131	-0.14%
Middle Atlantic	806	5.4	779	190	-0.15%
Mountain	409	2.3	404	52	-0.08%
New England	198	1.4	195	23	-0.06%
Pacific	862	6.3	848	128	-0.08%
South Atlantic	1,699	10.5	1,642	475	-0.19%
West North Central	508	2.2	494	78	-0.09%
West South Central	1,074	6.6	1,012	217	-0.13%
US Territories ²	47	0.3	47	46	-1.57%
Facility Size (# of total treatments)					
Less than 4,000 treatments	1,206	2.5	1,114	220	-0.15%
4,000-9,999 treatments	2,644	11.9	2,620	488	-0.11%
Over 10,000 treatments	3,159	29.8	3,149	882	-0.18%
Unknown	377	0.5	264	67	-0.22%

¹Small Entities include hospital-based and satellite facilities, and non-chain facilities based on DFC self-reported status.²Includes American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and Virgin Islands.

c. Effects on Other Providers

The ESRD QIP is applicable to dialysis facilities. We are aware that several of our measures impact other providers. For example, with the introduction of the SRR clinical measure in PY 2017 and the SHR clinical measure in PY 2020, we anticipate that hospitals may experience financial savings as dialysis facilities work to reduce the number of

unplanned readmissions and hospitalizations. We are exploring various methods to assess the impact these measures have on hospitals and other facilities, such as through the impacts of the Hospital Readmission Reduction Program and the Hospital-Acquired Conditions Reduction Program, and we intend to continue examining the interactions between our quality programs to the greatest extent feasible.

d. Effects on the Medicare Program

For PY 2024, we estimate that the ESRD QIP would contribute approximately \$15,586,453.64 in Medicare savings. For comparison, Table 18 shows the payment reductions that we estimate will be applied by the ESRD QIP from PY 2018 through PY 2024.

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TABLE 18: Estimated Payment Reductions Payment Years 2018 through 2024

Payment year	Estimated payment reductions
PY 2024	\$15,586,453.64
PY 2023	\$15,586,453.64
PY 2022	\$18,247,083.76 (84 FR 60794)
PY 2021	\$32,196,724 (83 FR 57062)
PY 2020	\$31,581,441 (81 FR 77960)
PY 2019	\$15,470,309 (80 FR 69074)
PY 2018	\$11,576,214 (79 FR 66257)

e. Effects on Medicare Beneficiaries

The ESRD QIP is applicable to dialysis facilities. Since the Program's inception, there is evidence on improved performance on ESRD QIP measures. As we stated in the CY 2018 ESRD PPS final rule, one objective measure we can examine to demonstrate the improved quality of care over time is the improvement of performance standards (82 FR 50795). As the ESRD QIP has refined its measure set and as facilities have gained experience with the measures included in the Program, performance standards have generally continued to rise. We view this as evidence that facility performance (and therefore the quality of care provided to Medicare beneficiaries) is objectively improving. We are in the process of

monitoring and evaluating trends in the quality and cost of care for patients under the ESRD QIP, incorporating both existing measures and new measures as they are implemented in the Program. We will provide additional information about the impact of the ESRD QIP on beneficiaries as we learn more. However, in future years we are interested in examining these impacts through the analysis of available data from our existing measures.

f. Alternatives Considered

In section IV.B.7 of this proposed rule, we are proposing that facilities selected to participate in the NHSN data validation study can submit a total of 20 records across two quarters. We considered retaining our current reporting requirement, under which

facilities must submit 20 records per quarter for each of the first two quarters of the CY, for a total of 40 records. However, we concluded that the reduction in patient records provides an adequate sample size for the validation. This approach would lower administrative costs and would reduce the burden on facilities.

C. Accounting Statement

As required by OMB Circular A-4 (available at <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf>), in Table 19, we have prepared an accounting statement showing the classification of the transfers and costs associated with the various provisions of this proposed rule.

TABLE 19: Accounting Statement: Classification of Estimated Transfers and Costs/Savings	
ESRD PPS and AKI (CY 2021)	
Category	Transfers
Annualized Monetized Transfers	\$150 million
From Whom to Whom	Federal government to ESRD providers
Category	Transfers
Increased Beneficiary Co-insurance Payments	\$40 million
From Whom to Whom	Beneficiaries to ESRD providers
ESRD QIP for PY 2023	
Category	Transfers
Annualized Monetized Transfers	-\$16 million
From Whom to Whom	Federal government to ESRD providers.
ESRD QIP for PY 2024	
Category	Transfers
Annualized Monetized Transfers	-\$16 million
From Whom to Whom	Federal government to ESRD providers

In accordance with the provisions of Executive Order 12866, this proposed rule was reviewed by the Office of Management and Budget.

D. Regulatory Flexibility Act Analysis (RFA)

The Regulatory Flexibility Act requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Approximately 11 percent of ESRD dialysis facilities are considered small entities according to the Small Business Administration's (SBA) size standards, which classifies small businesses as those dialysis facilities having total revenues of less than \$41.5 million in any 1 year. Individuals and states are not included in the definitions of a small entity. For more information on SBA's size standards, see the Small Business Administration's website at <http://www.sba.gov/content/small-business-size-standards> (Kidney Dialysis Centers are listed as 621492 with a size standard of \$41.5 million).

We do not believe ESRD facilities are operated by small government entities such as counties or towns with populations of 50,000 or less, and therefore, they are not enumerated or included in this estimated RFA analysis. Individuals and states are not included in the definition of a small entity.

For purposes of the RFA, we estimate that approximately 11 percent of ESRD facilities are small entities as that term

is used in the RFA (which includes small businesses, nonprofit organizations, and small governmental jurisdictions). This amount is based on the number of ESRD facilities shown in the ownership category in Table 10. Using the definitions in this ownership category, we consider 534 facilities that are independent and 299 facilities that are shown as hospital-based to be small entities. The ESRD facilities that are owned and operated by Large Dialysis Organizations (LDOs) and regional chains would have total revenues of more than \$41.5 million in any year when the total revenues for all locations are combined for each business (individual LDO or regional chain), and are not, therefore, included as small entities.

For the ESRD PPS updates proposed in this rule, a hospital-based ESRD facility (as defined by type of ownership, not by type of dialysis facility) is estimated to receive a 0.1 percent increase in payments for CY 2021. An independent facility (as defined by ownership type) is estimated to have no change in payments for CY 2021.

For AKI dialysis, we are unable to estimate whether patients would go to ESRD facilities, however, we have estimated there is a potential for \$56 million in payment for AKI dialysis treatments that could potentially be furnished in ESRD facilities.

For the ESRD QIP, we estimate that of the 1,657 ESRD facilities expected to receive a payment reduction as a result of their performance on the PY 2024 ESRD QIP, 817 are ESRD small entity facilities. We present these findings in

Table 15 ("Estimated Distribution of PY 2024 ESRD QIP Payment Reductions") and Table 17 ("Impact of Proposed QIP Payment Reductions to ESRD Facilities for PY 2024"). We estimate that the payment reductions would average approximately \$9,406.43 per facility across the 1,657 facilities receiving a payment reduction, and \$8,698.69 for each small entity facility. We also estimate that there are 817 small entity facilities in total, and that the aggregate ESRD PPS payments to these facilities would decrease 0.30 percent in CY 2022.

Therefore, the Secretary has determined that this proposed rule would not have a significant economic impact on a substantial number of small entities. The economic impact assessment is based on estimated Medicare payments (revenues) and HHS's practice in interpreting the RFA is to consider effects economically "significant" only if greater than 5 percent of providers reach a threshold of 3 to 5 percent or more of total revenue or total costs. We solicit comment on the RFA analysis provided.

In addition, section 1102(b) of the Act requires us to prepare a RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We do not believe this proposed rule would have a significant impact on operations of a substantial number of

small rural hospitals because most dialysis facilities are freestanding. While there are 127 rural hospital-based dialysis facilities, we do not know how many of them are based at hospitals with fewer than 100 beds. However, overall, the 127 rural hospital-based dialysis facilities would experience an estimated 0.3 percent decrease in payments.

Therefore, the Secretary has determined that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

E. Unfunded Mandates Reform Act Analysis (UMRA)

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2020, that threshold is approximately \$156 million. This proposed rule does not mandate any requirements for state, local, or tribal governments in the aggregate, or by the private sector. Moreover, HHS interprets UMRA as applying only to unfunded mandates. We do not interpret Medicare payment rules as being unfunded mandates, but simply as conditions for the receipt of payments from the federal government for providing services that meet federal standards. This interpretation applies whether the facilities or providers are private, state, local, or tribal.

F. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. We have reviewed this proposed rule under the threshold criteria of Executive Order 13132, Federalism, and have determined that it would not have substantial direct effects on the rights, roles, and responsibilities of states, local or Tribal governments.

G. Regulatory Reform Analysis Under Executive Order 13771

Executive Order 13771, entitled Reducing Regulation and Controlling Regulatory Costs (82 FR 9339), was issued on January 30, 2017. It has been determined that this is a transfer rule, which imposes no more than de minimis costs. As a result, this rule is not considered a regulatory or

deregulatory action under Executive Order 13771.

VIII. Files Available to the Public via the internet

The Addenda for the annual ESRD PPS proposed and final rulemakings will no longer appear in the Federal Register. Instead, the Addenda will be available only through the internet and is posted on the CMS website at http://www.cms.gov/ESRDPayment/PAY/list.asp. In addition to the Addenda, limited data set files are available for purchase at http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/EndStageRenalDiseaseSystemFile.html. Readers who experience any problems accessing the Addenda or LDS files, should contact ESRDPayment@cms.hhs.gov.

List of Subjects in 42 CFR Part 413

Diseases, Health facilities, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as follows:

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES; PAYMENT FOR ACUTE KIDNEY INJURY DIALYSIS

■ 1. The authority citation for part 413 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww.

■ 2. Section 413.232 is amended by—

- a. Revising paragraphs (b) introductory text, (b)(1), (e), and (g) introductory text; and
■ b. Adding paragraphs (g)(4) and (h).

The revisions and additions read as follows:

§ 413.232 Low-volume adjustment.

* * * * *

(b) A low-volume facility is an ESRD facility that, as determined based on the documentation submitted pursuant to paragraph (g) of this section:

- (1) Furnished less than 4,000 treatments in each of the 3 cost reporting years (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent, except as specified in paragraph (g)(4) of

this section) preceding the payment year; and

* * * * *

(e) Except as provided in paragraph (f) of this section and unless extraordinary circumstances justify an exception, to receive the low-volume adjustment an ESRD facility must provide an attestation statement, by November 1st of each year preceding the payment year, to its Medicare Administrative Contractor (MAC) that the facility meets all the criteria established in this section, except that:

- (1) For payment year 2012, the attestation must be provided by January 3, 2012;
(2) For payment year 2015, the attestation must be provided by December 31, 2014;
(3) For payment year 2016, the attestation must be provided by December 31, 2015; and
(4) For payment year 2021, the attestation must be provided by December 31, 2020.

* * * * *

(g) To receive the low-volume adjustment, an ESRD facility must include in their attestation provided pursuant to paragraph (e) of this section a statement that the ESRD facility meets the definition of a low-volume facility in paragraph (b) of this section. To determine eligibility for the low-volume adjustment, the MAC on behalf of CMS relies upon as filed or final settled 12-consecutive month cost reports, except as specified in paragraph (g)(4) of this section, for the 3 cost reporting years preceding the payment year to verify the number of treatments, except that:

* * * * *

(4) For payment years 2021, 2022, and 2023, the attestation specified in paragraph (e)(4) of this section must indicate that the ESRD facility meets all the criteria specified in this section, except that, for a facility that would not otherwise meet the number of treatments criterion specified in paragraph (b)(1) of this section because of the COVID-19 PHE, the facility may attest that it furnished less than 2,000 treatments in any six months during the cost-reporting period ending in 2020. For any facility that so attests—

(i) The facility must also attest that it furnished treatments equal to or in excess of 4,000 in the payment year due to temporary patient shifting as a result of the COVID-19 PHE; and

(ii) The MAC relies on the attestation and multiplies the total number of treatments for the 6 months period by 2.

(h) When an ESRD facility provides an attestation in accordance with paragraph (e) of this section, for the

third eligibility year, the MAC verifies the as-filed cost report and takes one of the following actions:

(1) If the MAC determines an ESRD facility meets the definition of a low-volume facility as described in paragraph (b) of this section, CMS adjusts the low-volume facility's base rate for the entire payment year; or

(2) If the MAC determines an ESRD facility does not meet the definition of a low-volume facility as described in paragraph (b) of this section, the MAC reprocesses claims and recoups low-volume adjustments paid during the payment year.

■ 3. Section 413.234 is amended by adding paragraph (f) to read as follows:

§ 413.234 Drug designation process.

* * * * *

(f) *Methodology for modifying the ESRD PPS base rate to account for the costs of calcimimetics in the ESRD PPS bundled payment.* Beginning January 1, 2021, payment for calcimimetics are included in the ESRD PPS base rate using the following data sources and methodology:

(1) The methodology specified in paragraph (f)(2) of this section for determining the average per treatment payment amount for calcimimetics that is added to the ESRD PPS base rate uses the following data sources:

(i) Total units of oral and injectable calcimimetics and total number of paid hemodialysis-equivalent dialysis treatments furnished, as derived from Medicare ESRD facility claims, that is, the 837-institutional form with bill type 072X, for calendar years 2018 and 2019.

(ii) The weighted average ASP based on the most recent determinations by CMS.

(2) CMS uses the following methodology to calculate the average per treatment payment amount for calcimimetics that is added to the ESRD PPS base rate:

(i) Determines utilization of oral and injectable calcimimetics by aggregating the total units of oral and injectable calcimimetics in paragraph (f)(1) of this section.

(ii) Determines a price for each form of the drug by calculating 100 percent of the values from the most recent calendar quarter ASP calculations available to the public for the oral and injectable calcimimetic.

(iii) Calculates the total calcimimetic expenditure amount by multiplying the utilization of the oral and injectable calcimimetics determined in paragraph (f)(2)(i) of this section by their respective prices determined in paragraph (f)(2)(ii) of this section and

adding the expenditure amount for both forms.

(iv) Calculates the average per treatment payment amount by dividing the total calcimimetic expenditure amount determined in paragraph (f)(2)(iii) of this section by the total number of paid hemodialysis-equivalent dialysis treatments in calendar years 2018 and 2019.

(v) Calculates the amount added to the ESRD PPS base rate by reducing the average per treatment payment amount determined in paragraph (f)(2)(iv) of this section by 1 percent to account for the outlier policy under § 413.237.

■ 4. Section 413.236 is amended by—

■ a. Revising paragraphs (a), (b) introductory text, (b)(2), (4) through (6), (c), (d) introductory text, and (d)(2); and

■ b. Adding paragraph (f).

The revisions and addition read as follows:

§ 413.236 Transitional add-on payment adjustment for new and innovative equipment and supplies.

(a) *Basis and definitions.* (1) Effective January 1, 2020, this section establishes an add-on payment adjustment to support ESRD facilities in the uptake of new and innovative renal dialysis equipment and supplies under the ESRD prospective payment system under the authority of section 1881(b)(14)(D)(iv) of the Social Security Act.

(2) For purposes of this section, the following definitions apply:

Capital-related asset. Asset that an ESRD facility has an economic interest in through ownership (regardless of the manner in which it was acquired) and is subject to depreciation. Equipment obtained by the ESRD facility through operating leases are not considered capital-related assets.

Depreciation. The amount that represents a portion of the capital-related asset's cost and that is allocable to a period of operation.

Home dialysis machines. Hemodialysis machines and peritoneal dialysis cyclers in their entirety, meaning that one new part of a machine does not make the entire capital-related asset new, that receive FDA marketing authorization for home use and when used in the home for a single patient.

Particular calendar year. The year in which the payment adjustment specified in paragraph (d) of this section would take effect.

Straight-line depreciation method. A method in accounting in which the annual allowance is determined by dividing the cost of the capital-related asset by the years of useful life.

Useful life. The estimated useful life of a capital-related asset is its expected

useful life to the ESRD facility, not necessarily the inherent useful or physical life.

(b) *Eligibility criteria.* CMS provides for a transitional add-on payment adjustment for new and innovative equipment and supplies (as specified in paragraph (d) of this section) to an ESRD facility for furnishing a covered equipment or supply only if the item:

* * * * *

(2) Is new, meaning within 3 years beginning on the date of the Food and Drug Administration (FDA) marketing authorization;

* * * * *

(4) Has a complete Healthcare Common Procedure Coding System (HCPCS) Level II code application submitted, in accordance with the HCPCS Level II coding procedures on the CMS website, by the HCPCS Level II code application deadline for biannual Coding Cycle 2 for durable medical equipment, orthotics, prosthetics and supplies (DMEPOS) and services as specified in the HCPCS Level II coding guidance on the CMS website prior to the particular calendar year;

(5) Is innovative, meaning it meets the criteria specified in § 412.87(b)(1) of this chapter; and

(6) Is not a capital-related asset, except for capital-related assets that are home dialysis machines.

(c) *Announcement of determinations and deadline for consideration of new renal dialysis equipment or supply applications.* CMS will consider whether a new renal dialysis supply or equipment meets the eligibility criteria specified in paragraph (b) of this section and announce the results in the **Federal Register** as part of its annual updates and changes to the ESRD prospective payment system. CMS will only consider a complete application received by CMS by February 1 prior to the particular calendar year. FDA marketing authorization for the equipment or supply must occur by the HCPCS Level II code application deadline for biannual Coding Cycle 2 for DMEPOS items and services as specified in the HCPCS Level II coding guidance on the CMS website prior to the particular calendar year.

(d) *Transitional add-on payment adjustment for new and innovative equipment and supplies.* A new and innovative renal dialysis equipment or supply will be paid for using a transitional add-on payment adjustment for new and innovative equipment and supplies based on 65 percent of the MAC-determined price, as specified in paragraph (e) of this section. For capital-related assets that are home dialysis

machines, payment is based on 65 percent of the pre-adjusted per treatment amount, as specified in paragraph (f)(1)(ii) of this section.

* * * * *

(2) Following payment of the transitional add-on payment adjustment for new and innovative equipment and supplies, the ESRD PPS base rate will not be modified and the new and innovative renal dialysis equipment or supply will be an eligible outlier service as provided in § 413.237, except a capital-related asset that is a home dialysis machine will not be an eligible outlier service as provided in § 413.237.

* * * * *

(f) *Pricing of new and innovative renal dialysis equipment and supplies that are capital-related assets that are home dialysis machines.* (1) The MACs calculate a pre-adjusted per treatment amount, using the prices they establish under paragraph (e) of this section for a capital-related asset that is a home dialysis machine, as defined in

paragraph (a)(2) of this section, as follows:

(i) Calculate an annual allowance to determine the amount that represents the portion of the cost allocable to 1 year for use in calculating the pre-adjusted per treatment amount, using the straight-line depreciation method, by dividing the MAC-determined price by its useful life of 5 years.

(ii) Calculate a pre-adjusted per treatment amount to determine the amount that is adjusted by the 65 percent under paragraph (d) of this section, by dividing the annual allowance, as determined in paragraph (f)(1)(i) of this section, by the expected number of treatments.

(2) [Reserved]

■ 5. Section 413.237 is amended—

■ a. In paragraphs (a)(1)(i) through (iii) by removing the semicolon at the end of the sentence and adding a period in its place;

■ b. In paragraph (a)(1)(iv) by removing “; and” and adding a period in its place; and

■ c. By revising paragraph (a)(1)(v).

The revision reads as follows:

§ 413.237 Outliers.

(a) * * *

(1) * * *

(v) Renal dialysis equipment and supplies, except for capital-related assets that are home dialysis machines (as defined in § 413.236(a)(2)), that receive the transitional add-on payment adjustment as specified in § 413.236, after the payment period has ended.

* * * * *

Dated: June 12, 2020.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: June 19, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2020-14671 Filed 7-6-20; 4:15 pm]

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Part IV

Environmental Protection Agency

40 CFR Part 121

Clean Water Act Section 401 Certification Rule; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 121

[EPA-HQ-OW-2019-0405; FRL-10009-80-OW]

RIN 2040-AF86

Clean Water Act Section 401 Certification Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is publishing this final rule to update and clarify the substantive and procedural requirements for water quality certification under Clean Water Act (CWA or the Act) section 401. CWA section 401 is a direct grant of authority to States (and Tribes that have been approved for “treatment as a State” status) to review for compliance with appropriate federal, State, and Tribal water quality requirements any discharge into a water of the United States that may result from a proposed activity that requires a federal license or permit. This final rule is intended to increase the predictability and timeliness of CWA section 401 certification actions by clarifying timeframes for certification, the scope of certification review and conditions, and related certification requirements and procedures.

DATES: This rule is effective on September 11, 2020.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA-HQ-OW-2019-0405, at <https://www.regulations.gov>. All documents in the docket are listed and available at <https://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g. Confidential Business Information or other information whose disclosure is restricted by statute. Certain other materials, 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: Lauren Kasparek, Oceans, Wetlands, and Communities Division, Office of Water (4504-T), Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone number: (202) 564-5700; email address: cwa401@epa.gov.

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I. General Information

A. How can I get copies of this document and related information?

1. *Docket.* An official public docket for this action has been established under Docket ID No. EPA-HQ-OW-2019-0405. The official public docket consists of the documents specifically referenced in this action, and other information related to this action. The official public docket is the collection of materials that is available for public viewing at the OW Docket, EPA West, Room 3334, 1301 Constitution Ave. NW, Washington, DC 20004. This Docket Facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The OW Docket telephone number is 202-566-2426. A reasonable fee will be charged for copies.

2. *Electronic Access.* You may access this **Federal Register** document electronically under the “**Federal Register**” listings at <https://www.regulations.gov>. An electronic version of the public docket is available through the EPA’s electronic public docket and comment system, the EPA Dockets. You may access the EPA Dockets at <https://www.regulations.gov> to view submitted public comments, access the index listing of the contents of the official public docket, and access those documents in the public docket that are available electronically. For additional information about the EPA’s public docket, visit the EPA Docket Center homepage at <http://www.epa.gov/epahome/dockets.htm>. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the Docket Facility.

B. What action is the Agency taking?

In this notice, the Agency is publishing a final rule updating the water quality certification regulations in 40 CFR 121.

C. Under what legal authority is this final rule issued?

The authority for this action is the Federal Water Pollution Control Act, 33 U.S.C. 1251 *et seq.*, including sections 304(h), 401, and 501(a).

II. Background

A. Executive Summary

Congress enacted section 401 of the CWA to provide States and authorized Tribes with an important tool to help

protect the water quality of federally regulated waters within their borders in collaboration with federal agencies. Under section 401, a federal agency may not issue a license or permit to conduct any activity that may result in any discharge into waters of the United States,¹ unless the State or authorized Tribe where the discharge would originate either issues a section 401 water quality certification finding compliance with applicable water quality requirements or certification is waived. As described in greater detail below, section 401 envisions a robust State and Tribal role in the federal licensing or permitting proceedings, including those in which local authority may otherwise be preempted by federal law. Section 401 also places important limitations on how that role may be implemented to maintain an efficient process, consistent with the overall cooperative federalism construct established by the CWA, as explained below in section II.F.1 of this notice.

Section 401 provides that a State or authorized Tribe must act on a section 401 certification request “within a reasonable period of time (which shall not exceed one year).”² Section 401 does not guarantee a State or Tribe a full year to act on a certification request, as the statute only grants as much time as is reasonable. 33 U.S.C. 1341(a)(1). The CWA provides that the timeline for action on a section 401 certification begins “after receipt” of a certification request. *Id.* If a State or Tribe does not grant, grant with conditions, deny, or expressly waive the section 401 certification within a reasonable time period, section 401 states that the “the certification requirements of this subsection shall be waived with respect to such Federal application.” *Id.* If the certification requirement has been waived and the federal license or permit is issued, any subsequent action by a State or Tribe to grant, grant with

conditions, or deny section 401 certification has no legal force or effect.

Section 401 authorizes States and Tribes to certify that a discharge into waters of the United States that may result from a proposed activity will comply with certain enumerated sections of the CWA, including the effluent limitations and standards of performance for new and existing discharge sources (sections 301, 302, and 306 of the CWA), water quality standards and implementation plans (section 303), and toxic pretreatment effluent standards (section 307). When granting a section 401 certification, States and Tribes are directed by CWA section 401(d) to include conditions, including “effluent limitations and other limitations, and monitoring requirements” that are necessary to assure that the applicant for a federal license or permit will comply with applicable provisions of CWA sections 301, 302, 306, and 307, and with “any other appropriate requirement of State law.”

As the Agency charged with administering the CWA,³ as well as a certifying authority in certain instances, the EPA is responsible for developing a common regulatory framework for certifying authorities to follow when completing section 401 certifications. See 33 U.S.C. 1251(d), 1361(a). In 1971, the EPA promulgated regulations for implementing the certification provisions pursuant to section 21(b) of the Federal Water Pollution Control Act of 1948 (FWPCA), but the EPA has never updated those regulations to reflect the 1972 amendments to the FWPCA (commonly known as the Clean Water Act or CWA), which created section 401, despite the fact that there were changes to the relevant statutory text. Since the 1972 CWA amendments, the EPA issued two guidance documents and participated as amicus curiae in court cases concerning CWA section 401, but the Agency has not updated its regulations to comport with the 1972 amendments and has not, to date, established robust internal procedures for implementing its roles under section 401. Over the last several years, litigation over the section 401 certifications for several high-profile infrastructure projects have highlighted the need for the EPA to update its regulations to provide a common framework for consistency with CWA section 401 and to give project proponents, certifying authorities, and federal licensing and permitting

agencies additional clarity and regulatory certainty.

On April 10, 2019, the President issued Executive Order 13868, entitled *Promoting Energy Infrastructure and Economic Growth* (the Executive Order or Order), which directed the EPA to engage with States, Tribes, and federal agencies and update the Agency’s outdated guidance and regulations, including the 1971 certification framework. Pursuant to the Executive Order, on August 8, 2019, the EPA signed the proposed rule “Updating Regulations on Water Quality Certifications,” and the proposal was published on August 22, 2019. 84 FR 44080. The 60-day public comment period for the proposal closed on October 21, 2019. Consistent with Executive Order 13868 and the 1972 CWA amendments, this final rule provides an updated common framework that is consistent with the Act and which seeks to increase predictability and timeliness.

The following sections provide an overview of section 401, relevant court cases, outreach, and other actions that inform today’s rule, as well as provides responses to salient comments received on these topics.

B. Executive Order 13868: Promoting Energy Infrastructure and Economic Growth

The policy objective of the Executive Order is to encourage greater investment in energy infrastructure in the United States by promoting efficient federal licensing and permitting processes and reducing regulatory uncertainty. The Executive Order identified the EPA’s outdated section 401 federal guidance and regulations as one source of confusion and uncertainty hindering the development of energy infrastructure.

Several commenters on the proposed rule argued that the EPA failed to demonstrate that the rule would meet the objectives of the Executive Order and the CWA, and they maintained that Presidential policy objectives cannot override the CWA’s plain language and Supreme Court jurisprudence. One commenter stated that the EPA’s actions under this Executive Order were driven by political considerations and the desire to undertake the rulemaking process as expeditiously as possible to meet the President’s purportedly unlawful directions as stated in the Executive Order.

Other commenters asserted that the proposed rule is consistent with the Executive Order. These commenters appreciated the administration’s recognition of the importance of energy infrastructure projects; the

¹ The CWA, including section 401, uses “navigable waters,” defined as “waters of the United States, including territorial seas.” 33 U.S.C. 1362(7). This final rule uses “waters of the United States” throughout. In January 2020, the EPA revised the definition of waters of the United States and expects the final definition of the term to control in all CWA contexts. See 85 FR 22250 (April 21, 2020).

² In some circumstances, the EPA can act as the certifying authority. See section III.H of this notice for further discussion. “If the State, interstate agency, or Administrator, as the case may be, fails or refuses to act on a request for certification, within a reasonable period of time (which shall not exceed one year) after receipt of such request, the certification requirements of this subsection shall be waived with respect to such Federal application.” 33 U.S.C. 1341(a)(1); see also *Hoopa Valley Tribe v. FERC*, 913 F.3d 1099 (D.C. Cir. 2019).

³ The EPA co-administers section 404 with the Army Corps of Engineers (the Corps).

administration's recognition of the economic impact the section 401 process has had on some important energy infrastructure projects; and the EPA's review of the section 401 process. Such commenters supported the Executive Order's goal of promoting economic growth and supported the proposed rule's attempts to protect interstate and foreign commerce from unconstitutional discrimination and unreasonable burdens and to clearly define the steps and timing for section 401 certifications.

As discussed throughout this final rule preamble, the Agency has determined that the final rule implements the fundamental statutory objectives of the CWA, while also complying with the Executive Order. The Agency disagrees with commenters who asserted that the rulemaking process was inappropriately initiated or inappropriately directed by the Executive Order. As noted above, the EPA's 1971 certification regulations⁴ (36 FR 22487, Nov. 25, 1971; redesignated at 37 FR 21441, October 11, 1972; further redesignated at 44 FR 32899, June 7, 1979) had not been updated since they were promulgated in 1971, pursuant to section 21(b) of the FWPCA. Additionally, at the time the Executive Order was issued, the EPA's only guidance to the public on section 401 implementation was an interim handbook (now rescinded) entitled *Clean Water Act Section 401 Water Quality Certification: A Water Quality Protection Tool for States and Tribes* ("Interim Handbook"), which had not been updated since its release in 2010 and therefore did not reflect the current case law interpreting CWA section 401.

The Executive Order directed the EPA to review CWA section 401 and the EPA's 1971 certification regulations and interim guidance, issue new guidance to States, Tribes, and federal agencies within 60 days of the Order, and propose (as appropriate and consistent with law) new section 401 regulations within 120 days of the Order. The Executive Order also directed the EPA to consult with States, Tribes, and relevant federal agencies while reviewing its existing guidance and regulations to identify areas that would benefit from greater clarity.

As part of this review, the Executive Order directed the EPA to take into

account the federalism considerations underlying section 401 and to consider the appropriate scope of water quality reviews and conditions, the scope of information needed to act on a certification request in a reasonable period of time, and expectations for reasonable certification review times. Section 3.a. of Executive Order 13868, *Promoting Energy Infrastructure and Economic Growth*. Following the release of the EPA's new guidance document, the Executive Order directed the EPA to lead an interagency review of all existing federal regulations and guidance pertaining to section 401 to ensure consistency with the EPA's new guidance and rulemaking efforts. The Executive Order directs all federal agencies to update their existing section 401 guidance within 90 days after publication of the EPA's new guidance. Additionally, the Executive Order directs other federal agencies to initiate rulemaking, if necessary, within 90 days of the completion of the EPA's rulemaking, to ensure that their own CWA section 401 regulations are consistent with the EPA's new rules and with the Executive Order's policy goals. Although the Executive Order focuses on section 401's impact on the energy sector, section 401 applies broadly to any proposed federally licensed or permitted activity that may result in any discharge into a water of the United States. Therefore, updates to the EPA's 1971 certification regulations and guidance are relevant to all water quality certifications, not just those related to energy sector projects.

Additional information on the EPA's State and Tribal engagement is provided in section II.C of this notice, and additional information on the EPA's updated guidance document is provided in section II.D of this notice.

C. Summary of Stakeholder Engagement

On June 11, 2018, the Agency published its 2018 Spring Unified Agenda of Regulatory and Deregulatory Actions⁵ announcing that the Agency was considering, as a long-term action, the issuance of a notice soliciting public comment on whether the section 401 certification process would benefit from a rulemaking to promote nationwide consistency and regulatory certainty for States, authorized Tribes, and stakeholders. The Agency's stakeholder outreach and engagement efforts since that announcement are summarized below.

On August 6, 2018, the Agency sent a letter to the Environmental Council of

the States, the Association of Clean Water Administrators, the Association of State Wetland Managers, the National Tribal Water Council, and the National Tribal Caucus identifying the Agency's interest in engaging in potential clarifications to the section 401 process. The Agency discussed section 401 during several association meetings and calls and received correspondence from several stakeholders between Fall 2018 and Spring 2019. Early stakeholder feedback received prior to the issuance of the Executive Order, the August 6, 2018 letter described above, and the Agency's presentations given between Fall 2018 and Spring 2019, may be found in the pre-proposal recommendations docket (Docket ID No. EPA-HQ-OW-2018-0855).

Following release of the Executive Order, the EPA continued its effort to engage with States and Tribes on how to increase clarity in the section 401 certification process, including creating a new website to provide information on section 401 and notifying State environmental commissioners and Tribal environmental directors of a two-part webinar series for States and Tribes. See www.epa.gov/cwa-401. The first webinar was held on April 17, 2019, and discussed the Executive Order and the EPA's next steps, and solicited feedback from States and Tribes consistent with the Executive Order. Shortly thereafter, the EPA initiated formal consultation efforts under Executive Order 13132 on Federalism with States and Executive Order 13175 on Consultation and Coordination with Indian Tribal Governments regarding provisions that require clarification within section 401 of the CWA and related federal regulations and guidance. The Agency held an initial federalism consultation meeting on April 23, 2019, and sent notification of the consultation period to States and Tribes on April 24, 2019. Consultation ran through May 24, 2019, and the EPA opened a docket for pre-proposal recommendations during this time period (Docket ID No. EPA-HQ-OW-2018-0855). On May 7, 2019, and May 15, 2019, the EPA held Tribal informational webinars, and on May 8, 2019, the EPA held an informational webinar for both States and Tribes. See sections V.F and V.G of this notice for further details on the Agency's federalism and Tribal consultations. Questions and recommendations from the webinar attendees are available in the pre-proposal docket (Docket ID No. EPA-HQ-OW-2018-0855).

During the consultation period, the EPA participated in phone calls and in-person meetings with inter-

⁴ These regulations were redesignated in 1972 and 1979 under the CWA, but no substantive change to the regulatory text has been made since 1971 notwithstanding changes to the relevant statutory text in the 1972 CWA. Therefore, throughout this final rule preamble, the Agency refers to these regulatory provisions as the "1971 certification regulations."

⁵ Available at <https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201804&RIN=2040-AF86>.

governmental and Tribal associations, including the National Governors Association and National Tribal Water Council. The EPA also attended the EPA Region 9 Regional Tribal Operations Committee meeting on May 22, 2019, to solicit recommendations for the rulemaking effort. The EPA engaged with federal agencies that issue licenses or permits subject to section 401, including the United States Department of Agriculture, the Federal Energy Regulatory Commission (FERC), the U.S. Army Corps of Engineers (Corps), the Alcohol and Tobacco Tax and Trade Bureau, the Nuclear Regulatory Commission, and the Bureau of Reclamation through several meetings and phone calls to gain additional feedback from federal partners.

At the webinars and meetings, the EPA provided a presentation and sought input on aspects of section 401 and the 1971 certification regulations that may benefit from clarification or require updating, including timeframe, scope of certification review, and coordination among certifying authorities, federal licensing or permitting agencies, and project proponents. The EPA also requested input on issues and process improvements for the Agency's consideration. Participant recommendations from webinars, meetings, and the docket represent a diverse range of interests, positions, and suggestions. Several themes emerged throughout this process, including support for ongoing State and Tribal engagement, support for retention of State and Tribal authority, and suggestions for process improvements for CWA section 401 water quality certifications. The EPA considered all of this information and stakeholder input during development of the proposed rule, including all recommendations submitted to the pre-proposal docket and feedback received prior to the initiation of, during, and after the formal consultation period.

On August 8, 2019, the EPA signed the proposed rule, "Updating Regulations on Water Quality Certifications," and the proposal was published on August 22, 2019. 84 FR 44080. The 60-day public comment period for the proposal closed on October 21, 2019. After signing the proposed rule, the EPA conducted a variety of stakeholder outreach engagements on the contents of the proposed rule. For example, on August 20, 2019, the EPA held a public webcast to present key elements of the proposed rule (see <https://www.youtube.com/watch?v=eBI7Mj5ucyM&feature=youtu.be>). The EPA also held a public hearing in Salt Lake City, Utah,

on September 5 and 6, 2019, to hear feedback from individuals from regulated industry sectors, environmental and conservation organizations, State agencies, Tribal governments, and private citizens. The EPA continued its engagement throughout the public comment period with States and Tribes through in-person meetings with representatives in Salt Lake City, Utah, and Chicago, Illinois. During these meetings, the Agency provided an overview of the proposed rule, responded to clarifying questions from participants, discussed implementation considerations, and heard comments reflecting a range of positions on the proposal and varying interpretations of CWA section 401. A transcript of the public hearing and related materials and summaries of the State and Tribal meetings can be found in the docket for the final rule. At the request of individual Tribes, the EPA also held staff-level and leader-to-leader meetings with those Tribes.

A few commenters commended the EPA for its outreach efforts during the rule development process. Other commenters asserted that the EPA held an abbreviated public engagement process. Some commenters asserted that the EPA's consultation efforts with States, Tribes and local governments during the rulemaking process were inadequate. The Agency disagrees with commenters that its consultation with States or Tribes was inadequate. As discussed in section II.C, section V.F, and section V.G of this notice, the Agency consulted with States, Tribes, and local governments throughout the rulemaking process. See also the Agency's response to comments document in the docket for this final rule for further response on the Agency's outreach efforts.

In developing the final rule, the EPA reviewed and considered more than 125,000 comments on the proposed rule from a broad spectrum of interested parties. Commenters provided a wide range of feedback on various aspects of the proposal, including the legal basis for the proposed rule and the Agency's proposed definitions and certification procedures. Commenters also explained their views on how the proposal may impact project proponents, certifying authorities, and federal licensing and permitting agencies. The Agency summarizes the most salient public comments received on the proposed rule and provides responses in the applicable sections of this final rule preamble. A separate response to comments document is also available in the docket for the final rule at Docket ID No. EPA-HQ-OW-2019-0405.

D. Guidance Document

Pursuant to the Executive Order, the Agency released updated section 401 guidance on June 7, 2019 ("the 2019 Guidance"), available at <https://www.epa.gov/cwa-401/clean-water-act-section-401-guidance-federal-agencies-states-and-authorized-tribes>. Coincident with the release of the 2019 Guidance, the EPA rescinded the 2010 Interim Handbook on section 401 water quality certification. The Interim Handbook had not been updated or revised since its release in 2010, had never been finalized, and did not reflect current case law interpreting CWA section 401.

The 2019 Guidance provided information and recommendations for implementing the substantive and procedural requirements of section 401, consistent with the areas of focus in the Executive Order. More specifically, the 2019 Guidance focused on aspects of the certification process, including the timeline for review and decision-making and the appropriate scope of review and conditions. Additionally, the 2019 Guidance provided recommendations for how federal licensing and permitting agencies, States, and Tribes can better coordinate to improve the section 401 certification process. The emphasis on early coordination and collaboration to increase process efficiency aligns with other agency directives under Executive Order 13807, *Establishing Discipline and Accountability in the Environmental Review and Permitting Process for Infrastructure Projects*, which established the "One Federal Decision" policy. For major infrastructure projects, Executive Order 13807 directs federal agencies to use a single, coordinated process for compliance with the National Environmental Policy Act (NEPA), 42 U.S.C. 4321 *et seq.*, and emphasizes advance coordination to streamline federal permitting actions.

Some commenters asserted the 2019 Guidance is inconsistent with 50 years of practice and that it created confusion and uncertainty. Other commenters disagreed with the 2019 Guidance's limitations on timing of section 401 certifications and the scope of information that States may require to fully evaluate section 401 certification requests. Several commenters stated that the 2019 Guidance was inappropriately issued prior to rulemaking and should be withdrawn, and they asserted that either the Interim Handbook should be reinstated or the 2019 Guidance should be modified. Some commenters suggested that the issuance of the 2019 Guidance before rule finalization indicates that the EPA has

predetermined the outcome of the rulemaking process, contrary to the Administrative Procedure Act (APA), and therefore that the guidance should be rescinded or superseded by new guidance consistent with the final rule.

The Agency disagrees with commenters who asserted that the 2019 Guidance was unnecessary. As discussed above and as outlined in the Executive Order, the Interim Handbook created regulatory uncertainty and confusion because it no longer reflected the current case law interpreting CWA section 401, nor had it been updated or finalized. The 2019 Guidance was intended only to facilitate consistent implementation of section 401 and the 1971 certification regulations during this rulemaking process, and the Agency disagrees with commenters who suggested the 2019 Guidance reflected a predetermined outcome of this rulemaking process. The 2019 Guidance addressed the appropriate timeline for a State's or Tribe's review and section 401 certification decision-making and the appropriate scope of a State's or Tribe's certification review and conditions based on the EPA's 1971 certification regulations. The final rule, on the other hand, is based on the Agency's holistic review of the 1972 statutory language, addresses a number of additional topics, and reflects and responds to public comments.

Some commenters said the 2019 Guidance should be retained but updated once the proposed rule is finalized. Other commenters stated the 2019 Guidance should be withdrawn once the proposed rule is finalized. One commenter asserted that additional guidance may be appropriate, but that the need for guidance depends on the degree of clarity in the final rule.

Coincident with issuing this final rule, the EPA is rescinding the 2019 Guidance. The EPA continues to support and encourage the extent of coordination recommended in the 2019 Guidance, including recommendations for project proponents, certifying authorities, and federal licensing and permitting authorities to engage in substantive discussions as early as possible, and for all parties to operate in good faith throughout the certification process. However, the EPA has concluded that retaining the 2019 Guidance after issuing this final rule could cause confusion. The Agency has determined that the final rule provides sufficient additional specificity and clarity on the issues discussed in the 2019 Guidance to both meet the expectations of the Executive Order and render the 2019 Guidance unnecessary. The EPA retains the option to develop

new guidance to facilitate implementation of this final rule should the need arise.

E. Effect on Existing Federal, State, and Tribal Laws

According to the Executive Order, the EPA is to lead an interagency effort to review and examine existing federal guidance and regulations "for consistency with EPA guidance and rulemaking." Section 3.d. of the Executive Order provides that, within 90 days after the EPA issues its final section 401 regulations, "if necessary, the heads of each 401 implementing Agency shall initiate a rulemaking to ensure that their respective agencies' regulations are consistent with" the EPA's final section 401 regulations and "the policies set forth in section 2 of [the Executive Order]." Pursuant to the Executive Order, the other federal agencies that issue licenses or permits subject to the certification requirements of section 401 are expected to ensure that any regulations governing their own processing, disposition, and enforcement of section 401 certifications are consistent with the EPA's final regulations and the policies articulated in section 2 of the Executive Order. The EPA engaged with other section 401 implementing agencies before and after the proposed rule was issued, and the EPA considered federal agency feedback in developing the proposal and this final rule. This final rule preamble includes suggested recommendations for federal agencies as they update or draft their section 401 implementing regulations. For instance, section III.F.2.a of this notice encourages federal agencies to establish in their regulations a minimum reasonable period of time for State and Tribal action to provide notice and regulatory certainty to project proponents and certifying authorities about applicable deadlines. However, these are only recommendations and the federal agencies themselves must determine how to update their own regulations to ensure consistency with this final rule and efficient administration of their license and permit programs. For its part, the EPA plans to review its National Pollutant Discharge Elimination System (NPDES) regulations to ensure its own permitting program certification regulations are consistent with this final rule.

In addition to conforming changes that federal agencies may make to federal regulations that implement section 401, it is likely that States and Tribes will want to evaluate their existing certification statutes or

regulations to ensure consistency with the EPA's final rule.

Certain commenters stated that the proposed rule would not be consistent with existing State law, such as State statutes or regulations regarding notice and comment, completeness, impact and degradation avoidance, and mitigation. Many of these commenters were particularly concerned that existing State-enacted procedures require more information and time for State certification review and action than provided by the proposed rule. A few commenters challenged the EPA's authority to dictate State procedures and stated that the EPA should provide flexibility for State regulatory procedures in this rulemaking. Several commenters maintained that the proposed rule would require statutory and regulatory changes on the State level and encouraged the EPA to give States sufficient time to adapt by providing an extended effective date for the new rule. One commenter asserted that if States were not provided additional time to assess the new rule's impact on their State laws and regulations, the new rule could require the States to either violate their own laws or deny more section 401 certifications, which could result in litigation and further delay for projects subject to section 401.

Several commenters asserted that the proposed rule would make State and Tribal section 401 programs less efficient and would lead to national inconsistency. Several commenters asserted that the EPA's interpretation of the CWA and case law will result in legal challenges to the final rule, which would in turn lead to confusion and delays in its implementation contrary to the intent of the Executive Order. Several commenters also indicated that because States may need to change their statutes and regulations in response to the final rule, litigation will ensue over those State changes resulting in further regulatory uncertainty, defeating the intent of the proposal to make the section 401 process more efficient.

The EPA has considered and appreciates the concerns raised by these commenters and is mindful that the lack of clear federal guidance and implementation of CWA section 401 following enactment of the 1972 CWA amendments has resulted in a patchwork of State and Tribal programs with different timing, request, and review requirements for water quality certifications. However, the EPA's decades-long delay in promulgating section 401 implementing regulations does not undercut the EPA's authority and obligation to promulgate

implementing regulations for this important CWA program. The EPA's delay in promulgating regulations also does not change the 1972 CWA amendment's statutory language or underlying congressional intent, nor does it allow for States or Tribes to implement water quality certification programs that exceed the authority granted by Congress.

The EPA acknowledges that some States and Tribes may update their regulations to be consistent with the procedural and substantive elements of this final rule. Regulatory consistency across federal, State, and Tribal governments with respect to issues like timing, waiver, and scope of section 401 reviews and conditions would help ensure that section 401 is implemented nationally in an efficient, effective, and transparent manner. Although such updates may have an initial burden on certifying authorities, they will ultimately result in more efficient certification and federal permitting processes. The Agency will face a similar task in updating its own NPDES regulations after this final rule is published, but will similarly benefit from more efficient, effective and transparent certification processes under updated regulations. Making the rule effective 30 days after publication in the **Federal Register** would be consistent with applicable law; however, the Agency is establishing the effective date 60 days after publication of the final rule in the **Federal Register**. This additional time will allow EPA to develop implementation materials for States, Tribes and federal agencies, as necessary or appropriate. The Agency stands ready to provide technical assistance to States, Tribes, and federal agencies seeking to update their certification procedures, guidance or regulations.

By promulgating these long-overdue regulations, it is not the EPA's intent that States or Tribes violate either federal, State, or Tribal law pending completion of updates to applicable State or Tribal law. The Agency is aware that most if not all States have emergency rulemaking authorities that may help avoid such outcomes. Furthermore, as States and Tribes enact conforming changes to their existing laws, pursuant to section 401(b), the EPA remains ready and willing to provide any necessary technical assistance.

A few commenters supporting the proposed rule acknowledged the EPA's desire to preserve State sovereignty and principles of cooperative federalism while at the same time creating greater national consistency in both federal and

State regulations implementing section 401. One commenter observed that the proposed rule would make the regulations consistent with the intent of the 1972 CWA amendments while allowing the States to retain their primary roles in the section 401 water quality certification process. Some commenters stated the current regulations have allowed States to impose conditions beyond the appropriate scope set forth in the statute, leading to lengthy delays in the certification process and resulting in a certification process that is ill-defined, confusing in scope, and lacking clear deadlines. A number of commenters asserted that the proposed rule would promote regulatory certainty, help streamline the federal permitting process for critical infrastructure development, enhance the ability of project proponents to plan for construction, and facilitate early and constructive engagement between project proponents, States or authorized Tribes, and federal agencies to ensure that proposed projects will be protective of local water quality.

The EPA acknowledges that although many certifications reflect an appropriately limited interpretation of the purpose and scope of section 401 and are issued without controversy, some certifying authorities have implemented water quality certification programs that exceed the boundaries set by Congress in section 401. After considering all of the comments received, the Agency has made several changes, described further below, to provide greater clarity and regulatory certainty in the final rule.

F. Legal Background

This final rule concludes the EPA's first comprehensive effort to promulgate federal rules governing the implementation of CWA section 401. The Agency's 1971 water quality certification regulations pre-dated the 1972 CWA amendments. This final rule therefore provides the EPA's first holistic analysis of the statutory text, legislative history,⁶ and relevant case law informing the implementation of the CWA section 401 program by the Agency and its federal, State, and Tribal partners. The final rule, while focused on the relevant statutory provisions and case law interpreting those provisions, is informed by the Agency's expertise developed over nearly 50 years of

⁶ The EPA observes that some legislative history related to section 401 is internally inconsistent. When interpreting section 401 for purposes of this rulemaking, the Agency has generally accorded such inconsistent and ambiguous legislative history less weight.

implementing the CWA and policy considerations where necessary to address certain ambiguities in the statutory text. The following sections describe the basic operational construct and history of the 1972 CWA amendments, how section 401 fits within that construct, and certain core administrative and legal principles that provide the foundation for this final rule.

1. The Clean Water Act

Congress amended the CWA⁷ in 1972 to address longstanding concerns regarding the quality of the nation's waters and the federal government's ability to address those concerns under existing law. Prior to 1972, responsibility for controlling and redressing water pollution in the nation's waters largely fell to the Corps under the Rivers and Harbors Act of 1899 (RHA). While much of that statute focused on restricting obstructions to navigation on the nation's major waterways, section 13 of the RHA made it unlawful to discharge refuse "into any navigable water of the United States, or into any tributary of any navigable water from which the same shall float or be washed into such navigable water."⁸ 33 U.S.C. 407. Congress had also enacted the Water Pollution Control Act of 1948, Public Law 80-845, 62 Stat. 1155 (June 30, 1948), to address interstate water pollution, and subsequently amended that statute in 1956 (giving the statute its current formal name), in 1961, and in 1965. The early versions of the CWA promoted the development of pollution abatement programs, required States to develop water quality standards, and authorized the federal government to bring enforcement actions to abate water pollution.

These earlier statutory frameworks, however, proved challenging for regulators, who often worked backwards from an overly-polluted waterway to determine which dischargers and which sources of pollution may be responsible. See *EPA v. State Water Resources Control Bd.*, 426 U.S. 200, 204 (1976). In fact, Congress determined that the prior

⁷ The FWPCA has been commonly referred to as the CWA following the 1977 amendments to the FWPCA. Public Law 95-217, 91 Stat. 1566 (1977). For ease of reference, the Agency will generally refer to the FWPCA in this notice as the CWA or the Act.

⁸ The term "navigable water of the United States" is a term of art used to refer to a water subject to federal jurisdiction under the RHA. See, e.g., 33 CFR 329.1. The term is not synonymous with the phrase "waters of the United States" under the CWA, see *id.*, and the general term "navigable waters" has different meanings depending on the context of the statute in which it is used. See, e.g., *PPL Montana, LLC v. Montana*, 132 S. Ct. 1215, 1228 (2012).

statutes were inadequate to address the decline in the quality of the nation's waters, see *City of Milwaukee v. Illinois*, 451 U.S. 304, 310 (1981), so Congress performed a “total restructuring” and “complete rewriting” of the existing statutory framework of the Act in 1972, *id.* at 317 (quoting legislative history of 1972 amendments). That restructuring resulted in the enactment of a comprehensive scheme designed to prevent, reduce, and eliminate pollution in the nation's waters generally, and to regulate the discharge of pollutants into waters of the United States specifically. See, e.g., *S.D. Warren Co. v. Maine Bd. of Env'tl. Prot.*, 547 U.S. 370, 385 (2006) (“[T]he Act does not stop at controlling the ‘addition of pollutants,’ but deals with ‘pollution’ generally[.]”).

The objective of the new statutory scheme was “to restore and maintain the chemical, physical, and biological integrity of the Nation's waters.” 33 U.S.C. 1251(a). In order to meet that objective, Congress declared two national goals: (1) “that the discharge of pollutants into the navigable waters be eliminated by 1985;” and (2) “that wherever attainable, an interim goal of water quality which provides for the protection and propagation of fish, shellfish, and wildlife and provides for recreation in and on the water be achieved by July 1, 1983” *Id.* at 1251(a)(1)–(2).

Congress established several key policies that direct the work of the Agency to effectuate those goals. For example, Congress declared as a national policy “that the discharge of toxic pollutants in toxic amounts be prohibited; . . . that Federal financial assistance be provided to construct publicly owned waste treatment works; . . . that areawide waste treatment management planning processes be developed and implemented to assure adequate control of sources of pollutants in each State; . . . [and] that programs for the control of nonpoint sources of pollution be developed and implemented in an expeditious manner so as to enable the goals of this Act to be met through the control of both point and nonpoint sources of pollution.” *Id.* at 1251(a)(3)–(7).

Congress provided a major role for the States in implementing the CWA, balancing the traditional power of States to regulate land and water resources within their borders with the need for a national water quality regulation. For example, the statute highlighted “the policy of the Congress to recognize, preserve, and protect the primary responsibilities and rights of States to prevent, reduce, and eliminate pollution” and “to plan the

development and use . . . of land and water resources” *Id.* at 1251(b). Congress also declared as a national policy that States manage the major construction grant program and implement the core permitting programs authorized by the statute, among other responsibilities. *Id.* Congress added that “[e]xcept as expressly provided in this Act, nothing in this Act shall . . . be construed as impairing or in any manner affecting any right or jurisdiction of the States with respect to the waters (including boundary waters) of such States.” *Id.* at 1370.⁹ Congress also pledged to provide technical support and financial aid to the States “in connection with the prevention, reduction, and elimination of pollution.” *Id.* at 1251(b).

To carry out these policies, Congress broadly defined “pollution” to mean “the man-made or man-induced alteration of the chemical, physical, biological, and radiological integrity of water,” *id.* at 1362(19), to parallel the broad objective of the Act “to restore and maintain the chemical, physical, and biological integrity of the Nation's waters.” *Id.* at 1251(a). Congress then crafted a non-regulatory statutory framework to provide technical and financial assistance to the States to prevent, reduce, and eliminate pollution in the nation's waters generally. See, e.g., *id.* at 1256(a) (authorizing the EPA to issue “grants to States and to interstate agencies to assist them in administering programs for the prevention, reduction, and elimination of pollution”); see also 84 FR 56626, 56632 (Oct. 22, 2019) (discussing non-regulatory program provisions); 85 FR 22250, 22253 (April 21, 2020) (same).

In addition to the Act's non-regulatory measures to control pollution of the nation's waters, Congress created a federal regulatory program designed to address the discharge of pollutants into a subset of those waters identified as “the waters of the United States.” See 33 U.S.C. 1362(7). Section 301 contains the key regulatory mechanism: “Except as in compliance with this section and sections 302, 306, 307, 318, 402, and 404 of this Act, the discharge of any pollutant by any person shall be unlawful.” *Id.* at 1311(a). A “discharge of a pollutant” is defined to include “any addition of any pollutant to navigable waters from any point source,” such as a pipe, ditch or other “discernible, confined and discrete conveyance.” *Id.* at 1362(12), (14). The

⁹ 33 U.S.C. 1370 also prohibits states with EPA-approved CWA programs from adopting any limitations, prohibitions, or standards that are less stringent than required by the CWA.

term “pollutant” means “dredged spoil, solid waste, incinerator residue, sewage, garbage, sewage sludge, munitions, chemical wastes, biological materials, radioactive materials, heat, wrecked or discarded equipment, rock, sand, cellar dirt and industrial, municipal, and agricultural waste discharged into water.” *Id.* at 1362(6). Thus, it is unlawful to discharge pollutants into waters of the United States from a point source unless the discharge is in compliance with certain enumerated sections of the CWA, including by obtaining authorizations pursuant to the section 402 NPDES permit program or the section 404 dredged or fill material permit program. See *id.* at 1342, 1344. Congress therefore intended to achieve the Act's objective “to restore and maintain the chemical, physical, and biological integrity of the Nation's waters” by addressing pollution of all waters via non-regulatory means and federally regulating the discharge of pollutants to the subset of waters identified as “navigable waters.”¹⁰

Within the regulatory programs established by the Act, two principal components focus on “achieving maximum ‘effluent limitations’ on ‘point sources,’ as well as achieving acceptable water quality standards,” and the development of the NPDES permitting program that imposes specific discharge limitations for regulated entities. *EPA v. State Water Resources Control Bd.*, 426 U.S. at 204. Together these components provide a framework for the Agency to focus on

¹⁰ Fundamental principles of statutory interpretation support the Agency's recognition of a distinction between “nation's waters” and “navigable waters.” As the Supreme Court has observed, “[w]e assume that Congress used two terms because it intended each term to have a particular, nonsuperfluous meaning.” *Bailey v. United States*, 516 U.S. 137, 146 (1995) (recognizing the canon of statutory construction against superfluity). Further, “the words of a statute must be read in their context and with a view to their place in the overall statutory scheme.” *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000) (internal quotation marks and citation omitted); see also *United Savings Ass'n v. Timbers of Inwood Forest Associates*, 484 U.S. 365, 371 (“Statutory construction . . . is a holistic endeavor. A provision that may seem ambiguous in isolation is often clarified by the remainder of the statutory scheme—because the same terminology is used elsewhere in a context that makes its meaning clear[.]”) (citation omitted). The non-regulatory sections of the CWA reveal Congress' intent to restore and maintain the integrity of the nation's waters using federal assistance to support state and local partnerships to control pollution in the nation's waters in addition to a federal regulatory prohibition on the discharge of pollutants into the navigable waters. If Congress intended the terms to be synonymous, it would have used identical terminology. Instead, Congress chose to use separate terms, and the Agency is instructed by the Supreme Court to presume Congress did so intentionally. For further discussion, see 84 FR at 56632 and 85 FR at 22253.

reducing or eliminating discharges while creating accountability for each regulated entity that discharges into a waterbody, facilitating greater enforcement and overall achievement of the CWA water quality goals. *Id.*; see *Oregon Natural Desert Association v. Dombeck*, 172 F.3d 1092, 1096 (9th Cir. 1998) (observing that 1972 amendments “largely supplanted” earlier versions of CWA “by replacing water quality standards with point source effluent limitations”).

Under this statutory scheme, the States¹¹ are authorized to assume program authority for issuing section 402 and 404 permits within their borders, subject to certain limitations. 33 U.S.C. 1342(b), 1344(g). States are also responsible for developing water quality standards for “waters of the United States” within their borders and reporting on the condition of those waters to the EPA every two years. *Id.* at 1313, 1315. States must develop total maximum daily loads (TMDLs) for waters that are not meeting established CWA water quality standards and must submit those TMDLs to the EPA for approval. *Id.* at 1313(d). And, central to this final rule, States under CWA section 401 have authority to grant, grant with conditions, deny, or waive water quality certifications for every federal license or permit issued within their borders that may result in a discharge into waters of the United States. *Id.* at 1341. These same regulatory authorities can be assumed by Indian Tribes under section 518 of the CWA, which authorizes the EPA to treat eligible Tribes with reservations in a similar manner to States (referred to as “treatment as States” or TAS) for a variety of purposes, including administering the principal CWA regulatory programs. *Id.* at 1377(e). In addition, States and Tribes retain authority to protect and manage the use of those waters that are not waters of the United States under the CWA. See, e.g., *id.* at 1251(b), 1251(g), 1370, 1377(a).

In enacting section 401, Congress recognized that where States and Tribes do not have direct permitting authority (because they do not have section 402 or 404 program authorization or where Congress has preempted a regulatory field, e.g., under the Federal Power Act), they may still play a valuable role in protecting the water quality of federally regulated waters within their borders in collaboration with federal agencies.

Under section 401, a federal agency may not issue a license or permit for an activity that may result in a discharge into waters of the United States, unless the appropriate authority provides a section 401 certification or waives its ability to do so. The authority to certify a federal license or permit lies with the agency (the certifying authority) that has jurisdiction over the location of the discharge to the receiving water of the United States. *Id.* at 1341(a)(1). Examples of federal licenses or permits potentially subject to section 401 certification include, but are not limited to, CWA section 402 NPDES permits in States where the EPA administers the permitting program; CWA section 404 and RHA sections 9 and 10 permits issued by the Corps; bridge permits issued by the U.S. Coast Guard (USCG); and hydropower and pipeline licenses issued by the Federal Energy Regulatory Commission (FERC).

Under section 401, a certifying authority may grant, grant with conditions, deny, or waive certification in response to a request from a project proponent. The certifying authority determines whether the potential discharge from the proposed activity will comply with the applicable provisions of sections 301, 302, 303, 306, and 307 of the CWA and any other appropriate requirement of state law. *Id.* Certifying authorities may also add to a certification “any effluent limitations and other limitations, and monitoring requirements” necessary to assure compliance. *Id.* at 1341(d). These additional provisions must become conditions of the federal license or permit should it be issued. *Id.* A certifying authority may deny certification if it is unable to determine that the discharge from the proposed activity will comply with the applicable sections of the CWA and appropriate requirements of state law. If a certifying authority denies certification, the federal license or permit may not be issued. *Id.* at 1341(a)(1). A certifying authority may waive certification by “fail[ing] or refus[ing] to act on a request for certification, within a reasonable period of time (which shall not exceed one year) after receipt of such request.” *Id.*

With the exception of section 401, the EPA has promulgated regulatory programs designed to ensure that the CWA is implemented as Congress intended in the 1972 CWA.¹² This includes pursuing the overall

“objective” of the CWA to “restore and maintain the chemical, physical, and biological integrity of the Nation’s waters,” *id.* at 1251(a), while implementing the specific “policy” directives from Congress to, among other things, “recognize, preserve, and protect the primary responsibilities and rights of States to prevent, reduce, and eliminate pollution” and “to plan the development and use . . . of land and water resources.” *Id.* at 1251(b); see also *Webster’s II, New Riverside University Dictionary* (1994) (defining “policy” as a “plan or course of action, as of a government[,] designed to influence and determine decisions and actions;” an “objective” is “something worked toward or aspired to: Goal”). The Agency therefore recognizes a distinction between the specific word choices of Congress, which reflect the need to develop regulatory programs that aim to accomplish the goals of the Act while implementing the specific policy directives of Congress. For further discussion of these principles, see 84 FR 56638–39 and 85 FR at 22269–70.

Congress’ authority to regulate navigable waters, including waters subject to CWA section 401 water quality certification, derives from its power to regulate the “channels of interstate commerce” under the Commerce Clause. *Gibbons v. Ogden*, 22 U.S. (9 Wheat.) 1 (1824); see also *United States v. Lopez*, 514 U.S. 549, 558–59 (1995) (describing the “channels of interstate commerce” as one of three areas of congressional authority under the Commerce Clause). The Supreme Court explained in *Solid Waste Agency of Northern Cook County v. U.S. Army Corps of Engineers (SWANCC)* that the term “navigable” indicates “what Congress had in mind as its authority for enacting the Clean Water Act: Its traditional jurisdiction over waters that were or had been navigable in fact or which could reasonably be so made.” 531 U.S. 159, 172 (2001). The Court further explained that nothing in the legislative history of the Act provides any indication that “Congress intended to exert anything more than its commerce power over navigation.” *Id.* at 168 n.3. The Supreme Court, however, has recognized that Congress intended “to exercise its powers under the Commerce Clause to regulate at least some waters that would not be deemed ‘navigable’ under the classical understanding of that term.” *United States v. Riverside Bayview Homes*, 474 U.S. 121, 133 (1985); see also *SWANCC*, 531 U.S. at 167.

¹¹ The CWA defines “state” as “a State, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, and the Trust Territory of the Pacific Islands.” 33 U.S.C. 1362(3).

¹² As noted in section II.F.3 of this notice, the EPA’s 1971 certification regulations were promulgated prior to the 1972 CWA Amendments and had not been updated to reflect the current statutory text until this final rule was developed.

The classical understanding of the term navigable was first articulated by the Supreme Court in *The Daniel Ball*:

Those rivers must be regarded as public navigable rivers in law which are navigable in fact. And they are navigable in fact when they are used, or are susceptible of being used, in their ordinary condition, as highways of commerce, over which trade and travel are or may be conducted in the customary modes of trade and travel on water. And they constitute navigable waters of the United States within the meaning of the Acts of Congress, in contradistinction from the navigable waters of the States, when they form in their ordinary condition by themselves, or by uniting with other waters, a continued highway over which commerce is or may be carried on with other States or foreign countries in the customary modes in which such commerce is conducted by water.

77 U.S. (10 Wall.) 557, 563 (1871). Over the years, this traditional test has been expanded to include waters that had been used in the past for interstate commerce, see *Economy Light & Power Co. v. United States*, 256 U.S. 113, 123 (1921), and waters that are susceptible for use with reasonable improvement, see *United States v. Appalachian Elec. Power Co.*, 311 U.S. 377, 407–10 (1940).

By the time the 1972 CWA amendments were enacted, the Supreme Court had held that Congress' authority over the channels of interstate commerce was not limited to regulation of the channels themselves but could extend to activities necessary to protect the channels. See *Oklahoma ex rel. Phillips v. Guy F. Atkinson Co.*, 313 U.S. 508, 523 (1941) ("Congress may exercise its control over the non-navigable stretches of a river in order to preserve or promote commerce on the navigable portions."). The Supreme Court also had clarified that Congress could regulate waterways that formed a part of a channel of interstate commerce, even if they are not themselves navigable or do not cross State boundaries. See *Utah v. United States*, 403 U.S. 9, 11 (1971). Congress therefore intended to assert federal regulatory authority over more than just waters traditionally understood as navigable, while rooting that authority in "its commerce power over navigation." *SWANCC*, 531 U.S. at 168 n.3.

The EPA recognizes and respects the primary responsibilities and rights of States to regulate their land and water resources, as reflected in CWA section 101(b). 33 U.S.C. 1251(b), see also *id.* at 1370. The oft-quoted objective of the CWA to "restore and maintain the chemical, physical, and biological integrity of the Nation's waters," *id.* at 1251(a), must be implemented in a manner consistent with Congress' policy directives. The Supreme Court long ago

recognized the distinction between waters subject to federal authority, traditionally understood as navigable, and those waters "subject to the control of the States." *The Daniel Ball*, 77 U.S. (10 Wall.) 557, 564–65 (1870). Over a century later, the Supreme Court in *SWANCC* reaffirmed the States' "traditional and primary power over land and water use." 531 U.S. at 174. Ensuring that States retain authority over their land and water resources helps carry out the overall objective of the CWA and ensures that the Agency is giving full effect and consideration to the entire structure and function of the Act. See, e.g., *Hibbs v. Winn*, 542 U.S. 88, 101 (2004) ("A statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant.") (citation omitted); see also *Rapanos v. United States*, 547 U.S. 715, 755–56 (2006) (Scalia, J., plurality) ("[C]lean water is not the *only* purpose of the statute. So is the preservation of primary state responsibility for ordinary land-use decisions. 33 U.S.C. 1251(b).") (original emphasis).

In summary, Congress relied on its authority under the Commerce Clause when it enacted the CWA and intended to assert federal authority over more than just waters traditionally understood as navigable, but it limited the exercise of that authority to "its commerce power over navigation." *SWANCC*, 531 U.S. at 168 n.3. The Court in *SWANCC* found that "[r]ather than expressing a desire to readjust the federal-state balance [in a manner that would result in a significant impingement of the States' traditional and primary power over land and water use], Congress chose [in the CWA] to 'recognize, preserve, and protect the primary responsibilities and rights of States . . . to plan the development and use . . . of land and water resources . . .'" *Id.* at 174 (quoting 33 U.S.C. 1251(b)). The Court found no clear statement from Congress that it had intended to permit federal encroachment on traditional State power and construed the CWA to avoid the significant constitutional questions related to the scope of federal authority authorized therein. *Id.* at 173–74. That is because the Supreme Court has instructed that "[w]here an administrative interpretation of a statute invokes the outer limits of Congress' power, we expect a clear indication that Congress intended that result." *Id.* at 172. The Court has further stated that this is particularly true "where the administrative interpretation alters the federal-state framework by permitting

federal encroachment upon a traditional state power." *Id.* at 173; see also *Will v. Michigan Dept. of State Police*, 491 U.S. 58, 65 (1989) ("[I]f Congress intends to alter the 'usual constitutional balance between the States and the Federal Government,' it must make its intention to do so 'unmistakably clear in the language of the statute.'" (quoting *Atascadero State Hospital v. Scanlon*, 473 U.S. 234, 242 (1985)); *Gregory v. Ashcroft*, 501 U.S. 452, 461 (1991) ("[The] plain statement rule . . . acknowledg[es] that the States retain substantial sovereign powers under our constitutional scheme, powers with which Congress does not readily interfere"). This means that the executive branch's authority under the CWA, while broad, is not unlimited, and the waters to which CWA regulatory programs apply must necessarily respect those limits. For further discussion of these principles, see 84 FR 56655 and 85 FR at 22264. See section II.F.6 of this final rule preamble for a summary of public comments and Agency responses on interstate commerce.

In some cases, CWA section 401 denials have been challenged on grounds that the denial improperly interfered with interstate commerce. See, e.g., *Lighthouse Resources, Inc. v. Inslee*, No. 3:18-cv-5005, Complaint at ¶¶ 206–210; ¶¶ 224–248 (W.D. Wash. filed Jan. 8, 2018) (alleging that State's denial of section 401 certification violated dormant Commerce Clause and dormant foreign Commerce Clause). In *Lake Carriers Association v. EPA*, 652 F.3d 1 (D.C. Cir. 2011), the court of appeals found that the section 401 statutory scheme of delegation of authority to States, by itself, does not create an impermissible burden on interstate commerce; however, the court signaled that certain actions taken by States pursuant to section 401 could be subject to dormant Commerce Clause challenges. 652 F.3d at 10 ("If [petitioners] believe that the certification conditions imposed by any particular state pose an inordinate burden on their operations, they may challenge those conditions in that state's courts. If [petitioners] believe that a particular state's law imposes an unconstitutional burden on interstate commerce, they may challenge that law in federal (or state) court.").

2. The EPA's Role in Implementing Section 401

The EPA, as the federal agency charged with administering the CWA, is responsible for developing regulations and guidance to ensure effective implementation of all CWA programs,

including section 401.¹³ In addition to administering the statute and promulgating implementing regulations, the Agency has several other roles under section 401.

The EPA acts as the section 401 certification authority under two circumstances. First, the EPA will certify on behalf of a State or Tribe where the jurisdiction in which the discharge will originate does not itself have certification authority. 33 U.S.C. 1341(a)(1). In practice, this results in the EPA certifying on behalf of the many Tribes that do not have TAS authority for section 401. Second, the EPA will act as the certifying authority where the discharge would originate on lands of exclusive federal jurisdiction.¹⁴

The EPA also notifies neighboring jurisdictions when the Administrator determines that a discharge may affect the quality of such jurisdictions' waters. *Id.* at 1341(a)(2). Although section 401 certification authority lies with the jurisdiction where the discharge originates, a neighboring jurisdiction whose water quality is potentially affected by the discharge may have an opportunity to raise objections to a certification issued for a federal license or permit. Where the EPA Administrator determines that a discharge subject to section 401 "may affect" the water quality of a neighboring jurisdiction, the EPA is required to notify that other jurisdiction. *Id.* If the neighboring jurisdiction determines that the discharge "will affect" the quality of its waters in violation of a water quality requirement of that jurisdiction, it may notify the EPA and the federal licensing or permitting agency of its objection to the license or permit. *Id.* It may also request a hearing on its objection with the federal licensing or permitting agency. At such a hearing, section 401

requires the EPA to submit its evaluation and recommendations with respect to the objection. The federal agency will consider the jurisdiction's and the EPA's recommendations, and any additional evidence presented at the hearing, and "shall condition such license or permit in such manner as may be necessary to insure compliance with the applicable water quality requirements" of the neighboring jurisdiction. *Id.* If the conditions cannot ensure compliance, the federal agency shall not issue the license or permit.

The EPA also must provide technical assistance for section 401 certifications upon the request of any federal or State agency or project proponent. *Id.* at 1341(b). Technical assistance might include provision of any relevant information on or comment on methods to comply with applicable effluent limitations, standards, regulations, requirements, or water quality standards.

Finally, the EPA is responsible for developing regulations and guidance to ensure effective implementation of all CWA programs, including section 401. Legislative history indicates that Congress created the water quality certification requirement to "recognize[] the responsibility of Federal agencies to protect water quality whenever their activities affect public waterways." S. Rep. No. 91-351, at 3 (1969). "In the past, these [Federal] licenses and permits have been granted without any assurance that the [water quality] standards will be met or even considered." *Id.* As an example, the legislative history discusses the Atomic Energy Commission's failure to consider the impact of thermal pollution on receiving waters when evaluating "site selection, construction, and design or operation of nuclear powerplants." *Id.*

The certification requirement first appeared in section 21(b) of the FWPCA, and it required States to certify that "such activity will be conducted in a manner which will not violate applicable water quality standards." Public Law 91-224, 21(b)(1), 84 Stat. 91 (1970) (emphasis added). As described above, the 1972 amendments restructured the CWA and created a framework for compliance with effluent limitations that would be established in discharge permits issued pursuant to the new federal permitting program. The pre-existing water quality certification requirement was retained in section 401 of the 1972 amendments but modified to be consistent with the overall restructuring of the CWA. The new section 401 required a water quality certification to assure that the "discharge will comply" with effluent

limitations and other enumerated regulatory provisions of the Act. 33 U.S.C. 1341(a) (emphasis added). The 1972 amendments also established a new section 401(d), which provides that certifications "shall set forth any effluent limitations and other limitations, and monitoring requirements necessary to assure" compliance with the same enumerated CWA provisions and with "any other appropriate requirement" of State or Tribal law. 33 U.S.C. 1341(d).

The EPA first promulgated water quality certification regulations in 1971 to implement section 21(b) of the FWPCA.¹⁵ Some operative provisions of the EPA's 1971 certification regulations contain language from section 21(b) of the FWPCA that Congress changed in the 1972 amendments. For example, the EPA's 1971 certification regulations directed authorities to certify that "the activity will be conducted in a manner which will not violate applicable water quality standards." 40 CFR 121.2(a)(2)-(3) (emphasis added). These outdated provisions do not reflect the language of section 401 (as discussed elsewhere in this preamble) and have caused confusion for States, Tribes, stakeholders, and courts reviewing section 401 certifications. In section 304(h) of the CWA, Congress commanded the EPA to promulgate certification guidelines within 180 days of enactment of the 1972 amendments. See 33 U.S.C. 1314(h) (directing EPA to "promulgate," by April 1973, "guidelines establishing test procedures for the analysis of pollutants that shall include the factors which must be provided in any certification pursuant to section 401 of this Act"). Yet the EPA has not updated its certification regulations to conform with the 1972 amendments until now. A primary goal for this final rule is to update and clarify the Agency's regulations to ensure that they are consistent with the CWA.

3. The EPA's 1971 Certification Regulations

The EPA's 1971 certification regulations required certifying authorities to act on a certification request within a "reasonable period of time." 40 CFR 121.16(b). The regulations provided that the federal licensing or permitting agency

¹³ See 33 U.S.C. 1251(d) ("Except as otherwise expressly provided in this chapter, the Administrator of the Environmental Protection Agency . . . shall administer this chapter."); *id.* at 1361(a); *Mayo Found. for Medical Educ. and Res. v. United States*, 562 U.S. 44, 45 (2011); *Hoopa Valley Tribe v. FERC*, 913 F.3d 1099, 1104 (D.C. Cir. 2019); *Ala. Rivers Alliance v. FERC*, 325 F.3d 290, 296-97 (D.C. Cir. 2003); *Cal. Trout v. FERC*, 313 F.3d 1131, 1133 (9th Cir. 2002); *Am. Rivers, Inc. v. FERC*, 129 F. 3d 99, 107 (2d Cir. 1997).

¹⁴ The federal government may obtain exclusive federal jurisdiction over lands in multiple ways, including where the federal government purchases lands consistent with article 1, section 8, clause 17 of the U.S. Constitution and a state chooses to cede jurisdiction to the federal government, or where the federal government reserved jurisdiction upon granting statehood. See *Collins v. Yosemite Park Co.*, 304 U.S. 518, 529-30 (1938); *James v. Dravo Contracting Co.*, 302 U.S. 134, 141-42 (1937); *Surplus Trading Co. v. Cook*, 281 U.S. 647, 650-52 (1930); *Fort Leavenworth Railroad Co. v. Lowe*, 114 U.S. 525, 527 (1895). Examples of lands of exclusive federal jurisdiction include Denali National Park.

¹⁵ The EPA's 1971 certification regulations were located at 40 CFR part 121. The EPA has also promulgated regulations addressing how 401 certification applies to the CWA section 402 NPDES program, found at 40 CFR 124.53, 124.54, 124.55. See 48 FR 14264 (Apr. 1, 1983). This final rule does not address the NPDES regulations, and the Agency will make any necessary conforming regulatory changes in a subsequent rulemaking.

determines what constitutes a “reasonable period,” and that the period shall generally be six months but in any event shall not exceed one year. *Id.*

The 1971 certification regulations also provided that certifying authorities may waive the certification requirement under two circumstances: First, when the certifying authority sends written notification expressly waiving its authority to act on a request for certification; and second, when the federal licensing or permitting agency sends written notification to the EPA Regional Administrator that the certifying authority failed to act on a certification request within a reasonable period of time after receipt of such a request. *Id.* at 121.16(a)–(b). Once waiver occurs, certification is not required, and the federal license or permit may be issued. 33 U.S.C. 1341(a).

The 1971 certification regulations established different requirements that applied when the EPA was the certifying authority, including specific information that must be included in a certification request and additional procedures. Under these requirements, the project proponent was required to submit to the EPA Regional Administrator the name and address of the project proponent, a description of the facility or activity and of any related discharge into waters of the United States, a description of the function and operation of wastewater treatment equipment, dates on which the activity and associated discharge would begin and end, and a description of the methods to be used to monitor the quality and characteristics of the discharge. 40 CFR 121.22. Once the request was submitted to the EPA, the Regional Administrator was required to provide public notice of the request and an opportunity to comment, specifically stating that “all interested and affected parties will be given reasonable opportunity to present evidence and testimony at a public hearing on the question whether to grant or deny certification if the Regional Administrator determines that such a hearing is necessary or appropriate.” *Id.* at 121.23. If, after consideration of relevant information, the Regional Administrator determined that there is “reasonable assurance that the proposed activity will not result in a violation of applicable water quality standards,” the Regional Administrator would issue the certification.¹⁶ *Id.* at 121.24.

¹⁶ Use of the terms “reasonable assurance” and “activity” in this operative provision of the EPA’s 1971 certification regulations was consistent with section 21(b) of the pre-1972 statutory language. However, those terms are not used in the operative provision of CWA section 401, which replaced the

The 1971 certification regulations identified a number of requirements that all certifying authorities must include in a section 401 certification. *Id.* at 121.2. For example, the regulations provided that a section 401 certification shall include the name and address of the project proponent. *Id.* at 121.2(a)(2). They also provided that the certification shall include a statement that the certifying authority examined the application made by the project proponent to the federal licensing or permitting agency and bases its certification upon an evaluation of the application materials which are relevant to water quality considerations or that it examined other information sufficient to permit the certifying authority to make a statement that there is a “reasonable assurance that the activity will be conducted in a manner which will not violate applicable water quality standards.” *Id.* at 121.2(a)(2)–(3). Finally, the regulations provided that the certification shall state “any conditions which the certifying agency deems necessary or desirable with respect to the discharge of the activity,” and other information that the certifying authority deems appropriate.¹⁷ *Id.* at 121.2(a)(4)–(5).

The 1971 certification regulations also established a process for the EPA to provide notification to neighboring jurisdictions in a manner that is similar to that provided in CWA section 401(a)(2). Under the 1971 certification regulations, the Regional Administrator was required to review the federal license or permit application, the certification, and any supplemental information provided to the EPA by the federal licensing or permitting agency, and if the Regional Administrator determined that there was “reason to believe that a discharge may affect the quality of the waters of any State or States other than the State in which the discharge originates,” the Regional Administrator would notify each affected State within thirty days of receipt of the application materials and certification. *Id.* at 121.13. If the documents provided were insufficient to make the determination, the Regional Administrator could request any supplemental information “as may be required to make the determination.” *Id.* at 121.12. In cases where the federal licensing or permitting agency held a public hearing on the objection raised by a neighboring jurisdiction, notice of such objection was required to be

pre-1972 language. See Public Law 91–224, 21(b)(1), 84 Stat. 91 (1970).

¹⁷ The term “desirable” is also not used in CWA section 401.

forwarded to the Regional Administrator by the licensing or permitting agency no later than 30 days prior to the hearing. *Id.* at 121.15. At the hearing, the Regional Administrator was required to submit an evaluation and “recommendations as to whether and under what conditions the license or permit should be issued.” *Id.*

The 1971 certification regulations established that the Regional Administrator “may, and upon request shall” provide federal licensing and permitting agencies with information regarding water quality standards and advise them as to the status of compliance by dischargers with the conditions and requirements of applicable water quality standards. *Id.* at 121.30.

Finally, the 1971 certification regulations established an oversight role for the EPA when a certifying authority modified a prior certification. The regulation provided that a certifying authority could modify its certification “in such manner as may be agreed upon by the certifying agency, the licensing or permitting agency, and the Regional Administrator.” *Id.* at 121.2(b) (emphasis added).

As noted throughout this final rule preamble, the EPA’s 1971 certification regulations were promulgated prior to the 1972 CWA amendments and in many respects do not reflect the current statutory language in section 401. In addition, the EPA’s 1971 certification regulations do not address some important procedural and substantive components of section 401 certification review and action. This final rule is intended to modernize the EPA’s regulations, align them with the current text and structure of the CWA, and provide additional regulatory procedures that the Agency believes will help promote consistent implementation of section 401 and streamline federal license and permit processes, consistent with the objectives of the Executive Order.

4. Judicial Interpretations of Section 401

During the 48 years since its passage, the federal courts on numerous occasions have interpreted key provisions of section 401. The United States Supreme Court has twice addressed questions related to the scope and triggering mechanism of section 401, and lower courts also have addressed certain elements of section 401 certifications. This section of the preamble summarizes the U.S. Supreme Court decisions and major lower court decisions.

a. U.S. Supreme Court Decisions

i. PUD No. 1 of Jefferson County

In 1994, the Supreme Court reviewed a water quality certification issued by the State of Washington for a new hydroelectric project on the Dosewallips River. See *PUD No. 1 of Jefferson County v. Washington Dep't of Ecology*, 511 U.S. 700 (1994) (*PUD No. 1*). This particular decision, though narrow in its holding, has been read by other courts as well as the EPA (in past years) and some States and Tribes to significantly broaden the scope of section 401 beyond its plain meaning.

The principal dispute adjudicated in *PUD No. 1* was whether a State or Tribe may require a minimum stream flow as a condition in a certification issued under section 401. In this case, the project proponent identified two potential discharges from its proposed hydroelectric facility: “the release of dredged and fill material during construction of the project, and the discharge of water at the end of the tailrace after the water has been used to generate electricity.” 511 U.S. at 711. The project proponent argued that the minimum stream flow condition was unrelated to these discharges and therefore beyond the scope of the State’s authority under section 401. *Id.*

The Court analyzed sections 401(a) and 401(d); specifically, it analyzed the use of different terms in those sections of the statute to inform the scope of a section 401 certification. Section 401(a) requires the certifying authority to certify that the discharge from a proposed federally licensed or permitted project will comply with enumerated CWA provisions, and section 401(d) allows the certifying authority to include conditions to assure that the applicant will comply with enumerated CWA provisions and “any other appropriate” state law requirements.” 511 U.S. at 700. Emphasizing that the text of section 401(d) “refers to the compliance of the applicant, not the discharge,” the Court concluded that section 401(d) “is most reasonably read as authorizing additional conditions and limitations on the activity as a whole once the threshold condition, the existence of a discharge, is satisfied.” *Id.* at 712.

The Court then concluded that this interpretation of the statute was consistent with the EPA’s 1971 certification regulations, to which the Court accorded *Chevron* deference.¹⁸ The Court favorably quoted the EPA’s

1971 certification regulations at 40 CFR 121.2(a)(3); quoted the EPA’s guidance titled *Wetlands and 401 Certification*; and stated that “EPA’s conclusion that activities—not merely discharges—must comply with state water quality standards is a reasonable interpretation of § 401 and is entitled to deference.” 511 U.S. at 712 (citing, *inter alia*, *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984)).

The Court was careful to note that a State’s authority to condition a certification “is not unbounded” and that States “can only ensure that the project complies with ‘any applicable effluent limitations and other limitations, under [33 U.S.C. 1311, 1312] or certain other provisions of the Act, and with any other appropriate requirement of State Law.’” 511 U.S. at 712. The Court concluded that “state water quality standards adopted pursuant to § 303 are among the ‘other limitations’ with which a State may ensure compliance through the § 401 certification process” and noted that its view “is consistent with EPA’s view of the statute,” again citing the EPA’s pre-1972 regulations and subsequent guidance. *Id.* at 713.

Although *PUD No. 1* has been interpreted broadly by some to expand State authority under section 401—beyond assessing water quality impacts from the discharge, so as to allow conditions beyond the enumerated CWA provisions—the Court did not stray from the bedrock principles that a section 401 certification must address water quality and that appropriate conditions include those necessary to assure compliance with the State’s water quality standards. Indeed, referring to the section 401 language allowing certification conditions based on “any other appropriate requirements of state law,” the Court explicitly declined to speculate “on what additional state laws, if any, might be incorporated by this language. But at a minimum, limitations imposed pursuant to state water quality standards adopted pursuant to § 303 are appropriate requirements of state law.” 511 U.S. at 713 (emphasis added).

On the scope of section 401, the dissenting opinion in *PUD No. 1* would have declined to adopt the interpretation suggested by the EPA’s regulations and guidance and instead analyzed the statutory section as a whole, attempting to harmonize sections 401(a) and (d). The dissent first noted that, if the majority’s conclusion that States can impose conditions unrelated to discharges is correct, “Congress’ careful focus on discharges in

§ 401(a)(1)—the provision that describes the scope and function of the certification process—was wasted effort,” and that the majority’s conclusion “effectively eliminates the constraints of § 401(a)(1).” 511 U.S. at 726 (Thomas, J., dissenting). The dissent then “easily reconciled” the two provisions by concluding that “it is reasonable to infer that the conditions a State is permitted to impose on certification must relate to the very purpose the certification process is designed to serve. Thus, while section 401(d) permits a State to place conditions on a certification to ensure compliance of ‘the applicant,’ those conditions must still be related to discharges.” *Id.* at 726–27. The dissent further noted that each of the CWA provisions enumerated in section 401 “describes discharge-related limitations” and therefore that the plain language of section 401(d) supports the conclusion that certification conditions must address water quality concerns from the discharge, not the proposed activity as a whole. *Id.* at 727. Finally, the dissent applied the principle *ejusdem generis* in its analysis of statutory construction and concluded that because “other appropriate requirements of state law” are included in a list of more specific discharge-related CWA provisions, this “general reference to ‘appropriate’ requirements of state law is most reasonably construed to extend only to provisions that, like the other provisions in the list, impose discharge-related restrictions.” *Id.* at 728.

The dissent also took issue with the majority’s reliance, at least in part, on the EPA’s regulations and its application of *Chevron* deference. The dissent noted that the Court had not first identified ambiguity in the statute and that the federal government had not sought judicial deference to EPA’s regulations. 511 U.S. at 728–29 (Thomas, J., dissenting). See also Brief for the United States as Amicus Curiae Supporting Affirmance, *PUD No. 1 of Jefferson County v. Washington Dep’t of Ecology*, No. 92–1911, (Dec. 1993). The dissent noted that there was no EPA interpretation directly addressing the relationship between sections 401(a) and (d), and that the only existing EPA regulation that addresses the conditions that may appear in section 401 certifications “speaks exclusively in terms of limiting discharges.”¹⁹ *Id.* (citing 40 CFR 121.2(a)(4)).

¹⁸The Court apparently failed to identify or understand that the EPA’s regulations were promulgated prior to the 1972 CWA amendments and thus do not interpret the 1972 Act.

¹⁹The amicus brief filed by the Solicitor General on behalf of the EPA in this case did not grapple with the language in 401(a) and (d) at all, but

The *PUD No. 1* decision addressed two other scope-related elements of section 401: Whether certification conditions may be designed to address impacts to designated uses, and whether conditions related to minimum stream flows are appropriate under section 401. First, the Court conducted a plain language analysis of the CWA and concluded that, “under the literal terms of the statute, a project that does not comply with a designated use of the water does not comply with the applicable water quality standards.” *Id.* at 715. This means that a section 401 certification may appropriately include conditions to require compliance with designated uses, which, pursuant to the CWA, are a component of a water quality standard. *Id.* Second, the Court acknowledged that the Federal Power Act (FPA) empowers FERC “to issue licenses for projects ‘necessary or convenient . . . for the development, transmission, and utilization of power across, along, from, or in any of the streams . . . over which Congress has jurisdiction,’” and that the FPA “requires FERC to consider a project’s effect on fish and wildlife.” *Id.* at 722. Although the Court had previously rejected a State’s minimum stream flow requirement that conflicted with a stream flow requirement in a FERC license, the Court found no similar conflict in this case because FERC had not yet issued the hydropower license. *Id.* Given the breadth of federal permits that CWA section 401 applies to, the Court declined to assert a broad limitation on stream flow conditions in certifications but concluded that they may be appropriate if necessary to enforce a State’s water quality standard, including designated uses. *Id.* at 723.

ii. S.D. Warren

In 2006, the Court revisited section 401 in connection with the State of Maine’s water quality certification of FERC license renewals for five hydroelectric dams on the Presumpscot

primarily argued that the proposed project had two distinct discharges (which were undisputed) and that “both discharges could reasonably be said to cause a violation of the State’s water quality standards,” including the designated uses and anti-degradation components. Brief for the United States as Amicus Curiae Supporting Affirmance, *PUD No. 1 of Jefferson County v. Washington Dep’t of Ecology*, No. 92–1911 at 12 n. 2 (Dec. 1993) (“It is therefore unnecessary to determine in this case whether Congress intended by the use of the term ‘applicant,’ rather than ‘discharge,’ in section 401(d) to grant States a broader power to condition certifications under section 401(d) than to deny them under section 401(a) and, if so, whether there are limitations on the States’ authority to impose such conditions.”) The amicus brief also did not inform the Court that the Agency’s implementing regulations included language from the prior version of the Act.

River. *S.D. Warren Co. v. Maine Bd. of Env’tl. Prot.*, 547 U.S. 370 (2006) (*S.D. Warren*). The issue presented in *S.D. Warren* was whether operation of a dam may result in a “discharge” into the waters of the United States, triggering the need for a section 401 certification, even if the discharge did not add any pollutants. The Court analyzed the use of different terms—“discharge” and “discharge of pollutants”—within the CWA, how those terms are defined, and how they are used in CWA sections 401 and 402. The Court noted that section 402 expressly uses the term “discharge of pollutants” and requires permits for such discharges; and that section 401, by contrast, provides a tool for States to maintain water quality within their jurisdiction and uses the term “discharge,” which is not independently defined in the Act.²⁰ Finding no specific definition of the term “discharge” in the statute, the Court turned to its common dictionary meaning: A “flowing or issuing out” and concluded that the term is “presumably broader” than “discharge of a pollutant.” *Id.* at 375–76.

The Court held that operating a dam “does raise a potential for a discharge” and, therefore, triggers section 401. 547 U.S. at 373. In so holding, the Court observed that Congress had defined “pollution” under the Act to mean “the man-made or man-induced alteration of the chemical, physical, biological, and radiological integrity of water,” 33 U.S.C. 1362(19), and that “[t]he alteration of water quality as thus defined is a risk inherent in limiting river flow and releasing water through turbines.” 547 U.S. at 385. Such changes in a river “fall within a State’s legitimate legislative business, and the Clean Water Act provides for a system that respects the State’s concerns.” *Id.* at 386. The Court concluded by observing that “[s]tate certifications under [section] 401 are essential in the scheme to preserve state authority to address the broad range of pollution.” *Id.* This sentence, when read in isolation, has been interpreted as broadening the scope of section 401 to allow certifying authorities to consider potential environmental impacts from a proposed federally licensed or permitted project that have nothing to do with water quality. However, the Court followed that sentence with a quote from Senator Muskie’s floor statement during the enactment of section 401:

²⁰ The Court noted that the Act provides that “the term ‘discharge’ when used without qualification includes a discharge of a pollutant, and a discharge of pollutants.” 547 U.S. at 375 (quoting 33 U.S.C. 1362(16)).

No polluter will be able to hide behind a Federal license or permit as an excuse for a violation of *water quality standard[s]*. No polluter will be able to make major investments in facilities under a Federal license or permit without providing assurance that the facility will comply with *water quality standards*. No State water pollution control agency will be confronted with a fait accompli by an industry that has built a plant without consideration of *water quality requirements*.

Id. (emphasis added). The Court then stated, “These are the *very reasons* that Congress provided the States with power to enforce ‘any other appropriate requirement of State law,’ 33 U.S.C. 1341(d), by imposing conditions on federal licenses for activities that may result in a discharge.” *Id.* (emphasis added). Thus, when read in context, the Court’s statement about a State’s authority to address a “broad range of pollution” under section 401 does not suggest that an “appropriate requirement of State law” means anything other than water quality requirements or that a State’s or Tribe’s action on a certification request can be focused on anything other than compliance with appropriate water quality requirements.

b. Circuit Court Decisions

Over the years, federal appellate courts have also addressed important aspects of section 401, including the timing for certifying authorities to act on a request and the scope of authority of federal agencies other than the EPA to make determinations on section 401 certifications. This section highlights a few of the most significant issues concerning section 401 and the most often cited decisions but does not cover the universe of lower federal court or State court case law. The Agency intends for this final rule to provide consistency and certainty where there may currently be conflicting or unclear but locally binding legal precedent.

Recent case law has provided insight concerning the timing and waiver provisions of section 401. In 2018, the Second Circuit addressed the question of when the statutory review clock begins. *N.Y. State Dep’t of Env’tl. Conservation v. FERC*, 884 F.3d 450, 455–56 (2d Cir. 2018). Considering Millennium Pipeline Company’s certification request, the court disagreed with the State of New York and held that the statutory time limit is *not* triggered when a State determines that a request for certification is “complete,” but that the “plain language of Section 401 outlines a bright-line rule regarding the beginning of review,” and that the clock starts after “receipt of such request” by the certifying authority. *Id.*

Otherwise, the court noted that States could “blur this bright-line into a subjective standard, dictating that applications are complete only when state agencies decide that they have all the information they need. The state agencies could thus theoretically request supplemental information indefinitely.” *Id.* at 456. The Agency agrees with this holding.

The D.C. Circuit has also recently analyzed the statutory timeline for review of a certification and has correctly held that, consistent with the plain language of CWA section 401(a)(1), “while a full year is the absolute maximum, [the statute] does not preclude a finding of waiver prior to the passage of a full year.” *Hoopa Valley Tribe v. FERC*, 913 F.3d 1099, 1104 (D.C. Cir. 2019), *cert. denied sub nom. Cal. Trout v. Hoopa Valley Tribe*, 140 S.Ct. 650 (2019). Significantly, the court observed that the EPA’s own regulations—promulgated by “the agency charged with administering the CWA”—allowed for waiver after only six months. *Id.*

In *Hoopa Valley Tribe*, the D.C. Circuit also correctly held that “the withdrawal-and-resubmission of water quality certification requests does not trigger new statutory periods of review.” *Id.* at 1101. The court found that the project proponent and the certifying authorities (California and Oregon) had improperly entered into an agreement whereby the “very same” request for State certification of its relicensing application was automatically withdrawn-and resubmitted every year by operation of “the same one-page letter,” submitted to the States before the statute’s one-year waiver deadline. *Id.* at 1104. The court observed that “[d]etermining the effectiveness of such a withdrawal-and-resubmission scheme is an undemanding inquiry” because the statute’s text “is clear” that failure or refusal to act on a request for certification within a reasonable period of time, not to exceed one year, waives the State’s ability to certify.²¹ *Id.* at 1103. The court found that, pursuant to the unlawful withdrawal-and-resubmission “scheme,” the States had not yet rendered a certification decision “more than a decade” after the initial request was submitted to the States. *Id.* at 1104. The court declined to “resolve the

legitimacy” of an alternative arrangement whereby an applicant may actually submit a new request in place of the old one. *Id.* Nor did it determine “how different a request must be to constitute a ‘new request’ such that it restarts the one-year clock.” *Id.* On the facts before it, the court found that “California’s and Oregon’s deliberate and contractual idleness” defied the statute’s one-year limitation and “usurp[ed] FERC’s control over whether and when a federal license will issue.” *Id.*

Another important area of case law deals with the scope of authority and deference provided to federal agencies other than the EPA in addressing issues arising under section 401. Many other federal agencies, including FERC and the Corps, routinely issue licenses and permits that require section 401 certifications and are responsible for enforcing State certification conditions that are incorporated into federal licenses and permits. However, because the EPA has been charged by Congress with administering the CWA, some courts have concluded that those other federal agencies are not entitled to deference on their interpretations of section 401. *See Ala. Rivers Alliance v. FERC*, 325 F.3d 290, 296–97 (D.C. Cir. 2002); *Am. Rivers, Inc. v. FERC*, 129 F.3d 99, 107 (2d. Cir. 1997). Other courts have concluded that FERC has an affirmative obligation to determine whether a certifying authority has complied with requirements related to a section 401 certification. *See City of Tacoma v. FERC*, 460 F.3d 53, 67–68 (D.C. Cir. 2006) (FERC had an obligation to “obtain some minimal confirmation of such compliance”); *see also Keating v. FERC*, 927 F.2d 616, 622–23, 625 (D.C. Cir. 1991) (while a federal agency may not question propriety of State certification before license has issued, “FERC must at least decide whether the state’s assertion of revocation satisfies section 401(a)(3)’s predicate requirements”).

In an important determination of procedural authorities, the Second Circuit has held that FERC—as the licensing agency—“may determine whether the proper state has issued the certification or whether a state has issued a certification within the prescribed period.” *Am. Rivers, Inc.*, 129 F.3d at 110–11. This holding is correct; the holding is consistent with and supported by the implied statutory authority of a federal agency to establish the “reasonable period of time (which shall not exceed one year)” in the first place. 33 U.S.C. 1341(a)(1).

Case law also highlights the potential enforcement challenges that federal

agencies face with section 401 certification conditions that are included in federal licenses and permits. Federal agencies have been admonished not to “second guess” a State’s water quality certification or its conditions, *see, e.g., City of Tacoma*, 460 F.3d at 67; *Am. Rivers Inc.*, 129 F.3d at 107; *U.S. Dept. of Interior v. FERC*, 952 F.2d 538, 548 (D.C. Cir. 1992) (“FERC may not alter or reject conditions imposed by the states through section 401 certificates.”), even where the federal agency has attempted to impose conditions that are more stringent than the State’s conditions. *See Sierra Club v. U.S. Army Corps of Engineers*, 909 F.3d 635, 648 (4th Cir. 2018) (“the plain language of the Clean Water Act does not authorize the Corps to replace a state condition with a meaningfully different alternative condition, even if the Corps reasonably determines that the alternative condition is more protective of water quality”); *see also Lake Carriers’ Assoc. v. EPA*, 652 F.3d 1, 6, 12 (D.C. Cir. 2011) (concluding that additional notice and comment on State certification conditions would have been futile because “the petitioners have failed to establish that EPA can alter or reject state certification conditions. . . .”). But in *Lake Carriers’ Assoc.*, the court also observed, “[n]otably, the petitioners never argued that the certifications failed to ‘comply with the terms of section 401,’ . . . by overstepping traditional bounds of state authority to regulate interstate commerce” (citing *City of Tacoma*, 460 F.3d at 67), and the court concluded that it “therefore need not consider whether EPA has authority to reject state conditions under such circumstances.” Also, in *Snoqualmie Indian Tribe v. FERC*, the Ninth Circuit upheld FERC’s inclusion of minimum flow requirements greater than those specified in the State of Washington’s certification as long as they “do not conflict with or weaken the protections provided by the [State] certification.” 545 F.3d 1207, 1219 (9th Cir. 2008). In that case, FERC had added license conditions increasing the minimum flows specified in the State’s certification in order to “produce a great amount of mist” which it determined would “augment the Tribe’s religious experience,” one of the water’s designated uses. *Id.*; *see also* cases discussed at section III.G of this notice affirming a role for federal agencies to confirm whether certifications comply with the requirements of section 401.

This final rule is intended to provide clarity to certifying authorities, federal agencies, and project proponents, as it

²¹ Two decisions from the Second Circuit recently acknowledged that project proponents have withdrawn and resubmitted certification requests to extend the reasonable time period for a state to review. *See N.Y. State Dep’t of Envtl. Conservation v. FERC*, 884 F.3d at 456; *Constitution Pipeline v. N.Y. State Dep’t of Envtl. Conservation*, 868 F.3d 87, 94 (2d Cir. 2018). However, in neither case did the court opine on the legality of such an arrangement.

addresses comprehensively and for the first time relevant competing case law and attempts to clarify the scope of conditions that may be included in a certification and the federal agencies' role in the certification process.

5. Administrative Law Principles

To understand the full context and legal basis for this final rule, it is useful to review some key governing principles of administrative law. In general, administrative agencies can exercise only the authority that has been provided to them by Congress, and courts must enforce unambiguous terms that clearly express congressional intent. However, when Congress delegates authority to administrative agencies, it sometimes enacts ambiguous statutory provisions. To carry out their congressionally authorized missions, agencies, including the EPA, must often interpret ambiguous statutory terms. However, they must do so consistent with congressional intent. In *Chevron, U.S.A. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984) (*Chevron*), the Supreme Court concluded that courts have a limited role when reviewing agency interpretations of ambiguous statutory terms. In such cases, reviewing courts defer to an agency's interpretation of ambiguous terms if the agency's interpretation is reasonable. Under *Chevron*, federal agencies—not federal courts—are charged in the first instance with resolving statutory ambiguities to implement delegated authority from Congress.

The Supreme Court has described the *Chevron* analysis as a “two-step” process. *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2124 (2016). At step one, the reviewing court determines whether Congress has “directly spoken to the precise question at issue.” *Chevron*, 467 U.S. at 842. If so, “that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.” *Id.* at 842–43. If the statute is silent or ambiguous, the reviewing court proceeds to the second step, in which the court must defer to the agency's “reasonable” interpretation of the statute. *Id.* at 844.

In the field of judicial review of agencies' regulations that interpret statutes that those agencies administer, *Chevron* deference relies on the principle that “when Congress grants an agency the authority to administer a statute by issuing regulations with the force of law, it presumes the agency will use that authority to resolve ambiguities in the statutory scheme.” *Encino Motorcars*, 136 S. Ct. at 2125 (citing

Chevron, 467 U.S. at 843–44). Courts thus have applied *Chevron* deference to an agency's statutory interpretation “when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority.” *Mayo Found. for Medical Educ. and Res. v. United States*, 562 U.S. 44, 45 (2011) (quoting *United States v. Mead Corp.*, 533 U.S. 218, 226–27 (2001)).

In *Chevron*, the Supreme Court reviewed the EPA's interpretation of statutory language from the Clean Air Act Amendments of 1977. Congress amended the Clean Air Act to impose requirements on States that had not achieved the national air quality standards promulgated by the EPA. States that had not attained the established air standards had to implement a permit program that would regulate “new or modified major stationary sources” of air pollution. Clean Air Act Amendments of 1977, Public Law 95–95, 91 Stat. 685 (1977). The EPA promulgated regulations defining a “stationary source” as the entire plant where pollutant-producing structures may be located. The EPA, therefore, treated numerous pollution-producing structures collectively as a single “stationary source,” even if those structures were part of the same larger facility or complex. *See* 40 CFR 51.18(j)(1)(i)–(ii) (1983). Under the EPA's regulation, a facility could modify or construct new pollution-emitting structures within the facility or complex as long as the stationary source—the facility as a whole—did not increase its pollution emissions.

In 1981, the Natural Resources Defense Council (NRDC) opposed the EPA's definition of “stationary source” and filed a challenge to the Agency's regulations. The D.C. Circuit agreed with the NRDC and set aside the EPA's regulations. The D.C. Circuit acknowledged that the Clean Air Act “does not explicitly define what Congress envisioned as a ‘stationary source,’ to which the permit program . . . should apply,” and also concluded that Congress had not clearly addressed the issue in the legislative history. *NRDC v. Gorsuch*, 685 F.2d 718, 723 (DC Cir. 1982). Without clear text or intent from Congress, the D.C. Circuit looked to the purposes of the program to guide the court's interpretation. *Id.* at 726. According to the court, Congress sought to improve air quality when it amended the Clean Air Act, and the EPA's definition of “stationary source”

merely promoted the maintenance of current air quality standards.

In a unanimous decision, the Supreme Court reversed, finding that the D.C. Circuit had committed a “basic legal error” by adopting “a static judicial definition of the term ‘stationary source’ when it had decided that Congress itself had not commanded that decision.” *Chevron*, 467 U.S. at 842. The Court explained that it is not the judiciary's place to establish a controlling interpretation of a statute delegating authority to an agency, but, rather, that it is the agency's job to “fill any gap left, implicitly or explicitly, by Congress.” *Id.* at 843. When Congress expressly delegates to an administrative agency the authority to interpret a statute through regulation, courts cannot substitute their own interpretation of the statute when the agency has provided a reasonable construction of the statute. *See id.* at 843–44.

During the rulemaking process, the EPA had explained that Congress had not fully addressed the definition of “source” in the amendments to the Clean Air Act or in the legislative history. *Id.* at 858. The Supreme Court agreed, concluding that “the language of [the statute] simply does not compel any given interpretation of the term ‘source.’” *Id.* at 860. And the legislative history associated with the amendments was “silent on the precise issue.” *Id.* at 862.

In its proposed and final rulemaking, the EPA noted that adopting an individualized equipment definition of “source” could disincentivize the modernization of plants, if industry had to go through the permitting process to create changes. *Id.* at 858. The EPA believed that adopting a plant-wide definition of “source” could result in reduced pollution emissions. *Id.* Considering the Clean Air Act's competing objectives of permitting economic growth and reducing pollution emissions, the Supreme Court stated that “the plantwide definition is fully consistent with one of those concerns—the allowance of reasonable economic growth—and, whether or not we believe it most effectively implements the other, we must recognize that the EPA has advanced a reasonable explanation for its conclusion that the regulations serve the environmental objectives as well.” *Id.* at 863. The Court upheld the EPA's definition of the term “stationary source,” explaining that “the Administrator's interpretation represents a reasonable accommodation of manifestly competing interests and is entitled to deference: The regulatory scheme is technical and complex, the

agency considered the matter in a detailed and reasoned fashion, and the decision involves reconciling conflicting policies.” *Id.* at 865.²²

In the *Brand X* decision, the Supreme Court further elaborated on the *Chevron* doctrine, upholding agencies’ broad power to interpret ambiguous statutes as against contrary judicial interpretations. Even if a court has ruled on the interpretation of a statute, the “court’s prior judicial construction of a statute trumps an agency construction otherwise entitled to *Chevron* deference only if the prior court decision holds that its construction follows from the unambiguous terms of the statute and thus leaves no room for agency discretion.” *Nat’l Cable & Telecomm. Ass’n v. Brand X internet Serv.*, 545 U.S. 967, 982 (2005) (emphasis added). Put another way, *Brand X* held that “a court’s choice of one reasonable reading of an ambiguous statute does not preclude an implementing agency from later adopting a different reasonable interpretation.” *United States v. Eurodif S.A.*, 555 U.S. 305, 315 (2009). This principle stems from *Chevron* itself, which “established a ‘presumption that Congress, when it left ambiguity in a statute meant for implementation by an agency, understood that the ambiguity would be resolved, first and foremost, by the agency, and desired the agency (rather than the courts) to possess whatever degree of discretion the ambiguity allows.’” *Brand X*, 545 U.S. at 982 (quoting *Smiley v. Citibank*, 517 U.S. 735, 740–41 (1996)). As *Chevron* itself noted, even the “initial agency interpretation is not instantly carved in stone.” *Chevron*, 467 U.S. at 863.

In *Brand X*, the Federal Communications Commission (FCC or Commission) interpreted the scope of the Communications Act of 1934, which subjects providers of “telecommunications service” to mandatory common-carrier regulations. *Brand X*, 545 U.S. at 977–78. *Brand X* internet Services challenged the FCC’s interpretation, and the Ninth Circuit concluded, based on the court’s precedent, that the Commission’s construction of the Communications Act was impermissible *Id.* at 979–80. The

Supreme Court granted certiorari and reversed. The Supreme Court upheld the FCC’s interpretation of the Communications Act by applying *Chevron*’s two-step analysis. The Court found that the relevant statutory provisions failed to unambiguously foreclose the Commission’s interpretation, while other provisions were silent. The FCC had “discretion to fill the consequent statutory gap,” and its construction was reasonable. *Id.* at 997.

As the Court noted, the entire “point of *Chevron* is to leave the discretion provided by the ambiguities of a statute with the implementing agencies.” 545 U.S. at 981 (quoting *Smiley*, 517 U.S. at 742). Thus courts cannot rely on judicial precedent to override an agency’s interpretation of an ambiguous statute. *Id.* at 982. Instead, as a “better rule,” a reviewing court can rely only on precedent that interprets a statute at “*Chevron* step one.” *Id.* “Only a judicial precedent holding that the statute unambiguously forecloses the agency’s interpretation, and therefore contains no gap for the agency to fill, displaces a conflicting agency construction.” *Id.* at 982–83. A contrary rule would produce anomalous results, because the controlling interpretation would then turn on whether a court or the agency had interpreted the statutory provision first. *See id.* at 983. “[W]hether Congress has delegated to an agency the authority to interpret a statute does not depend on the order in which the judicial and administrative constructions occur.” *Id.* Agencies have the authority to revise “unwise judicial constructions of ambiguous statutes.” *Id.*

6. Response to Comments on the Legal Background

The Agency solicited and received numerous comments on the legal background for the proposed rule. Among others, these comments included legal arguments pertaining to the Tenth Amendment, interstate commerce, cooperative federalism, the APA, and the Agency’s rulemaking authority. The sections below provide the EPA’s response to the most salient of those comments.

a. The Tenth Amendment and the Commerce Clause

Some commenters asserted the proposed rule would violate the Tenth Amendment, citing the sovereignty that States have over waters of the United States. One commenter asserted that jurisdictional power over waters of the State was reserved for the States and not delegated to Congress. Another commenter asserted that the proposal

would constitute a “usurping” of State authority and overstepping the Tenth Amendment rights of the States. The EPA disagrees with these commenters. For the reasons set forth in section II.F.1 of this notice and in the following paragraph, the Agency considers this final rule to be a careful and thoughtful clarification of State and Tribal involvement in federal licensing or permitting proceedings, including those in which State and Tribal authority may otherwise be preempted by federal law. The final rule does not “usurp” State authority. As discussed, the EPA’s final rule is consistent with section 401, strikes the appropriate balance Congress intended between federal and State authority, and does not limit State authority any more than Congress intended under section 401.

The Agency also received a comment asserting that the proposed rule would violate the Tenth Amendment because federal agencies cannot commandeer States to regulate interstate commerce in particular ways, citing *New York v. United States*, 505 U.S. 144, 166 (1992). The commenter noted that in *New York*, the Supreme Court, in striking down portions of the Low-Level Radioactive Waste Policy Amendments Act of 1985 that required States to regulate as Congress instructed or to take title to the waste, found that Congress cannot command States how to legislate and that Congress must exercise legislative authority only directly upon individuals. The Agency disagrees with this commenter. This final rule neither directs the functioning of the States nor commands States how to legislate or regulate. The final rule merely affirms and clarifies the scope of the authority that Congress granted to certifying authorities to review and condition a federal license or permit within certain reasonable bounds, informed by the text of the Act, and provides a procedural framework for States, Tribes, and federal agencies to follow that will promote consistency in 401 certification proceedings.

In the proposal, the EPA solicited comment on whether the proposed rule appropriately balanced the scope of State authority under section 401 with Congress’ goal of facilitating commerce on interstate navigable waters. Some commenters argued that the cases referenced in the proposed rule preamble, including *Lighthouse Resources, Inc. v. Inslee* and *Lake Carrier’s Association v. EPA*, 652 F.3d 1 (D.C. Cir. 2011), are not relevant to this rulemaking. The Agency disagrees with the suggestion that these cases are irrelevant because, among other things, they demonstrate that section 401

²² For other instructive applications of *Chevron*’s interpretative principles, see *Entergy Corp. v. Riverkeeper, Inc.* 556 U.S. 208, 222–23 (2009) (statutory silence interpreted as “nothing more than a refusal to tie the agency’s hands”); *Zuni Pub. School Dist. v. Dep’t of Educ.* 550 U.S. 81, 89–94 (2007) (court considered whether agency’s interpretation was reasonable in light of the “plain language of the statute” as well as the statute’s “background and basic purposes”); *Healthkeepers, Inc. v. Richmond Ambulance Auth.*, 642 F.3d 466, 471 (4th Cir. 2011) (“statutory construction . . . is a holistic endeavor”).

actions are not insulated from legal challenges asserting State or Tribal interference with interstate commerce and violations of the Commerce Clause. The Agency did not rely on these decisions to inform the substance of the final rule; rather, they were considered as part of the overall context of litigation and regulatory uncertainty that contributed to the need to update the 1971 certification regulations to be consistent with CWA section 401.

Other commenters supported the proposal and raised concerns that States and Tribes could use section 401 actions to override federal trade policy with which they disagree. At least one commenter asserted that coastal States and States that border Canada and Mexico could misuse section 401 to block the construction of international terminals for exports, including energy, agricultural, and manufacturing exports. This commenter asserted that such misuse could also result in blocking imports from trading partners based on objections of a single State. The EPA appreciates these comments and agrees that there is a risk that State or Tribal certification authority could be misused in the way described by the commenter. However, as described elsewhere in this final rule preamble and in the *Economic Analysis for the Clean Water Act Section 401 Certification Rule* (“the Economic Analysis,” available in the docket for this final rule), the EPA acknowledges that many certifications reflect an appropriately limited interpretation of the purpose and scope of section 401 and are issued without controversy, and that the limitations expressed in this rulemaking should further curb any improper invocation of section 401 authority.

The EPA has determined that this final rule appropriately balances the interests of State or Tribal participation in federal license or permit proceedings under section 401 with Congress’ goal of facilitating interstate commerce on navigable waters. Because Congress relied on its authority under the Interstate Commerce Clause when it enacted the CWA, including section 401, this rule respects that balance. The Agency has for the first time clearly defined the scope of certification, reducing the risk that States and Tribes would deny or condition certifications for reasons beyond the authority provided in section 401 or that such denials or conditions would place undue burdens on interstate commerce.

b. Cooperative Federalism

A number of commenters asserted that the proposed rule is inconsistent with the concept of cooperative

federalism and the important role of States and Tribes as co-regulators, and therefore, these commenters believed that the proposed rule undermines the cooperative federalism structure established by Congress in the CWA in section 101(b) and section 101(g). Most of these commenters noted that the CWA recognizes States’ primary authority over their water resources, designates States as co-regulators under a system of cooperative federalism, and expresses intent to preserve and protect States’ responsibilities and rights. Commenters stated that the CWA was founded on a principle of cooperative federalism, and that the EPA should not dictate what States can and cannot do. Another commenter asserted that the proposed rule would unduly limit States’ authority and autonomy to protect their water resources. A few commenters asserted that the proposed rule would harm Congress’ division of authority between certifying authorities and federal licensing and permitting agencies. Some commenters asserted that the proposed rule neglects States’ interests.

Other commenters asserted that the proposed rule is consistent with the overall cooperative federalism framework established by Congress in the CWA and appropriately balances federal and State authority. A few commenters argued that under section 401, Congress was conferring on States a narrow exception to act in areas that are otherwise preempted entirely by federal law. These commenters described section 401 certifications as playing a limited role in a much larger federal permitting scheme envisioned in the CWA. A few commenters supporting the proposed rule described an appreciation for the EPA’s desire to preserve State sovereignty and cooperative federalism in conjunction with greater consistency in implementing section 401. Several commenters observed that the proposed rule would promote efficiency and would be consistent with the intent of the 1972 CWA amendments, leading to consistent nationwide implementation, while allowing the States to retain their primary roles under the CWA. Other commenters stated that the current regulations have allowed States to impose conditions beyond the scope of water quality effects of a discharge, leading to lengthy delays and a process that is ill-defined, confusing in scope, and lacking clear deadlines. Other commenters suggested that the proposed rule supports timely issuance of permits and licenses and agreed that the proposed rule would ensure that section

401 certification does not exceed the scope of CWA jurisdiction.

The EPA has considered these diverse comments and concludes that the final rule does not infringe upon the roles of States as co-regulators, nor does it undermine cooperative federalism. The final rule does not and cannot alter the basic scope of authority granted by Congress to States and Tribes for the review of potential discharges associated with federal licenses and permits for compliance with water quality standards. States and authorized Tribes, for example, remain primarily responsible to develop the water quality standards with which federal projects must comply.

Accordingly, this rule neither diminishes nor undermines cooperative federalism. Rather, the final rule clearly identifies when a certification is required and the permissible scope of such a certification—including conditions of that certification—and reaffirms that certifying authorities have a reasonable period of time to act on a certification request, which cannot exceed one year. This clarity helps define the appropriate parameters of cooperative federalism contemplated by section 401, and does not undermine it.

The EPA disagrees with commenters who suggest that concepts of “cooperative federalism” preclude the EPA from establishing regulations to implement section 401. Cooperative federalism must be implemented consistent with the statutory framework under the CWA, which does not allow EPA to authorize, either explicitly or by implication, States to implement this important federal program in a manner beyond the authority established by Congress. Indeed, as the Agency charged with administering the CWA, EPA’s role here is similar to its baseline setting function in other aspects of the Act, to ensure that there are sufficient authorities and limitations in place for States and Tribes to effectively implement CWA programs within the scope that Congress established. The final rule provides, for the first time, a consistent framework to govern the implementation of CWA section 401 that complies with the 1972 CWA amendments.

c. Administrative Procedure Act

Some commenters asserted that the proposed rule is arbitrary and capricious and an abuse of discretion. Some commenters cited *Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto.*, 463 U.S. 29 (1983), and argued that the EPA “relied on factors which Congress has not intended it to consider, entirely failed to consider an

important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.” *Id.* at 43. One commenter asserted that the EPA was arbitrary and capricious because the proposed rule lacks analysis of water quality impacts and fails to consider whether the proposed rule, if adopted, will ensure that the CWA’s overarching goal to protect water quality is met. This commenter further asserted that when combined with the EPA’s recent action to significantly narrow the definition of “waters of the United States,” the effect of the proposed rule could be to leave a regulatory gap, especially in cases where federal law preempts State water quality regulations. Commenters also argued, citing *State Farm*, 463 U.S. at 43, that the EPA failed to “examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made.” These commenters also cited *Nat’l Cotton Council of Am. v. EPA*, 553 F.3d 927, 939 (6th Cir. 2009), and asserted that, when the EPA adopts CWA regulations, it cannot “ignore the directive given to it by Congress . . . which is to protect water quality.” One commenter argued that the Agency elevated industrial interests over State section 401 authority and therefore considered factors not allowed by Congress in violation of the APA, citing *Nat’l Lifeline Ass’n v. FCC*, 915 F.3d 19 (D.C. Cir. 2019) (quoting *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983)).

The final rule is neither arbitrary nor capricious nor an abuse of the EPA’s discretion. In crafting the final rule, the Agency started with the statutory language of the CWA; where the plain language of the Act was unclear or otherwise ambiguous, the EPA considered the structure and purposes of the Act, relevant legal precedent, and legislative history. The EPA also carefully considered the widely varying and competing comments received during the pre-proposal outreach, including Tribal and State engagement, and more than 125,000 public comments filed in the public docket, which are described throughout this final rule preamble. These are factors that Congress intended the Agency to consider. 5 U.S.C. 553(b) and (c). The Agency carefully examined the statutory language and the legislative history when determining the scope of certification and the appropriate role of

federal licensing and permitting agencies. The final rule promotes the overarching goals of the CWA to prevent, reduce, and eliminate pollution in the nation’s waters and to regulate discharges into waters of the United States, while preserving States’ major role in implementing the CWA. The Agency has examined relevant and available data and articulated a robust basis for the rulemaking in the proposed and final rule preambles. See the Economic Analysis and the Supporting Statement for the Information Collection Request for the Clean Water Act Section 401 Certification Rule for further discussion of available data.

Some commenters asserted the proposed rule is arbitrary and capricious because it is a reversal of existing policy and that the Agency did not provide adequate support for the policy reversal. Some commenters argued that when an agency undertakes a new interpretation, it needs a factual record on which to make such a change. These commenters asserted that no record exists in the proposed rule and that no recognition of prior State and EPA practice is evident. One commenter argued that the EPA failed to provide a valid, reasoned basis for departing from decades of agency practice. Some commenters also asserted that the Agency did not demonstrate that the existing regulations are inadequate or explain how the proposed rule will provide increased predictability in comparison, noting that litigation over section 401 denials falls short of a reasoned explanation. These commenters argued that the proposed rule is just as likely to create more confusion, unpredictability, and delay given the sweeping changes that the proposed rule seeks to implement. Some commenters asserted that the EPA was required to and has failed to conduct a careful analysis of past certification reviews to demonstrate the need for the proposed rule. Some commenters argued that the proposed rule does not consider and analyze alternatives, as these commenters assert the Agency is required to do, particularly when it proposes to reverse its policy, citing *State Farm*, 463 U.S. at 46–48; *Ctr. For Science in the Pub. Interest v. Dep’t of Treasury*, 797 F.2d 995, 999 (D.C. Cir. 1986).

The Agency disagrees with these commenters and concludes that its justification in this rulemaking is more than adequate. The Agency’s final rule includes for the first time a well-defined scope for State and Tribal review and actions under section 401. As articulated throughout the proposal and this final rule preamble, the 1971

certification regulations were promulgated to implement section 21(b) of the 1970 FWPCA, not section 401 of the 1972 CWA amendments. See section II.F.3 of this notice. The 1972 amendments made two major changes affecting the scope of the certification requirement: It changed “activity” to “discharge” in section 401(a) and added section 401(d), which describes effluent limitations, other limitations, and monitoring requirements that may be included in a certification. These important statutory elements were not present or contemplated in the 1971 certification regulations, which the EPA is updating with this final rule. It is entirely appropriate, and necessary, for the EPA to conform to the 1972 CWA amendments when updating its almost 50-year-old certification regulations. As noted throughout the proposal preamble and the Economic Analysis, the EPA acknowledges that many certifications reflect an appropriately limited interpretation of the purpose and scope of section 401 and are issued without controversy. Although a few high profile certification denials are part of the factual and administrative record for this rulemaking, and EPA has considered these facts during the rulemaking process, the EPA has not relied on these facts as the sole or primary basis for this rulemaking. The Agency’s longstanding failure to update its regulations created the confusion and regulatory uncertainty that were ultimately the cause of those controversial section 401 certification actions and the resulting litigation. To illustrate the type of uncertainty this rule is attempting to resolve, recent court cases indicate that some project proponents, certifying authorities and federal agencies have different ideas about when the time for review of a certification begins and—once begun—whether the review period can be tolled or extend beyond one year. See *Hoopa Valley Tribe v. FERC*, 913 F.3d 1099 (D.C. Cir. 2019); *New York State Dep’t of Env’tl. Conservation v. FERC*, 884 F.3d 450 (2d Cir. 2018); *Constitution Pipeline Co., LLC v. New York State Dep’t of Env’tl. Conservation*, 868 F.3d 87 (2d Cir. 2017). Questions have also arisen regarding the role of the federal agency in determining whether a waiver has occurred. *Millennium Pipeline Co. v. Seggos*, 860 F.3d 696 (D.C. Cir. 2017). Recent litigation also raises the issue of a certifying authority’s ability to deny certification for other than water quality-related reasons. See *Lighthouse Resources, Inc. v. Inslee*, No. 3:18-cv-5005 (W.D. Wash. filed Jan. 8, 2018).

This rule updates the EPA's regulations to be consistent with the language of section 401 as enacted in 1972. The final rule, while focused on the relevant statutory provisions and case law interpreting those provisions, is informed by the Agency's expertise developed over nearly 50 years of implementing the CWA and policy considerations where necessary to address certain ambiguities in the statutory text. For the first time, this final rule aligns the EPA's regulations with the 1972 amendments and provides clarity to certifying authorities, federal licensing and permitting agencies, project proponents, and the general public.

Other commenters asserted that the proposed rule is carrying out the direction given by the Executive Order to stop States from "hindering the development of energy infrastructure" and asserted that administrative action with such a predestined result should not be afforded the level of deference typically afforded. Certain commenters also cited *Watt v. Alaska*, 451 U.S. 259, 273 (1981), and *General Electric Co. v. Gilbert*, 429 U.S. 125, 143 (1976), to argue that the EPA is overturning fifty years of practice under the CWA in violation of the clear language of 33 U.S.C. 1251(b), 33 U.S.C. 1341, and 33 U.S.C. 1370; and asserted that the EPA is entitled to less deference when overturning past practice.

The Agency disagrees that this rulemaking result was predetermined by the Executive Order. As discussed in this final rule preamble, the Executive Order does not specify details about what the regulation must say, deferring to the Agency and its technical expertise, as informed by public input, to develop a regulation consistent with the CWA. The EPA issued a proposed rule, received public comment on that rule, made changes in this final rule in response to comments and to increase clarity and regulatory certainty for the section 401 certification process, and explained the basis for these changes. None of that was predetermined. The EPA further disagrees with commenters' assertions that either the proposed rule or this final rule violates the CWA. As described throughout this notice, the EPA for the first time conducted a holistic analysis of the text, structure, and history of CWA section 401. The final rule is based on this holistic analysis and is consistent with the language and congressional intent of section 401 and is informed by important policy considerations and the Agency's expertise. Commenter's reliance on *Watt v. Alaska*, 451 U.S. 259 273, (1981), and *General Electric Co. v.*

Gilbert, 429 U.S. 125, 143 (1976), is misplaced because both decisions pre-date *Chevron* and *Brand X*. As described in section II.F.5 above, EPA has undertaken this rulemaking in accordance with key principles of administrative law, respecting unambiguous terms of the CWA and interpreting ambiguous language in section 401 consistent with congressional intent. The EPA's approach and rationale are set out in detail in the proposal and this final rule preamble and are supported by applicable Supreme Court precedent.

d. Rulemaking Authority

Several commenters cited *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495, 537–38 (1935), and argued that the proposed rule is unconstitutional because it reflects the executive branch legislating absent congressional delegation to do so. One commenter asserted that federal executive agencies have no inherent authority to make law and are subject to the legislative powers of the Congress. This commenter cited *Louisiana Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986), and argued that agency authority is limited to the authority granted by Congress, and that the EPA cannot add conditions outside the scope of the CWA for which Congress provided. Other commenters asserted that by seeking to limit how States exercise their authority under section 401, the proposed rule would exceed the Agency's statutory authority "to prescribe such regulations as are necessary to carry out [the EPA Administrator's] functions under [the Clean Water Act]" (33 U.S.C. 1361(a)) and would instead intrude upon the "responsibilities and rights" Congress expressly reserved to the States. *See* 33 U.S.C. 1251(b). Other commenters agreed with the proposal, stating that the EPA is tasked with promulgating rules for the implementation of the CWA, including one commenter citing *Alabama Rivers Alliance v. FERC*, 325 F.3d 290, 296–97 (2003).

The EPA agrees that the section 401 rulemaking must be consistent with the CWA and the EPA's authority under the Act, but disagrees with commenters who asserted that the proposal or this final rule exceeded that authority. Section 501 of the CWA gives the Administrator the authority to adopt rules "as are necessary to carry out his functions under this chapter." 33 U.S.C. 1361(a). Section 101(d) of the CWA expressly provides that the Administrator shall administer the CWA. 33 U.S.C. 1251(d). Section 401 of the CWA includes responsibilities for

the Administrator to issue certifications when a State or interstate agency has no authority to issue a certification under section 401(a)(1), to ensure the protection of other States' waters under section 401(a)(2), and to provide technical assistance under section 401(b). Section 304(h) of the CWA also specifically directs the EPA to "promulgate guidelines establishing test procedures for the analysis of pollutants that shall include the factors which must be provided in any certification pursuant to section 401 of this Act." 33 U.S.C. 1314(h) (setting April 1973 deadline for doing so). The EPA is doing so with this final rule.

To carry out its functions under section 401, the EPA must adopt rules that ensure transparency and accountability for actions taken under section 401. This includes defining the scope of section 401 and adopting appropriate procedures to implement the timing, public notice and other requirements in section 401. Upon examination of the language of section 401, the relevant case law and legislative history, the Agency recognizes that section 401 contains some ambiguities and lacks clarity in some sections. The Administrator's role under section 101(d), as the person charged with administering the CWA, includes adopting reasonable interpretations of the statute to resolve ambiguities and provide clarity. For example, because CWA section 304(h) requires the Administrator to develop guidelines that "shall include the factors that must be provided" in any CWA section 401 certification, the EPA appropriately interprets that provision as authorizing the Administrator to identify "factors" that may not be included in a certification. The final rule presents a reasonable interpretation of the scope of section 401, which, given the ambiguities in sections 401(a) and 401(d), is properly the subject of Agency interpretation. The final rule also requires certification conditions and denials to be within that scope and that certain information be included in a certification or denial to support the action. These substantive and procedural regulations are necessary for the Administrator to act as a certifying authority, to administer section 401 provisions related to neighboring jurisdictions, and to provide technical assistance to other certifying authorities, federal agencies, and project proponents.

Other commenters objected to the proposed rule, asserting that it would disrespect the separation of powers by not implementing the will of Congress as expressed in the CWA. U.S. Const.

art. II, § 3. As discussed throughout this notice, the proposed rule was consistent with statutory language of the CWA and congressional intent, and this final rule appropriately implements the will of Congress as expressed in the CWA.

One commenter questioned the EPA's claim that it has the power to alter "unwise" judicial decisions. A few commenters stated that *Chevron* deference does not give a federal agency the power to rewrite federal law, and they asserted, citing *INS v. Cardozo-Fonseca*, 480 U.S. 421 (1987); *Adams Fruit Co. v. Barrett*, 494 U.S. 638, 649–650 (1990); *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117 (2016); and *Kisor v. Wilkie*, 139 S. Ct. 2400, 2417 (2019), that the proposed rule falls outside the scope of *Chevron* deference. A few commenters argued that the proposal's "holistic" review inappropriately found ambiguity in the statutory language to justify drastic changes to the federal-State relationship that section 401 established. These commenters argued that instances where federal authority is encroaching on State authority warrant heightened concern, citing *SWANCC*, 531 U.S. 159, 173 (2001), and asserted that any changes must be based on a clear statement from Congress.

Other commenters stated that the divergent language of section 401(a) and section 401(d) creates ambiguity that needs to be resolved. These commenters argued that the EPA's proposed interpretation is reasonable and necessary to fill that statutory gap. One commenter stated that the EPA correctly recognized that the Court's reliance on *Chevron* deference in *PUD No. 1* was entirely misplaced, as the Court did not begin by first identifying an ambiguity in the statute, and the Court ignored the fact that the EPA's own regulations at the time spoke only in terms of "discharges." A number of commenters agreed with the EPA's proposal to address the ambiguities in the CWA statutory language and the inconsistent application of the current regulations that impact project applicants and other States' sovereignty. These commenters agreed that the proposed rule would promote regulatory certainty, help streamline the federal licensing and permitting process for critical infrastructure development, enhance the ability of project proponents to plan for construction, and facilitate early and constructive engagement between permittees, States or authorized Tribes, and federal agencies to ensure that proposed projects will be protective of local water quality.

As discussed in section II.F.5 of this notice, *Chevron* supplies the

appropriate framework for judicial review of statutory interpretation. If the language of a congressional statute is clear, that unambiguous meaning controls. If, however, the congressional text is ambiguous, a reviewing court will defer to the implementing Agency's permissible interpretation. Where, as in CWA section 401(a), Congress used unambiguous terms like "which shall not exceed one year" and "after the receipt of such request," it is reasonable, indeed necessary, for the Agency to apply the plain meaning of those terms when drafting its implementing regulations. Where terms are ambiguous, such as "other appropriate requirement of State law" in CWA section 401(d), the EPA is authorized to fill the congressional gap and supply a reasonable interpretation. *Brand X* supports the EPA's authority to interpret ambiguous terms in section 401 and its ability to make reasonable regulatory choices. That case recognizes that an Agency's statutory interpretation is precluded only when, in a prior decision, a court concluded that its contrary interpretation was compelled by the plain language of the relevant text. *Brand X*, 545 U.S. at 982 ("[A] court's prior judicial construction of a statute trumps an agency construction otherwise entitled to *Chevron* deference *only if* the prior court decision holds that its construction follows from the unambiguous terms of the statute and thus leaves no room for agency discretion."). None of the EPA interpretations upon which its final regulatory language is based, including the Agency's decision that section 401(d) limitations and requirements may be placed only on the "discharge" and not on the "activity," are inconsistent with that principle.

G. Legal Construct for the Final Rule

As the preceding discussion demonstrates, the most challenging aspects of section 401 concern the scope of review and action on a certification request. The Agency is finalizing a regulation that will clarify these aspects and provide additional regulatory certainty for States, Tribes, federal agencies, and project proponents on the timing and procedural requirements of the CWA. This section summarizes some of the core legal principles that inform this final rule, and section III of this notice describes how the Agency is applying those legal principles to support the final rule.

1. Scope of Certification

The EPA has for the first time conducted a holistic analysis of the text, structure, and history of CWA section

401. As a result of that analysis, the EPA is establishing the scope of section 401 as protecting the quality of waters of the United States from point source discharges associated with federally licensed or permitted activities by requiring compliance with water quality requirements, as defined in this final rule.

Since at least 1973, the EPA has issued memoranda and guidance documents, and the Department of Justice has filed briefs in various court cases on behalf of the EPA, addressing section 401. Only a handful of these documents address the scope of section 401, and none was the product of a holistic examination of the statute or its legislative history. As a result, these documents included little or no explanation for the Agency's interpretations. For example, in 1989, the EPA issued a guidance document asserting that a section 401 certification could broadly address "all of the potential effects of a proposed activity on water quality—direct and indirect, short and long term, upstream and downstream, construction and operation. . . ." EPA, *Wetlands and 401 Certification* 23 (April 1989). The guidance document's only explanation for this assertion is a reference to section 401(a)(3), which provides that a certification for a construction permit may also be used for an operating permit that requires certification. The guidance document, which did not undergo notice and comment procedures, does not provide any analysis to support its assertion that a certification could address all potential impacts from the "proposed activity" as opposed to the discharge. Several years later, the United States filed an amicus brief in the Supreme Court on behalf of the EPA in the *PUD No. 1* case. The amicus brief asserted that petitioners were "mistaken" in their contention that the State's minimum flow condition is outside the scope of section 401 because the condition would be valid "if it is necessary to assure that discharges resulting from the project will comply with applicable provisions of the CWA or 'any other appropriate requirement of State law.'" See Brief for the United States as Amicus Curiae Supporting Affirmance, *PUD No. 1 of Jefferson County v. Washington Dep't of Ecology*, No. 92–1911 at 11–12 (Dec. 1993) (emphasis added). The brief went on to identify "two distinct discharges" that would result from the petitioner's facility and that would violate the CWA. The amicus brief did not offer an affirmative interpretation to harmonize the different language in sections 401(a)

and 401(d) and instead relied on the plain language in section 401(a). More than a decade later, the United States' Supreme Court amicus brief in the *S.D. Warren* case adopted without explanation the Supreme Court's analysis in *PUD No. 1* that once section 401 is triggered by a discharge, a certification can broadly cover impacts from the entire activity. Finally, in 2010, the EPA issued its now-rescinded Interim Handbook, which included a number of recommendations on scope, timing, and other issues, none of which were supported with robust analysis or interpretation of the Act. The Interim Handbook, which did not undergo notice and comment procedures either, also did not reference the fact that the 1971 certification regulations were not updated after the CWA was enacted in 1972.

This rulemaking is the first time that the EPA has undertaken a holistic review of the text of section 401 in the larger context of the structure and legislative history of the 1972 Act and earlier federal water protection statutes, and the first time the Agency has subjected its analysis to public notice and comment. The final rule is informed by this holistic review and presents a framework that the EPA considers to be most consistent with the text of the Act and congressional intent. After considering and taking into account the comments submitted on the proposed rule, the Agency has made some enhancements in this final rule to appropriately capture the scope of authority for granting, conditioning, denying, and waiving a section 401 certification. For further discussion and response to comments on the scope of certification, see section III.E of this notice.

a. Water Quality

The EPA concludes that the scope of a State's or Tribe's section 401 review or action is not unbounded and must be limited to considerations of water quality. Clarifying the proper scope in this manner aligns with the objective of the CWA to restore and maintain water quality (see CWA section 101(a)). Moreover, there is no suggestion in either the plain language or the structure of the statute that Congress envisioned section 401 to authorize action beyond that which is necessary to address water quality directly. Indeed, as described in greater detail above, the 1972 amendments to the CWA resulted in the enactment of a comprehensive scheme designed to prevent, reduce, and eliminate pollution in the nation's waters generally, and to regulate the

discharge of pollutants into waters of the United States specifically.

In its recent decision in *County of Maui, Hawaii v. Hawaii Wildlife Fund, et al.*, No. 18–260, the Supreme Court reaffirmed that “Congress’ purpose as reflected in the language of the Clean Water Act is to ‘restore and maintain the . . . integrity of the Nation’s waters,’ § 101(a)” (Op. at 2, emphasis added) and underscored the importance of interpreting the statutory text “in light of the statute’s language, structure, and purposes” in a manner that avoids the creation of “a massive loophole in the permitting scheme that Congress established” that would “allow[] easy evasion of the statutory provision’s basic purposes.” (Op. at 12, 15 (April 23, 2020)). The EPA’s interpretation of the scope of CWA section 401 as limited to considerations of water quality is fully consistent with these fundamental principles and respects the congressional scheme at issue in *County of Maui*. As discussed below and throughout the preamble, this is also true of the Agency’s other textual interpretations that inform the definitions and requirements of this rule relating to, for example, “discharge,” “a reasonable period of time (which shall not exceed one year,” “water quality requirements,” and “any other appropriate requirement of State law.”

The EPA is aware that some certifying authorities may have previously interpreted the scope of section 401 in a way that resulted in the incorporation of non-water quality-related considerations into their certification review process. For example, certifying authorities have on occasion required in a certification condition the construction of biking and hiking trails, requiring one-time and recurring payments to State agencies for improvements or enhancements that are unrelated to the proposed federally licensed or permitted project, and the creation of public access for fishing along waters of the United States. Certifying authorities have also attempted to address all potential environmental impacts from the creation, manufacture, or subsequent use of products generated by a proposed federally licensed or permitted activity or project that may be identified in an environmental impact statement or environmental assessment, prepared pursuant to the NEPA or a State law equivalent. This includes, for example, consideration of impacts associated with air emissions and transportation effects.

The Agency has concluded that interpreting the scope of section 401 to allow States and Tribes to regulate and

consider effects of an activity rather than a discharge would invoke the outer limits of power that Congress delegated to the Agency under the CWA. The imposition of conditions unrelated to water quality is not consistent with the scope of the CWA generally or section 401. There is nothing in the text of the statute or its legislative history that signals that Congress intended to impose, using section 401, federal requirements on licensed or permitted activities beyond those addressing water quality-related impacts. Indeed, Congress knows how to craft statutes to require consideration of multi-media effects (see, e.g., NEPA), and has enacted specific statutes addressing impacts to air (Clean Air Act), wildlife (Endangered Species Act), and cultural resources (National Historic Preservation Act), by way of example.²³ Subsequent congressional action directly addressing a particular subject is relevant to determining whether a previously adopted statute reaches that subject matter. See *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 155 (2000) (determining that “actions by Congress over the past 35 years” that addressed tobacco directly, when “taken together,” “preclude[d] an interpretation” that a previously adopted statute, the Food, Drug, and Cosmetic Act, “grant[ed] the FDA jurisdiction to regulate tobacco products.”).

If Congress had intended section 401 of the CWA to authorize consideration or the imposition of certification conditions based on air quality or transportation concerns, public access to waters, energy policy, or other multi-media or non-water quality impacts, it would have provided a clear statement to that effect. Neither the CWA nor section 401 contains any such clear statement. In fact, Congress specifically contemplated a broader policy direction in the 1972 amendments that would have authorized the EPA to address impacts to land, air, and water through implementation of the CWA, but it was rejected.²⁴ The Agency has concluded

²³ See, e.g., 42 U.S.C. 4321 *et seq.* (NEPA); 42 U.S.C. 7401 *et seq.* (Clean Air Act); 16 U.S.C. 1531 *et seq.* (Endangered Species Act); and 16 U.S.C. 470 *et seq.* (National Historic Preservation Act).

²⁴ As Congress drafted the 1972 CWA amendments, the House bill (H.R. 11896) included section 101(g) within its “Declaration of Goals and Policy” providing, “(g) In the implementation of this Act, agencies responsible therefor shall consider all potential impacts relating to the water, land, and air to insure that other significant environmental degradation and damage to the health and welfare of man does not result.” H.R. 11896, 92nd Cong. (1971) (emphasis added). Section 101(g) of the House bill was “eliminated” at conference, and the Act was ultimately passed with no federal policy, goal, or directive to address

that inclusion of the phrase “any other appropriate requirement of State law” in section 401(d) hardly provides clear direction from Congress that section 401(d) could extend beyond water quality. Therefore EPA concludes that section 401(d)—like section 401(a) and the rest of the Act—is limited to considerations of “water quality.”²⁵

Pursuant to the plain language of section 401, when a State or authorized Tribe (and in some cases, the EPA) issues a certification, it has determined that the discharge into waters of the United States from a proposed federally licensed or permitted activity will comply with applicable effluent limitations for new and existing sources (CWA sections 301, 302, and 306), water quality standards and implementation plans (section 303), toxic pretreatment effluent standards (section 307), and—by way of its power to add conditions pursuant to section 401(d)—other “appropriate requirements” of State or Tribal law. 33 U.S.C. 1341(a)(1), (d). The enumerated CWA provisions identify requirements to ensure that discharges of pollutants do not degrade water quality,²⁶ and specifically referenced throughout section 401 is the requirement to ensure compliance with “applicable effluent limitations” and “water quality requirements,” underscoring the focused intent of this provision on the protection of water quality from discharges.²⁷ See 33 U.S.C. 1341(a), (b), (d). The legislative history for the Act provides further support for

non-water quality impacts through the CWA. S. Rep. 92–1236, at 100 (1972) (Conf. Rep.).

²⁵ The Agency also concludes that the term “applicant” in section 401(d) creates ambiguity in the statute. See section II.G.1.b of this notice for discussion of the use of the term “applicant” in section 401(d).

²⁶ For example, CWA section 306 defines the standard of performance for new sources of discharges as “a standard for the control of the discharge of pollutants which reflects the greatest degree of effluent reduction which the Administrator determines to be achievable through application of best available demonstrated control technology, processes, operating methods, or other alternatives, including, where practicable, a standard permitting no discharge of pollutants.” 33 U.S.C. 1316(a)(1). Section 303 notes that new or revised state water quality standards “[s]hall be such as to protect the public health or welfare, enhance the quality of water and serve the purposes of this chapter.” *Id.* at 1313(c)(2)(A).

²⁷ The term “effluent limit” is defined as, “any restriction established by a State or the Administrator on quantities, rates, and concentrations of chemical, physical, biological, and other constituents which are discharged from point sources into navigable waters, the waters of the contiguous zone, or the ocean, including schedules of compliance[.]” 33 U.S.C. 1362(11); and the CWA requires that “water quality standards” developed by states and tribes “consist of the designated uses of the navigable waters involved and the water quality criteria for such waters based upon such uses.” *Id.* at 1313(c)(2)(A).

the EPA’s interpretation, as it frequently notes that the focus of the section is on assuring compliance with water quality requirements and water quality standards and the elimination of any discharges of pollutants. See, e.g., S. Rep. No. 92–414, at 69 (1971).

The CWA does not define what is an “appropriate requirement” of State law for purposes of adding conditions to a section 401 certification.²⁸ In interpreting this term, the Agency acknowledges the need to respect the clear policy direction from Congress to recognize and preserve State authority over land and water resources within their borders, see 33 U.S.C. 1251(b), and the Agency must avoid interpretations of the CWA that infringe on traditional State land use planning authority. See *SWANCC*, 531 U.S. at 172–73; *Will*, 491 U.S. at 65. One interpretation of this clause in section 401(d) could be that it authorizes the denial of certification or the imposition of conditions in a federal license or permit based on non-water quality-related impacts if those requirements are based on any existing State or Tribal law. Such an interpretation, however, is counterintuitive in a statute aimed at protecting the “chemical, physical, and biological integrity of the nation’s waters.” For example, it is difficult to imagine what guiding principle would help one determine whether to import state labor law or professional licensing requirements into a section 401 certification; such requirements could arguably be relevant to a dam project, but mere relevance is not nearly sufficient to sweep these types of laws within the ambit of an environmental statute aimed at water quality. The CWA does not give EPA a clear basis to venture into such regulatory arenas, which (in the absence of clearly expressed congressional direction) are more appropriately reserved to the powers of the States, “powers with which Congress does not readily interfere.” *Gregory*, 501 U.S. at 461 (describing the “plain statement rule”).

The Agency does not believe that Congress intended the phrase “any other appropriate requirement of State law” to be read so broadly. Instead, the *ejusdem generis* canon helps to inform the appropriate interpretation of the statutory text. Under this principle, where general words follow an enumeration of two or more things, they

²⁸ The EPA notes that during congressional hearings on the 1972 amendments, the House Committee was presented with testimony that the term “applicable water quality requirements” should be defined, but no definition was included in the enacted bill. See section III.E.2.b for further discussion on this legislative history.

apply only to things of the same general kind or class specifically mentioned. See *Wash. State Dept. of Social and Health Services v. Keffeler*, 537 U.S. 371, 383–85 (2003). Here, the general term “appropriate requirement” in section 401(d) follows an enumeration of four specific sections of the CWA that are all focused on the protection of water quality from point source discharges to waters of the United States.²⁹ Given the text, structure, purpose, and legislative history of the CWA and section 401, and informed by important policy considerations and the Agency’s expertise, the EPA interprets “appropriate requirement” for section 401 certification purposes to include those provisions of State or Tribal law that contain requirements for point source discharges into waters of the United States, including provisions that are more stringent than federal law. See S. Rep. No. 92–414, at 69 (1971) (“In addition, the provision makes clear that any water quality requirements established under State law, more stringent than those requirements established under the Act, shall through certification become conditions on any Federal license or permit.”). In this respect, the EPA agrees with the logic of Justice Thomas’s dissent in *PUD No. 1*, wherein he concludes that “the general reference to ‘appropriate’ requirements of State law is most reasonably construed to extend only to provisions that, like other provisions in the list, impose discharge-related restrictions.” *PUD No. 1*, 511 U.S. at 728 (Thomas, J., dissenting). The Agency’s interpretation gives meaning to Congress’s decision to use the word “appropriate” in the phrase “any other appropriate requirement of State law set forth in such certification.”

Consistent with the proposal, the final rule limits the scope of section 401 and the term “appropriate requirements of State law” to those requirements directly related to water quality. As discussed in greater detail in section III.E.2.b of this notice, the final rule definition of “water quality requirements” has been modified from the proposal, but does not stray from the core principle and focus of Title IV of the CWA—to protect the quality of waters of the United States from point source discharges.

²⁹ See Section II.G.1.c for further discussion on point source discharges to waters of the United States in the context of section 401. Although section 401(a) mentions five sections of the CWA, section 401(d) omits section 303. In *PUD No. 1*, the Court interpreted section 303 to be included in section 401(d) by reference to section 301. *PUD No. 1*, 511 U.S. at 712–13.

b. Activity or Discharge

Based on the text, structure, and legislative history of the CWA, the EPA is affirming under this final rule that a certifying authority's review and action under section 401 must be limited to water quality impacts from the potential discharge associated with a proposed federally licensed or permitted project. Section 401(a) explicitly provides that the certifying authority, described as "the State in which the *discharge* originates or will originate," must certify that "any such *discharge* will comply with the applicable provisions of sections 301, 302, 303, 306, and 307 of this Act" (emphasis added). The plain language of section 401(a) therefore directs authorities to certify that the discharge resulting from the proposed federally licensed or permitted project will comply with the CWA. Section 401(d) uses different language and requires the certifying authority to "set forth any effluent limitations and other limitations, and monitoring requirements necessary to assure that any *applicant* for a Federal license or permit will comply with any applicable effluent limitations and other limitations, under section 301 or 302 of this title, standard of performance under section 306 of this title, or prohibition, effluent standard, or pretreatment standard under section 307 of this title, and with any other appropriate requirement of State law set forth in such certification" (emphasis added).³⁰ The use of the term "applicant" in section 401(d)—instead of "discharge" as found in section 401(a)—creates ambiguity, and has been interpreted as broadening the scope of section 401(a), beyond consideration of water quality impacts from the "discharge" which triggers the certification requirement, to allow certification conditions that address water quality impacts from any aspect of the construction or operation of the activity as a whole. See *PUD No. 1*, 511 U.S. at 712.

The ordinary meaning of the word "applicant" is "[o]ne who applies, as for a job or admission." See *Webster's II, New Riverside University Dictionary* (1994). In section 401(d), this term is used to describe the person or entity that applied for the federal license or permit that requires a certification. The use of this term in section 401(d) is consistent with the text of the CWA, which uses the term "applicant" throughout to describe an individual or

entity that has applied for a grant, a permit, or some other authorization.³¹ Importantly, the term is also used in section 401(a) to identify the person responsible for obtaining the certification: "Any applicant for a Federal license or permit to conduct any activity including, but not limited to, the construction or operation of the facilities, which may result in any discharge into the navigable waters, shall provide the licensing or permitting agency a certification from the State" In the section 401 context, the term "applicant" also may include in some circumstances the federal licensing or permitting agency, such as where the federal agency is seeking certification for a general license or permit.

Relying on the presence of the term "applicant" in section 401(d) to interpret section 401(d) as allowing certification conditions that are unrelated to a discharge would expand section 401 regulatory authority beyond the scope of those sections of the Act enumerated in section 401. Those enumerated CWA sections focus on regulating discharges to waters of the United States. The Agency is not aware of any other instance in which the term "applicant" (or permittee or owner or operator) as used in the CWA has been interpreted to significantly expand the jurisdictional scope or meaning of the statute. The Agency therefore understands the term "applicant" in section 401(d) as merely identifying the person or entity responsible for obtaining and complying with the certification and any associated conditions and not as expanding the regulatory scope of that section. This interpretation of the term "applicant," which appropriately ties the term to the discharges that are the regulatory focus of section 401 as a whole and to the purposes of this section, is consistent with and supported by the use in section 401(d) of the phrase "applicant for a Federal license or permit," which refers back to the fuller phrase set forth at the beginning of section 401(a): "applicant for a Federal license or permit to conduct any activity . . . which may result in any discharge into the navigable waters." (Emphasis added.) This interpretation also gives

reasonable, and permissible, meaning to the term "appropriate" in the phrase "any other appropriate requirement of State law set forth in such certification." The textual history and legislative history of section 401, discussed below, provide additional support for this interpretation.

Section 401 was updated as part of the 1972 CWA amendments to reflect the restructuring of the Act, as described in section II.F.1 of this notice. Two important phrases were modified between the 1970 and the 1972 versions of section 401 that help explain what Congress intended with the 1972 amendments. First, the 1970 version provided that an authority must certify "that such *activity* . . . will not violate water quality standards." Public Law 91-224 § 21(b)(1) (emphasis added). Significantly, Congress modified this language in 1972, requiring an authority to certify "that any such *discharge* shall comply with the applicable provisions of [the CWA]." 33 U.S.C. 1341(a) (emphasis added). On its face, this modification made the 1972 version of section 401 consistent with the overall framework of the amended statutory regime, which focuses on regulating discharges to attain water quality standards and adds new federal regulatory programs to achieve that purpose. 33 U.S.C. 1311, 1312, 1313, 1316, 1317, 1342 and 1344.

Second, the 1972 version included section 401(d) for the first time. This provision authorizes conditions to be imposed on a certification "to assure that any applicant for a Federal license or permit will comply with any applicable effluent limitations and other limitations, under section 301 or 302 of this Act, standard of performance under section 306 of this Act, or prohibition, effluent standard, or pretreatment standard under section 307 of this Act, and with any other appropriate requirement of State law set forth in such certification" *Id.* at 1341(d). This new section also requires such conditions to be included in the federal license or permit. *Id.*

Together, these amendments to the pre-1972 statute focus section 401 on discharges that may affect water quality, enumerate newly created federal regulatory programs with which section 401 mandates compliance, and require that water quality-related certification conditions be included in federal licenses and permits and thereby become federally enforceable. The legislative history describing these changes supports a conclusion that the provisions were added intentionally and with the purpose of making the new section 401 consistent with the new

³⁰ As a matter of practice, the Corps seeks State certification for "its own discharges of dredged or fill material," "[a]lthough the Corps does not process and issue permits for its own activities." 33 CFR 336.1(a)(1).

³¹ See, e.g., 33 U.S.C. 1311 ("An application for an alternative requirement under this subsection shall not stay the applicant's obligation to comply with the effluent limitation guideline or categorical pretreatment standard which is the subject of the application."); *id.* at 1344 ("Not later than the fifteenth day after the date an applicant submits all the information required to complete an application for a permit under this subsection, the Secretary shall publish the notice required by this subsection.")

framework of the Act. Indeed, the 1971 Senate Report provided that section 401 was “amended to assure consistency with the bill’s changed emphasis from water quality standards to effluent limitations based on the elimination of any discharge of pollutants.” S. Rep. No. 92–414, at 69 (1971).

An EPA attorney previously analyzed the modifications made to section 401 between the 1970 and 1972 Acts. See Memorandum from Catherine A. Winer, Attorney, EPA Office of General Counsel, Water Division, to David K. Sabock, North Carolina Department of Natural Resources (Nov. 12, 1985).³² In its analysis, the attorney characterized the legislative history quoted above as “not very explicit,” and characterized the new section 401 language as “not altogether clear.” *Id.* Based on this analysis, the attorney found at that time that “the overall purpose of section 401 is clearly ‘to assure that Federal licensing or permitting agencies cannot override water quality requirements’” and that “section 401 may reasonably be read as retaining its original [*i.e.*, pre-1972] scope, that is, allowing state certifications to address any water quality standard violation resulting from an activity for which a certification is required, whether or not the violation is directly caused by a ‘discharge’ in the narrow sense.” *Id.* (citing S. Rep. No. 92–414, at 69 (1971)).

The EPA has now performed a holistic analysis of the text and structure of the CWA, the language of section 401, and the amendments made between 1970 and 1972. Based on this review, the EPA now concludes that the 1972 version of section 401 made specific changes to ensure that discharges were controlled in compliance with the 1972 CWA regulatory programs and appropriate requirements of State law. For the reasons noted above in section II.F.1 of this notice, identifying and regulating discharges, as opposed to managing ambient water quality, promotes accountability and enforcement of the Act in a way that the 1970 and earlier versions did not. The EPA also observes that, had Congress intended the 1972 amendments to retain the original scope concerning “activity,” it could have easily crafted section 401(d) to authorize certification conditions to assure that “the activity” would comply with the specified CWA provisions, but it did not. Instead, Congress’ use of the term “discharge” in section 401(a) frames the scope of the certification requirement

under the Act. As a result, the Agency now considers a more natural and more reasonable interpretation of the 1972 amendments to be that Congress rejected the idea that the scope of a certifying authority’s review or its conditions should be defined by the term “activity.” Congress specifically did not carry forward the term “activity” in the operative phrase in section 401(a) and did not incorporate it into the new provision authorizing certification conditions in section 401(d). Under basic canons of statutory construction, the EPA begins with the presumption that Congress chose its words intentionally. See, e.g., *Stone v. INS*, 514 U.S. 386, 397 (1995) (“When Congress acts to amend a statute, we presume it intends its amendment to have real and substantial effect.”). This is also consistent with the dissent in *PUD No. 1*, wherein Justice Thomas concluded that “[i]t is reasonable to infer that the conditions a State is permitted to impose on certification must relate to the very purpose the certification process is designed to serve. Thus, while § 401(d) permits a State to place conditions on a certification to ensure compliance of the ‘applicant’[,] those conditions must still be related to discharges.” *PUD No. 1*, 511 U.S. at 726–27 (Thomas, J., dissenting). The EPA has concluded that this interpretation is reasonable and the most appropriate reading of the statute and related legal authorities.

As described in detail in section II.F.4.a.i of this notice, the Supreme Court in *PUD No. 1* considered the scope of a State’s authority to condition a section 401 certification. In response to petitioners’ argument in that case that certification conditions may only be limited to the “discharge” referenced in section 401(a), the Court noted that “[t]he text refers to the compliance of the applicant, not the discharge.” *Id.* at 712. Without further analysis of the ambiguity created by the use of the term “applicant” in section 401(d), the Court concluded that “§ 401(d) is most reasonably read as authorizing additional conditions and limitations on the activity as a whole once the threshold condition, the existence of a discharge, is satisfied.” *Id.* at 712. The Court did not grapple with the range of actions that its interpretation may require of the applicant, or whether the entire range would or should be within the scope of section 401. The Court did not evaluate or find support for its interpretation in the legislative history of the 1972 amendments to the CWA, nor did the Court find that Congress had established an intent that the term

“applicant” in section 401(d) should mean “activity.” Although some have argued that the Court’s conclusion is based on a plain language interpretation of section 401(d), for the reasons explained below, the EPA disagrees. The EPA concludes that the use of the term “discharge” in section 401(a) and “applicant” in section 401(d) creates ambiguity, that the plain text of 401(d) also is ambiguous, and that neither the Court’s analysis nor its holding in *PUD No. 1* foreclose alternative interpretations.

In its discussion of the CWA, the Supreme Court in *PUD No. 1* did not analyze section 401 at “*Chevron* step one” or rely on “the unambiguous terms” of the CWA to support its reading of section 401. See *Brand X*, 545 U.S. at 982. Instead, the Court “*reasonably read*” section 401(d) “as authorizing additional conditions and limitations on the activity as a whole once the threshold condition, the existence of a discharge, is satisfied.” *PUD No. 1*, 511 U.S. at 712 (emphasis added). To support what it considered to be a reasonable reading of section 401(d), the Court looked at the EPA’s 1971 certification regulations at 40 CFR 121.2(a)(3) and related guidance available at that time, *PUD No. 1*, 511 U.S. at 712, but the Court did not have before it the EPA’s interpretation of how sections 401(a) and 401(d) could be harmonized. In fact, the Court either was not aware of or did not mention that the EPA’s 1971 certification regulations in place at that time predated the 1972 CWA amendments and therefore contained outdated terminology implementing what was functionally a different statute. As described above, the EPA’s 1971 certification regulations were consistent with the text of the pre-1972 CWA, and they required a State to certify that the “activity” will comply with the Act. The 1972 CWA amendments changed this language to require a State to certify that the “discharge” will comply with the Act.

Based in part on what the EPA now recognizes was infirm footing, the Court found that “EPA’s conclusion that activities—not merely discharges—must comply with state water quality standards is a *reasonable interpretation* of § 401 and is entitled to deference.” *Id.* (emphasis added). As *amicus curiae* in the Supreme Court, the United States did not seek *Chevron* “deference for the EPA’s regulation in [the *PUD No. 1* case]” or for the EPA’s interpretation of section 401. *Id.* at 729 (Thomas, J., dissenting). In fact, the United States’ *amicus* brief for the Court did not analyze or interpret the different

³² Available at <https://www.epa.gov/sites/production/files/2015-01/documents/standards-marinas-memo.pdf>.

language in sections 401(a) and 401(d) and instead asserted that it was unnecessary to harmonize the provisions to resolve the dispute. See Brief for the United States as Amicus Curiae Supporting Affirmance, *PUD No. 1 of Jefferson County v. Washington Dep't of Ecology*, No. 92–1911 at 12 n. 2 (Dec. 1993). The amicus brief asked the Court to analyze the two undisputed discharges from the proposed federally licensed project and to determine whether they would cause violations of the State's water quality standards. *Id.* at 11–16.

Given the circumstances of the *PUD No. 1* litigation, and the fact that the Supreme Court did not analyze section 401 under *Chevron* step 1 or rely on unambiguous terms in the CWA to support its interpretation of the statute, *PUD No. 1* does not foreclose the Agency's interpretation of section 401 in this final rule. See *Brand X*, 545 U.S. at 982–83. The Supreme Court's "choice of one reasonable reading" of section 401 does not prevent the EPA "from later adopting a different reasonable interpretation."³³ *Eurodif S.A.*, 555 U.S. at 315. An agency may engage in "a formal adjudication or notice-and-comment rulemaking" to articulate its interpretation of an ambiguous statute. *Christensen v. Harris County*, 529 U.S. 576, 587 (2000). When it does, courts apply "*Chevron*-style" deference to the agency's interpretation. *Id.* That is exactly what the EPA is doing in this final rule. The EPA has for the first time, holistically interpreted the text of sections 401(a) and 401(d) to support this update to the Agency's 1971 certification regulations while ensuring consistency with the plain language of the 1972 CWA.

c. Discharges From Point Sources to Waters of the United States

Based on the text, structure, and purpose of the Act, the history of the 1972 CWA amendments, relevant legislative history, and supporting case law, and informed by important policy considerations and the Agency's expertise, the EPA has concluded that a certifying authority's review and action under section 401 is limited to water quality impacts to waters of the United States resulting from a potential *point*

³³ The EPA is not modifying the Agency's longstanding interpretation of the Act that was confirmed by the Court in *PUD No. 1* that "a water quality standard must 'consist of the designated uses of the navigable waters involved and the water quality criteria for such waters based upon such uses'" and that "a project that does not comply with a designated use of the water does not comply with the applicable water quality standards." 511 U.S. at 714–15 (emphasis in original; quoting 33 U.S.C. 1313(c)(2)(A)).

source discharge from a proposed federally licensed or permitted project. The text of section 401(a) clearly specifies that certification is required for any federal license or permit to "conduct any activity . . . which may result in any discharge into the navigable waters" (emphasis added). Prior interpretations extending section 401 applicability beyond such waters conflict with and would render meaningless the plain language of the statute. And although the statute does not define with specificity the meaning of the unqualified term *discharge*, interpreting section 401 to cover all discharges without qualification would undercut the bedrock structure of the CWA regulatory programs, which are focused on addressing *point source* discharges to waters of the United States. CWA section 502(14) defines "point source" as "any discernible, confined and discrete conveyance, including but not limited to any pipe, ditch, channel, tunnel, conduit, well, discrete fissure, container, rolling stock, concentrated animal feeding operation, or vessel or other floating craft, from which pollutants are or may be discharged."³⁴

As described in section II.F.1 of this notice, the CWA is structured such that the federal government provides assistance, technical support, and grant money to assist States in managing *all* of the nation's waters. By contrast, the federal regulatory provisions, including CWA sections 402 and 404, apply only to *point source* discharges to waters of the United States. 33 U.S.C. 1362(7). Section 401 is the first section of Title IV of the CWA, titled Permits and Licenses, and it requires water quality-related certification conditions to be legally binding and federally enforceable conditions of federal licenses and permits. *Id.* at 1341(d). Similar to the section 402 and 404 permit programs, section 401 is a core regulatory provision of the CWA. Accordingly, the scope of its application is most appropriately interpreted, consistent with the other federal regulatory programs, as addressing point source discharges into waters of the United States.

The EPA is not aware of any court decisions that have directly addressed the scope of waters covered by section 401; however, the plain text of section 401 is clear and EPA's interpretation is supported by legislative history (see section II.G.1.b of this notice).

³⁴ In the section 404 context, point sources include bulldozers, mechanized land clearing equipment, dredging equipment, and the like. See, e.g., *Avoyelles Sportsmen's League, Inc. v. Marsh*, 715 F.2d 897, 922 (5th Cir. 1983).

Additionally, public commenters noted that many state Attorneys General submitted comments on the Agency's rulemaking to define "waters of the United States" asserting that modifying that definition would modify the scope of state review under section 401, further supporting the EPA's interpretation that section 401 is limited to waters of the United States.

In *Oregon Natural Desert Association v. Dombek*, the Ninth Circuit relied on the text and structure of section 401 to interpret the meaning of "discharge" in section 401. 172 F.3d 1092 (9th Cir. 1998). In that case, a citizen's organization challenged a decision by the U.S. Forest Service to issue a permit to graze cattle on federal lands without first obtaining a section 401 certification from the State of Oregon. The government argued that a certification was not needed because the "unqualified" term "discharge"—as used in CWA section 401—is "limited to point sources but includes both polluting and nonpolluting releases." *Id.* at 1096. Finding that the 1972 amendments to the CWA "overhauled the regulation of water quality," the court said that "[d]irect federal regulation [under the CWA] now focuses on reducing the level of effluent that flows from point sources." *Id.* The court stated that the word "discharge" as used consistently in the CWA refers to the release of effluent from a point source. *Id.* at 1098. The court found that cattle—even if they wade in a stream—are not point sources. *Id.* at 1098–99. Accordingly, the court held that certification under section 401 was not required. *Id.* at 1099.

The EPA previously suggested that the scope of section 401 may extend to nonpoint discharges to non-federal waters³⁵ once the requirement for the section 401 certification is triggered. Specifically, in the EPA's now-withdrawn Interim Handbook, the Agency included the following paragraphs,

The scope of waters of the U.S. protected under the CWA includes traditionally navigable waters and also extends to include territorial seas, tributaries to navigable waters, adjacent wetlands, and other waters. Since § 401 certification only applies where there may be a discharge into waters of the U.S., how states or tribes designate their own waters does not determine whether § 401 certification is required. Note, however, that once § 401 has been triggered due to a potential discharge into a water of the U.S., additional waters may become a consideration in the certification decision if it [sic] is an aquatic resource addressed by

³⁵ Non-federal waters refer to those waters that are not waters of the United States.

“other appropriate provisions of state [or tribal] law.”

* * * * *

Section 401 applies to any federal permit or license for an activity that may discharge into a water of the U.S. The Ninth Circuit Court of Appeals ruled that the discharge must be from a point source, and agencies in other jurisdictions have generally adopted the requirement. Once these thresholds are met, the scope of analysis and potential conditions can be quite broad. As the U.S. Supreme Court has held, once § 401 is triggered, the certifying state or tribe may consider and impose conditions on the project activity in general, and not merely on the discharge, if necessary to assure compliance with the CWA and with any other appropriate requirement of state or tribal law.

Interim Handbook, 5, 18 (citations omitted). To support the first referenced paragraph on the scope of waters, the Interim Handbook cited section 401(d), presumably referring to the use of the term “applicant” rather than “discharge” used in section 401(a).³⁶ To support the second paragraph on the scope of discharges, the Interim Handbook cited the *PUD No. 1* and *S.D. Warren* Supreme Court decisions. It appears that both paragraphs from the Agency’s Interim Handbook relied on the *PUD No. 1* Court’s interpretation of the ambiguity created by the different language in sections 401(a) and 401(d).³⁷

For many of the same reasons why the Agency is not interpreting the use of the word “applicant” in section 401(d) as broadening the scope of certification beyond the discharge itself, the Agency is also declining to interpret section 401(d) as broadening the scope of waters and the types of discharges to which the CWA federal regulatory programs apply. As an initial matter, the Agency agrees with the Ninth Circuit’s analysis and holding in *Dombeck* that section 401 certification is not required for nonpoint source discharges. *Oregon Natural Desert Association v. Dombeck*, 172 F.3d 1092, 1098–99 (9th Cir. 1998). Were the Agency to interpret the use in section 401(d) of the term “applicant” instead of the term “discharge” as authorizing the federal government to implement and enforce CWA conditions

on, or that affect, non-federal waters, that single word (“applicant”) would effectively broaden the scope of the federal regulatory programs enacted by the 1972 CWA amendments beyond the limits that Congress intended. Such an interpretation could permit the application of the CWA’s regulatory programs, including section 401 certification conditions that are enforced by federal agencies, to land and water resources more appropriately subject to traditional State land use planning authority where not otherwise preempted by federal law. *See, e.g., SWANCC*, 531 U.S. at 172–73.

As described in section II.F.4.a.i of this notice and pursuant to its authority to reasonably interpret ambiguous statutes to fill gaps left by Congress, the EPA is interpreting the language in sections 401(a) and (d) differently than the Supreme Court did in *PUD No. 1*. The Court’s prior interpretation, that once a “discharge” triggers the certification requirement in section 401(a) the certification itself may cover the entire “activity,” was not based on the plain unambiguous text of the statute, but rather was based on the Court’s own interpretation of ambiguous text in light of the interpretation of the statute set forth in the 1971 certification regulations (*see* section II.F.4.a.i of this notice). The EPA’s interpretation under this final rule is also based on a reasonable interpretation of the text, structure, and legislative history of section 401 and is informed by important policy considerations and the Agency’s expertise, and the Agency’s current rule is not foreclosed by the Court’s prior interpretation. *See Brand X*, 545 U.S. at 982.

For the reasons above, the EPA is concluding that section 401 is a regulatory provision that creates federally enforceable requirements, and for this and other reasons, its application must be limited to point source discharges into waters of the United States. This interpretation is consistent with the text and structure of the CWA as well as the principal purpose of this rulemaking, *i.e.*, to ensure that the EPA’s regulations (including those defining a section 401 certification’s scope) are consistent with the current CWA.³⁸ For further

discussion on the Agency’s interpretation and comments received on discharges under section 401, see section III.A.2.a of this notice.

2. Timeline for Section 401 Certification Analysis

Based on the language of the CWA and consistent with the relevant case law, the EPA is clarifying that a certifying authority must act on a section 401 certification within a reasonable period of time, which shall not exceed one year, and that there is no tolling provision to stop the clock at any time.

The text of section 401 expressly states that a certifying authority must act on a section 401 certification request within a reasonable period of time, which shall not exceed one year. 33 U.S.C. 1341(a)(1). Importantly, as the words “shall not exceed” suggest, the CWA does not guarantee that a certifying authority may take a full year to act on a section 401 certification request. The certifying authority may be subject to a shorter period of time, provided it is reasonable. *See Hoopa Valley Tribe v. FERC*, 913 F.3d 1099, 1104 (DC Cir. 2019) (“Thus, while a full year is the absolute maximum, it does not preclude a finding of waiver prior to the passage of a full year. Indeed, the [EPA]—the agency charged with administering the CWA—generally finds a state’s waiver after only six months.” (citing 40 CFR 121.16)). The CWA’s legislative history indicates that inclusion of a maximum period of time was to “insure that sheer inactivity by the [certifying authority] will not frustrate the Federal application.” H.R. Rep. No. 92–911, at 122 (1972).

The timeline for action on a section 401 certification must conclude within a reasonable period of time (not to exceed one year) after receipt of a certification request. *Id.*; 33 U.S.C. 1341(a)(1). The CWA does not specify any legal requirements for what constitutes a request or otherwise define the term. As discussed further in section III.C, this final rule addresses that ambiguity to provide additional clarity and regulatory certainty. Additionally,

territorial seas.”); 118 Cong. Rec. 33,692, 33,698 (1972) (“[t]he Conferees agreed that a State may attach to any Federally issued license or permit such conditions as may be necessary to assure compliance with water quality standards in that State.”); S. Rep. No. 92–411, at 69 (1971) (“This section is substantially 21(b) of existing law amended to assure consistency with the bill’s changed emphasis from water quality standards to effluent limitations based on the elimination of any discharge of pollutants.” (parentheticals omitted)); 117 Cong. Rec. 38,797, 38,855 (1971) (Mr Muskie: “Sections 401 and 402 provide for controls over discharge.”)

³⁶ Interim Handbook, at 5 n. 23. Tellingly, footnote 23 of the Interim Handbook also states, “Note that the Corps may consider a 401 certification as administratively denied where the certification contains conditions that require the Corps to take an action outside its statutory authority or are otherwise unacceptable. *See, e.g., RGL 92–04, ‘Section 401 Water Quality Certification and Coastal Zone Management Act Conditions for Nationwide Permits.’*”

³⁷ The *S.D. Warren* decision did not analyze or adopt the *PUD No. 1* Court’s analysis of sections 401(a) and 401(d).

³⁸ Although the legislative history on section 401 sometimes lacks clarity and can be internally inconsistent, the Agency’s interpretation is consistent with much of the legislative history from the 1972 amendments. *See, e.g., H.R. Rep. No. 92–911, at 124* (1972) (“It should be clearly noted that the certifications required by section 401 are for activities which may result in any discharge into navigable waters. It is not intended that State certification is or will be required for discharges into the contiguous zone or the oceans beyond the

the EPA has long recommended that a project proponent requiring a federal license or permit subject to section 401 certification hold early discussions with both the certifying authority and the federal agency, to better understand the certification process and potential data or information needs.

The CWA does not contain provisions for tolling the timeline for any reason, including to request or receive additional information from the project proponent. If the certifying authority has not acted on a request for certification within the reasonable time period, the certification requirement will be waived and the federal agency may proceed to issue the license or permit.

The final rule provides for specific timeframes for certain procedural requirements (e.g., pre-meeting filing requests, discussed in final rule preamble section III.B; and public notice when EPA acts as the certifying authority, discussed in final rule preamble section III.H). Throughout this final rule, EPA intends that the term “days” refers to calendar days as opposed to business days. For further discussion on the Agency’s interpretation of the timeline for section 401 certification analysis and related comments, see section III.F of this notice. This final rule is intended to provide greater clarity and certainty and to address some of the delays and confusion associated with the timing elements of the section 401 certification process.

III. Final Rule

This final rule is intended to make the Agency’s regulations consistent with the current text of CWA section 401, increase efficiencies, and clarify aspects of CWA section 401 that have been unclear or subject to differing legal interpretations in the past. The Agency is replacing the entirety of the 1971 certification regulations at 40 CFR part 121 with this final rule. The following sections further explain the Agency’s rationale for the final rule, provide a detailed explanation and analysis for the substantive changes that the Agency is finalizing, and respond to significant public comments received on the proposed rule.

The EPA’s 1971 certification regulations were issued when the Agency was but a few months old and the CWA had not yet been amended to include the material revisions to section 401.³⁹ In modernizing 40 CFR part 121,

this final rule recognizes and responds to significant changes to the CWA that occurred after the 1971 regulations were finalized, especially the 1972 and 1977 amendments to the CWA.

Updating the 1971 certification regulations to clarify expectations, timelines, and deliverables also increases efficiencies. Some aspects of the 1971 certification regulations have been implemented differently by different authorities, likely because the scope and timing of review were not clearly addressed in EPA’s regulations. While the EPA recognizes that States and Tribes have broad authority to implement State and Tribal law to protect their water quality, *see* 33 U.S.C. 1251(b), section 401 is a federal regulatory program that contains limitations on when and how States and Tribes may exercise this particular authority. This final rule modernizes and clarifies the EPA’s regulations and will help States, Tribes, federal agencies, and project proponents know what is required and what to expect during a section 401 certification process, thereby reducing regulatory uncertainty. For further discussion on ways the final rule will reduce regulatory uncertainty, see the Economic Analysis available in the docket for this final rule.

The EPA’s 1971 certification regulations did not fully address the public notice requirements called for under CWA section 401(a)(1). The EPA is finalizing public notice requirements applicable to the EPA as the certifying authority but is not extending these requirements to other certifying authorities. The EPA encourages certifying authorities to consider how their public notice requirements can be developed or modified to ensure timely decision-making and to work with federal licensing and permitting agencies to minimize conflicts between State program administration and the federally established reasonable period of time.

Because the EPA has frequently received requests for information regarding certifying authority requirements, the Agency solicited comment on whether it would be appropriate or necessary to require certifying authorities to submit their section 401 procedures and regulations to the EPA for informational purposes. One commenter stated that it would be useful for the EPA to compile procedures of certifying authorities and make these publicly available in one location, while another commenter

stated that it was unnecessary and inappropriate for the EPA to compile procedures of certifying authorities. Some commenters stated that it is not necessary for certifying authorities to submit their section 401 certification procedures and regulations to the EPA. One commenter noted that their procedures are public information available on the state website. Another commenter stated that a regulation that requires submittal of section 401 procedures is unnecessary and duplicative because the State already works with the EPA on section 401 procedures.

The EPA has considered these comments, and the final rule does not include a requirement for certifying authorities to submit their procedures to the EPA. However, to promote transparency and regulatory certainty, the EPA strongly encourages certifying authorities to make their certification regulations and any “water quality requirements” that may be considered during a certification process available online. In the interest of transparency, clarity, and public accessibility, the EPA may consider compiling certifying authorities’ procedures and water quality requirements on its website in the future.

In addition to the substantive changes in the final rule described below, the Agency made a number of revisions to streamline and clarify the regulatory text, and to more closely align that text to the language in section 401. These changes include revising the definitions of “Administrator” and “discharge”; replacing the language “proposed discharge location” in section 121.11(a) with “facility or activity” for consistency with section 401; revising certain text in sections 121.7(f), 121.12, and 121.16 for consistency with section 401; and removing redundant language throughout the final rule.

A. When Section 401 Certification Is Required

1. What is the Agency finalizing?

Under this final rule, the requirement for a section 401 certification is triggered based on the potential for any federally licensed or permitted activity to result in a discharge from a point source into waters of the United States. Consistent with section 401(a)(1), section 121.2 of the final rule provides that:

Certification is required for any license or permit that authorizes an activity that may result in a discharge.

This provision is modified from the proposal to provide greater clarity regarding when a certification is

³⁹ See 36 FR 22487, Nov. 25, 1971, redesignated at 37 FR 21441, Oct. 11, 1972, further redesignated at 44 FR 32899, June 7, 1979; Reorganization Plan

No. 3 of 1970 (creating the EPA), 84 Stat. 2086, effective Dec. 2, 1970.

required, but the Agency does not intend for this change to alter the meaning of the provision from the proposal. This final rule preamble also clarifies in section III.M that certification also is required before a federal agency issues a general license or permit which may result in a discharge. As discussed further below, in the final rule the term “discharge” is defined to mean a point source discharge into a water of the United States, and the term “license or permit” is defined to mean a license or permit issued by a federal agency to conduct any activity which may result in a discharge. The final rule reflects that section 401 is triggered by the potential for a discharge to occur, rather than an actual discharge.

2. Summary of Final Rule Rationale and Public Comment

Section 121.2 of the final rule is consistent with the Agency’s longstanding interpretation and is not intended to alter the scope of applicability established in the CWA.

a. “Discharge”

In section 401 and under the final rule, the presence of, or potential for, a discharge is a key element of when a water quality certification is required. Consistent with the text of the statute, under the final rule section 401 is triggered by the potential for a discharge to occur, rather than the presence of an actual discharge. The final rule defines the term “discharge” consistent with the proposal but replaces the term “navigable waters” in the proposed definition with “waters of the United States” in the final definition. This change is not intended to change the meaning of the definition; rather, it provides clarity and consistency across other CWA programs.

Many commenters agreed that the requirement for a section 401 certification is triggered by the potential for a discharge from a federally licensed or permitted activity. One commenter stated that the EPA’s reliance on an actual discharge would disregard the broad scope of section 401, which is designed to consider all potential discharges over the life of a federally licensed or permitted activity. One commenter stated that the proposed definition of “discharge” does not contemplate a potential discharge. The commenter asserted that such an interpretation would conflict with the text of section 401 which states that water quality certification applies to any “federal license or permit to conduct any activity . . . which may result in a discharge.”

The EPA agrees with commenters that the language of the statute triggers the section 401 certification requirement based on a potential discharge.⁴⁰ Section 401 is different from other parts of the Act⁴¹ and provides certifying authorities with a broad opportunity to review proposed federally licensed or permitted projects that may result in a discharge into waters of the United States within their borders. The Agency does not agree that the concept of “potential” must be incorporated into the rule text definition of “discharge” itself; the final rule provision at section 121.2 clearly states that a 401 certification is required for “an activity which *may* result in a discharge” (emphasis added).

In the proposal, the EPA requested that certifying authorities and project proponents submit comment on prior experiences with undertaking the certification process and later determining that the proposed federally licensed or permitted project would not result in an actual discharge. The EPA also requested comment on whether there are specific procedures that could be helpful in determining whether a proposed federally licensed or permitted project will result in an actual discharge, and how project proponents may establish for regulatory purposes that there is no potential discharge and therefore no requirement to pursue a section 401 certification. *See* 84 FR 44080. One commenter supported allowing the certifying authority or project proponent to determine, after the certification process is triggered, that a section 401 certification is not required where there is no actual or potential discharge. Another commenter expressed concern that this would allow the project proponent to determine that a section 401 certification is no longer required if the project proponent determines, after the section 401 certification process is triggered, that there is no actual or potential discharge. Another commenter stated that a project that is clearly defined early in the federal licensing or permitting and certification processes would help project proponents, certifying authorities, and federal agencies establish whether there is a potential

discharge, and therefore promote compliance with section 401 obligations or clarify that 401 certification is not required. One commenter supported a process for determining when a project with a potential for a discharge will result in an actual discharge. A few commenters stated that a process for determining whether or not there will be an actual discharge ignores the statutory phrase “may result in a discharge,” and they asserted that giving project proponents a role in such a process is improper because they have no authority to find that section 401 would not apply.

This final rule does not provide a process for certifying authorities or project proponents to determine whether a federally licensed or permitted project may have a potential or actual discharge. However, the federal agencies whose licenses or permits may be subject to section 401 should consider whether such procedures, if incorporated into their implementing regulations, may provide additional clarity within their licensing and permitting programs. The EPA observes that, if a certifying authority or project proponent determines after the certification process is triggered that there is no actual discharge from the proposed federally licensed or permitted project and no potential for a discharge, there is no longer a need to request or obtain certification. The EPA notes that ultimately the project proponent is responsible for obtaining all necessary permits and authorizations, including a section 401 certification. If the federal licensing or permitting agency determines that there is a potential for a discharge, as part of its evaluation of the proposed project, it may not issue the federal license or permit unless a section 401 certification is granted or waived by the certifying authority. If a project proponent requests a section 401 certification and later asserts that section 401 does not apply, the EPA recommends that the project proponent discuss the matter with, and provide supporting information and documentation to, the certifying authority and the federal agency. As provided in section 401(b) and section 121.16 of the final rule, the EPA is available to provide technical assistance throughout the section 401 process when requested to do so.

The EPA has concluded that unlike other CWA regulatory provisions, section 401 is triggered by the potential for any unqualified discharge, rather than by a discharge of pollutants. This interpretation, reflected in both the proposal and this final rule, is consistent with the text of the statute

⁴⁰ A certification is required for “a Federal license or permit to conduct any activity . . . which *may* result in any discharge into the navigable waters . . .” 33 U.S.C. 1341(a)(1) (emphasis added).

⁴¹ *See, e.g., National Pork Producers Council v. EPA*, 635 F.3d 738, 751 (5th Cir. 2011) (holding that “the EPA cannot impose a duty to apply for a permit on a [concentrated animal feeding operation] that ‘proposes to discharge’ or any CAFO before there is an actual discharge.”); *Waterkeeper Alliance, Inc. v. EPA*, 399 F.3d 486, 505 (2d Cir. 2005) (same).

and with U.S. Supreme Court precedent. In *S.D. Warren*, the Court considered whether discharges from a dam⁴² were sufficient to trigger section 401, even if those discharges did not add pollutants to waters of the United States. Because section 401 uses the term *discharge* but the Act does not provide a specific definition for the term,⁴³ the Court applied its ordinary dictionary meaning, “flowing or issuing out.” *S.D. Warren Co. v. Maine Bd. of Env’tl. Prot. et al.*, 547 U.S. 370, 376 (2006). The Court concluded that Congress intended this term to be broader than the term “discharge of pollutants” that is used in other provisions of the Act, like section 402. *See, e.g.*, 33 U.S.C. 1342, 1344; *S.D. Warren*, 547 U.S. at 380–81. For further discussion of *S.D. Warren*, see section II.F.4.a.ii of this notice, and for further discussion of discharges, see section III.A.2.a of this notice. The Court held that discharges from the dam triggered section 401 because “reading § 401 to give ‘discharge’ its common and ordinary meaning preserves the state authority apparently intended.” *S.D. Warren*, 547 U.S. at 387. The EPA’s interpretation reflected in this final rule is consistent with the Court’s conclusion.

Many public commenters addressed the proposed definition of “discharge.” Some commenters stated that the definition of “discharge” in the proposed rule should not contain the word “discharge.” Some commenters stated that the proposed rule’s definition of discharge is unnecessary because there is no ambiguity in that statutory term. Many commenters cited *S.D. Warren* to argue that the EPA’s definition of “discharge” was too narrow, and that the rule should define discharge by its common meaning, “issuing or flowing out.” Several commenters were concerned that if discharge was defined as being from a point source then the discharge would need to contain pollutants, because of the CWA definition of “point source.”⁴⁴ One commenter recommended that “discharge” be defined as “the specific outflow from a point source into navigable waters.” Another commenter asserted that *S.D. Warren* was wrongly decided and that section 401 should be

triggered only by discharges of pollutants.

The EPA has considered these comments and concludes that, given the diverse interpretations presented in public comments, including a definition of “discharge” in the section 401 certification regulations will increase clarity. Consistent with the proposal, the Agency has concluded that a discharge need not involve pollutants in order to trigger section 401. The EPA disagrees with commenters who asserted that a point source discharge necessarily requires a discharge of pollutants. The definition of point source in section 502(14) of the CWA provides that a point source is a conveyance from which pollutants are or may be discharged. A discharge of pollutants is not required for a conveyance to be considered a point source. As discussed immediately above and in section III.A.2.a of this notice, the EPA’s longstanding position is that the term “discharge” as used in section 401 is limited to point sources but includes releases regardless of whether they contain pollutants. The Agency disagrees with commenters who stated that using the term “discharge” within the definition of “discharge” creates confusion or ambiguity. Indeed, the final rule definition is consistent with the CWA section 502(16) definition of “discharge,” which also contains the term “discharge.” The EPA also disagrees with commenters who asserted that the proposed definition was narrower than the Court’s opinion in *S.D. Warren*. As noted above, the final rule’s definition is consistent with the Court’s application of the ordinary meaning of the term. Finally, the EPA disagrees with the commenter’s recommendation to define “discharge” as the specific outflow from a point source into navigable waters. The EPA has concluded that this language could be construed quite narrowly to mean a discharge from a specific “outfall” such as a pipe or outlet, while excluding discharges from dredge or fill projects.

One commenter requested that the EPA clarify that section 401 certification is required only where there is a discharge of pollutants to a water of the United States, and not simply a withdrawal of water. As discussed above, the EPA does not interpret section 401 as requiring a discharge of pollutants. However, the EPA agrees with commenters that a section 401 certification is not required for a water withdrawal that has no associated potential for a point source discharge to a water of the United States. Multiple court decisions have concluded that a water withdrawal is not a discharge and

therefore does not trigger the need for a water quality certification.⁴⁵

b. “From a Point Source”

The final rule provides that, to trigger section 401, a discharge must be from a point source. Several commenters agreed that a section 401 certification is required only where there is a point source discharge. A few commenters agreed that Title IV of the CWA focuses on point source discharges, specifically in sections 402 and 404, leading them to conclude that section 401 should apply only to point sources as well. One commenter stated that the trigger for section 401 is specifically a potential point source discharge, citing to *Oregon Natural Desert Ass’n v. Dombeck*, 172 F.3d 1092 (9th Cir. 1998). Some commenters stated that the Supreme Court in *S.D. Warren* held that the certification requirement was not limited to discharges of pollutants, but that the discharge must nonetheless be a point source discharge, citing *Dombeck*. Other commenters also referred to *S.D. Warren* to assert that the Supreme Court refused to limit the term “discharge” to only include a point source discharge. These commenters stated that the Supreme Court held that the term “discharge of pollutants” was limited to point sources and the term “discharge” was significantly broader. In doing so, many commenters took issue with the EPA’s reliance on *Dombeck*. One commenter cited *Russello v. United States*, 464 U.S. 16 (1983), to argue generically that “when ‘Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.’”

The final rule requirement that a discharge must be from a point source to trigger section 401 is consistent with case law from the Ninth Circuit, which concluded that the word “discharge” as used consistently throughout the CWA refers to the release from a point source, and that use is also appropriate for section 401. *Dombeck*, 172 F.3d at 1099. The EPA has consistently implemented the interpretation of section 401 articulated by the *Dombeck* court and adopts the Ninth Circuit’s interpretation in this final rule. The interpretation that a discharge must be a point source discharge is consistent with the structure of the Act and with the other

⁴² In *S.D. Warren*, the Court was not asked to decide whether the discharges from the dams were point source discharges.

⁴³ The Act provides, “The term ‘discharge’ when used without qualification includes a discharge of a pollutant, and a discharge of pollutants.” 33 U.S.C. 1362(16).

⁴⁴ The CWA defines point source as “any discernible, confined and discrete conveyance . . . from which pollutants are or may be discharged.” 33 U.S.C. 1362(14) (emphasis added).

⁴⁵ *See, e.g., North Carolina v. FERC*, 112 F.3d 1175, 1187 (D.C. Cir. 1997) (holding that withdrawal of water from lake does not constitute discharge for CWA section 401 purposes).

CWA regulatory programs (see section III.A.2.a of this notice).⁴⁶

The EPA disagrees with commenters who asserted that the Supreme Court in *S.D. Warren* specifically addressed whether a discharge must be from a point source. The Court's focus in *S.D. Warren* was on whether pollutants must be added to constitute a "discharge." *S.D. Warren*, 547 U.S. at 376–87. See also *ONDA v. USFS*, 550 F.3d 778, 783–84 (9th Cir. 2008) (noting that "[t]he issue in *S.D. Warren* was narrowly tailored to determine whether a discharge from a point source could occur absent addition of any pollutant to the water emitted from the dam turbines"). The Court stated that the term discharge is broader than "discharge of a pollutant" and "discharge of pollutants," but noted that "discharge" is not defined in the statute. *S.D. Warren*, 547 U.S. at 376. The Court also noted that for purposes of section 401, "neither the EPA nor FERC has formally settled the definition, or even set out agency reasoning," and the Court therefore continued to rely on the dictionary definition of the term to mean "flowing or issuing out" or "to emit; to give outlet to; to pour forth . . ." *Id.* In 2008, after the *S.D. Warren* decision was issued, the Ninth Circuit was asked to revisit its 1998 decision in *Dombeck*. In response, the Ninth Circuit held that "[n]either the ruling nor the reasoning in *S.D. Warren* is inconsistent with this court's treatment of nonpoint sources in § 401 of the Act, as explained in *Dombeck*. Accordingly, the principles of *stare decisis* apply, and this court need not revisit the issue decided in *Dombeck*." *ONDA v. USFS*, 550 F.3d 778, 785 (9th Cir. 2008). The Agency agrees.

In this final rule, the EPA is formally establishing a definition for the term "discharge" for purposes of CWA section 401 and setting out its reasoning in support of the definition. The final rule's definition is consistent with the Agency's longstanding interpretation of the statute and with relevant Ninth Circuit case law, and nothing in *S.D. Warren* or *PUD No. 1* precludes the EPA from adopting the definition in the final rule.⁴⁷

⁴⁶ See, e.g., Briefs of the United States in *ONDA v. Dombeck*, Nos. 97–3506, 97–35112, 97–35115 (9th Cir. 1997), and *ONDA v. USFS*, No. 08–35205 (9th Cir. 2008).

⁴⁷ On April 23, 2020, the United States Supreme Court issued a decision in *County of Maui, Hawaii v. Hawaii Wildlife Fund, et al.*, No. 18–260, which addressed the question whether the Clean Water Act requires a NPDES permit under section 402 of the Act when pollutants originate from a point source but are conveyed to navigable waters by groundwater. The Court held that "the statute requires a permit when there is a direct discharge

c. "Into a Water of the United States"

Consistent with the proposal, the final rule reflects that section 401 is triggered by a potential discharge into a water of the United States. 33 U.S.C. 1341(a)(1), 1362(7). Potential discharges into State or Tribal waters that are not waters of the United States do not trigger the requirement to obtain section 401 certification. *Id.* at 1342(a)(1).

Many commenters agreed that certification is required where there is a discharge into a water of the United States. Some of these commenters agreed that section 401 would not apply to non-federal waters. A couple of commenters expressed concern that by limiting the requirement for a section 401 certification to activities that discharge directly to waters of the United States, there would be many federally permitted projects where section 401 certification would not be required even though discharges from those projects could impact State or Tribal waters. A few commenters argued that the EPA's deference to States has been inconsistent, noting that the Agency's proposed rulemaking to define "waters of the United States" placed strong emphasis on States' authority to protect their water resources, while the proposed section 401 rulemaking reduces States' authority to protect their water resources. These commenters said that they had difficulty reconciling the States' expanded role under the "waters of the United States" rule with the diminished role of States in the proposed rule.

The final rule's interpretation that a discharge must be into a water of the United States to trigger the section 401 certification requirement is consistent with the plain text of the statute, is supported by the legislative history, and is consistent with other CWA regulatory program requirements that apply to discharges to waters of the United States, not discharges to State or Tribal waters. *Id.*; see also H.R. Rep. No. 92–911, at 124 (1972) ("It should be clearly noted that the certifications required by section 401 are for activities which may

from a point source into navigable waters or when there is the functional equivalent of a direct discharge." Op. at 15 (emphasis in original). The Court articulated a number of factors that may prove relevant for purposes of section 402 permitting. *Id.* at 16. Consistent with the Court's decision, if a discharge of a pollutant is determined to require a federal permit under section 402 as the functional equivalent of a direct discharge, it will also be subject to section 401 because, as discussed above, the term "discharge" under section 401 includes a discharge of a pollutant subject to section 402. *S.D. Warren Co. v. Maine Bd. of Env'tl. Prot.*, 547 U.S. 370, 375 (2006) (citing 33 U.S.C. 1362(16)). This conclusion is consistent with the Court's decision in *Maui*.

result in any discharge into *navigable waters.*") (emphasis added); see also section III.A.2.a of this notice for discussion on discharges to waters of the United States. The EPA disagrees with commenters who suggested that this rule is inconsistent with the recently finalized rule defining "waters of the United States." Both rules are intended to provide clarity on the scope of federal authority and State or Tribal authority to regulate certain waters. The final definition of "waters of the United States" reestablishes the appropriate balance between waters subject to federal regulation and those waters or features that are subject to exclusive State or Tribal jurisdiction. As described further in section II.F of this notice, section 401 provides a role for States and authorized Tribes to participate in federal license or permitting processes, including those in which they may otherwise be preempted by federal law. States and Tribes retain authority to regulate and protect waters of the State or Tribe in accordance with State and Tribal law and where not preempted by federal law. As explained in detail in the proposed rule preamble, section 401 is a federal regulatory provision, as certification conditions are incorporated into federal licenses and permits and are enforceable by the federal government. If section 401 was expanded to cover activities with discharges to non-federal waters, such an expansion would authorize the federal government to regulate waters and features that are beyond the scope of CWA regulatory authority; Congress did not intend these waters to be subject to federal regulation.

d. Federal License or Permit

Section 401 certification requirements are triggered when a project proponent applies for a federal license or permit to conduct an activity which may result in any discharge into a water of the United States. 33 U.S.C. 1341(a)(1). However, in those cases where a federal agency discharges dredged or fill material into waters of the United States but does not issue itself a license or permit, the Corps' regulations require reasonable and appropriate efforts to demonstrate compliance with effluent limitations and state water quality standards, which typically includes seeking certification.⁴⁸ Consistent with the

⁴⁸ See Appendix C of Engineer Regulation 1105–2–100; 33 CFR 335.2 ("[T]he Corps does not issue itself a CWA permit to authorize Corps discharges of dredged material or fill material into U.S. waters, but does apply the 404(b)(1) guidelines and other substantive requirements of the CWA and other environmental laws.").

proposal, the final rule defines the term “license or permit” to mean “any license or permit granted by an agency of the Federal Government to conduct any activity which may result in a discharge.”

The CWA does not list specific federal licenses and permits that are subject to section 401 certification requirements. The EPA believes that the most common examples of licenses or permits that may be subject to section 401 certification are CWA section 402 NPDES permits issued by EPA in States where the EPA administers the NPDES permitting program; CWA section 404 permits for the discharge of dredged or fill material and Rivers and Harbors Act sections 9 and 10 permits issued by the Army Corps of Engineers; and hydropower and interstate natural gas pipeline licenses issued by FERC. The final rule does not provide an exclusive list of federal licenses and permits that may be subject to section 401. Instead, the final rule focuses on whether there is potential for the activity authorized by the federally issued license or permit to result in a discharge from a point source into a water of the United States.

A few commenters requested clarification on the requirement for a federal license or permit to trigger the need for a section 401 certification. One commenter asserted that the proposal was unclear because the proposed regulatory text did not tie the need for a section 401 certification to an application for a federal license or permit. The EPA disagrees with the suggestion that the proposal does not tie the need for a section 401 certification to the application for a federal license or permit. Section 121.2 of the proposed rule stated that “any applicant for a license or permit to conduct any activity which may result in a discharge shall provide the Federal agency a certification from the certifying authority . . .” As noted above, the proposal and this final rule define the term “license or permit” as one issued by a federal agency.

A few commenters suggested that additional language be added to the proposed definition of “discharge” to clearly describe what constitutes a point source, including language concerning equipment and construction activities associated with the discharge of dredged or fill material. The EPA believes that defining “point source” in the final rule is unnecessary in light of the statutory definition (33 U.S.C. 1362(14)) and court decisions concluding that bulldozers, mechanized land clearing machinery, and similar types of

equipment used for discharging dredge or fill material are “point sources.”⁴⁹

Another commenter asserted that States have required facilities to obtain a section 401 certification where the facility has a permit from a State with delegated authority under section 402. Section 401 certification is not required for State- or Tribally-issued permits when the State or Tribe has assumed operation of the permit program in lieu of the federal government.⁵⁰ The CWA statutory language is clear that the license or permit triggering the need for a section 401 certification must be a federal license or permit, that is, one issued by a federal agency. Implementation of a State or Tribal permit program in lieu of the federal program does not “federalize” the resulting licenses or permits for purposes of section 401. Section 401 certification does not apply to those authorizations issued by the State or Tribe.⁵¹ The CWA anticipates that States and Tribes issuing those permits will ensure consistency with CWA provisions and other appropriate requirements of State and Tribal law as part of their permit application evaluation.

One commenter noted that the proposal indicated that the Corps does not process and issue permits for its own activities and stated that federal agencies should be subject to the same certification request submittal requirements as non-federal agency

⁴⁹ See, e.g., *Avoyelles Sportsmen's League v. Marsh*, 715 F.2d 897 (5th Cir. 1983); *U.S. v. Larkins*, 657 F.Supp. 76 (W.D. Kent. 1987), *aff'd*, 852 F.2d 189 (6th Cir. 1988).

⁵⁰ State or Tribal implementation of a license or permit program in lieu of the federal program, such as a CWA section 402 permit issued by an authorized state, does not federalize the resulting licenses or permits and therefore does not trigger section 401 certification. This conclusion is supported by the legislative history of CWA section 401, which noted that “since permits granted by States under section 402 are not Federal permits—but State permits—the certification procedures are not applicable.” H.R. Rep. No. 92–911, at 127 (1972). The legislative history of the CWA amendments of 1977, discussing state assumption of section 404, also noted that “[t]he conferees wish to emphasize that such a State program is one which is established under State law and which functions in lieu of the Federal program. It is not a delegation of Federal authority.” H.R. Rep. No. 95–830, at 104 (1977).

⁵¹ As described elsewhere in this notice, the Corps’ existing certification regulations provide a reasonable period of time of 60 days for federally issued CWA section 404 permits. 33 CFR 325.2(b)(1)(ii); see also final rule preamble section III.F. To the extent that certifying authorities believe that this timeline is too short to provide certification for a Federally issued section 404 permit, States are authorized to assume administration of that program for certain waters. 40 CFR 233; see also *Final Report of the Assumable Waters Subcommittee* (May 2017), available at <https://www.epa.gov/cwa404g/nacept-assumable-waters-subcommittee-final-report-may-10-2017>.

project proponents. In response, the EPA notes that the CWA ties the requirement for a section 401 certification to a federal license or permit. As a result, in circumstances where there is no federal license or permit, including when federal agency activities do not require a license or permit, section 401 certification is not required. Nonetheless, the Corps’ current regulations indicate that section 401 requires the Corps to seek section 401 certification for dredge and fill projects involving a discharge into waters of the United States, regardless of whether the Corps issues itself a permit for those activities.⁵²

B. Pre-Filing Meeting Request

1. What is the Agency finalizing?

The EPA proposed to establish a pre-filing meeting process when the EPA is the certifying authority to ensure that the Agency receives early notification of anticipated projects and can discuss information needs with the project proponent. Many commenters stated that it would be helpful for project proponents to request pre-filing meetings with all certifying authorities (not just the EPA), although most commenters did not say that certifying authorities should be required to accept such meetings. In light of these comments, and because the benefits of the pre-filing process are applicable regardless of the identity of the certifying authority, the EPA is finalizing a requirement that all project proponents, including federal agencies when they seek certification for general licenses or permits, submit a request for a meeting with the appropriate certifying authority at least 30 days prior to submitting a certification request.⁵³ The final rule requires only that the project proponent request the pre-filing meeting and leaves to the discretion of the certifying authority whether a pre-filing meeting may be

⁵² See 33 CFR 336.1(a)(1) (“The CWA requires the Corps to seek state water quality certification for discharges of dredged or fill material into waters of the U.S.”).

⁵³ The EPA recognizes that some activities conducted in response to a hurricane or other similar event may require emergency procedures that do not allow for compliance with pre-request meeting procedures. Federal licensing and permitting agencies should establish such emergency procedures by regulation to ensure that project proponents, certifying authorities, and the public are made aware of the types of circumstances that could prevent compliance with ordinary pre-filing meeting request requirements. Nothing in this final rule precludes federal agencies from establishing emergency procedures to ensure continuation of operations or other appropriate emergency procedures, including procedures that may not allow for compliance with pre-request meeting procedures.

necessary or appropriate for a particular project. The meeting request itself provides advance notification to the certifying authority that a certification request may be forthcoming and therefore promotes early coordination, even when the certifying authority does not hold a pre-filing meeting.

2. Summary of Final Rule Rationale and Public Comment

The EPA is expanding the proposed pre-filing meeting request requirement, and under this final rule, all project proponents, including federal agencies when they seek certification for general licenses or permits, must submit a request for a pre-filing meeting with the appropriate certifying authority at least 30 days prior to submitting a certification request. This requirement will ensure that certifying authorities receive early notification and have an opportunity to discuss the project and potential information needs with the project proponent before the statutory timeframe for review begins. The final rule also encourages the certifying authority to take actions to initiate coordination with the Federal agency after receiving the pre-filing meeting request.

In order to facilitate early engagement and coordination, and using its discretion to interpret the term “request” as applied to certification procedures, the EPA is finalizing a regulatory requirement in section 121.4 of the final rule that all project proponents must submit a request for a pre-filing meeting at least 30 days in advance of submitting a certification request. Under the final rule, certifying authorities are given an opportunity to accept or host such a pre-filing meeting, but they retain discretion to decline the request or simply not respond. Under the final rule, if the certifying authority does not respond to the request, the project proponent may submit a certification request as long as it includes documentation, as required in section 121.5 of the final rule, that it requested the pre-filing meeting at least 30 days prior to submitting the certification request.

In addition to requiring the project proponent to request a pre-filing meeting, the proposed rule would have required EPA to respond within a certain period of time and also required the parties to discuss certain topics and to be prepared to share certain information during the pre-filing meeting. The final rule no longer requires those additional procedures and instead encourages certifying authorities, project proponents and federal licensing and permitting

agencies to engage in early coordination. Under the final rule, if the certifying authority grants the pre-filing meeting, the project proponent and the certifying authority are encouraged to discuss the nature of the proposed project and potential water quality effects. The final rule also encourages the project proponent to provide a list of other required State, interstate, Tribal, territorial, and federal authorizations and to describe the anticipated timeline for construction and operation. After receiving the pre-filing meeting request, the certifying authority is encouraged to contact the federal agency and to identify points of contact, so as to facilitate information sharing between the certifying authority and Federal agency throughout the certification process. In the final rule, the EPA encourages these important steps to help promote an efficient certification process. These recommendations are consistent with many recommendations in EPA’s 2019 Guidance (which EPA is rescinding in this action, as no longer necessary in light of this final rule) as well as with recommendations made in the proposed rule preamble.

The Agency believes that the term “request” as used in the statute is broad enough to include an implied requirement that, as part of the submission of a request for certification, a project proponent also provide the certifying authority with advance notice that a certification request is imminent. The relatively short time (no longer than one year and possibly much less) that certifying authorities are provided under the CWA to act on a certification request (or else waive the certification requirements of section 401(a)) provides additional justification in this context to interpret the term “request for certification” to allow the EPA to require a pre-filing meeting request.

Many commenters supported the EPA’s proposal to require project proponents to request pre-filing meetings. Several commenters supported the proposed pre-filing process where the EPA is the certifying authority, while others supported extending it to all certifying authorities. Several commenters stated that such meetings, while useful for a variety of purposes (e.g., identifying what information may be needed from a project proponent), should not be mandatory. Other commenters stated that such meetings should be used only for complex, non-routine projects. Some commenters asserted that the pre-filing process could penalize States who choose not to attend pre-filing meetings, even though it may not be feasible or necessary in all instances, and argued

that the EPA should not seek to supplant a State’s expertise on when a pre-filing meeting is necessary. Several commenters noted that some States have established their own pre-filing meeting requirements and should be encouraged to develop their own criteria, including choosing whether to hold such pre-filing meetings. Additionally, some commenters felt that the proposed 30-day notice for such meetings was too short, while another commenter requested that the EPA provide “safeguards” to ensure that States do not use the pre-filing meeting as an opportunity to request unreasonable information or studies that would delay a certification request. Some commenters noted that while likely to yield useful information, the proposed regulations lack a means of enforcing the pre-filing procedures and asserted that the process could reward applicants who fail to cooperate with pre-filing procedures. Some commenters noted that the proposal did not include expected outcomes from such early collaboration and asserted that this could result in inadequate certification requests. Some commenters stated that the EPA’s proposal did not include sufficient guidance on best practices for pre-filing meetings, such as what information the project proponent should be prepared to share with the certifying authority.

The EPA agrees with commenters who stated that pre-filing meetings would generally improve early coordination and promote efficiency in section 401 certification decision-making, although the utility of such meetings could depend on the complexity of the project and resources of the certifying authority. The EPA also agrees with commenters who stated that pre-filing meetings under the final rule should have an accountability mechanism, and thus the final rule requires the project proponent to include documentation of its pre-filing meeting request in any certification request filed with the certifying authority (*see* section III.C of this notice). The EPA recommends that project proponents submit a pre-filing meeting request in writing and maintain a copy of the written request, as the final rule requires such documentation to be submitted in a certification request. If a project proponent does not submit a pre-filing meeting request or does not maintain documentation that it made the request, the subsequent certification request will not meet the requirements of the final rule, and in such circumstances the reasonable period of time would not start.

The final rule does not set a limit on how early a project proponent may submit a pre-filing meeting request or initiate discussions with a certifying authority in order to encourage early and ongoing coordination between the project proponent and the certifying authority. The Agency disagrees with the suggestion that a pre-filing meeting requirement could delay a certification request. Even if the certifying authority does not agree to meet, the project proponent is free to submit a certification request 30 days after submitting the meeting request. *See* section III.C of this notice. In some cases, a project proponent may find it beneficial to engage with a certifying authority well in advance of the 30-day pre-filing meeting period, particularly for complex projects. The 30-day period after submittal of the pre-filing meeting request and prior to the submission of a certification request provides an opportunity for the project proponent to verify whether a section 401 certification is required and for the certifying authority to identify potential information, in addition to the certification request requirements in this rule, that may be necessary for the certifying authority to act on the certification request. Ultimately, the Agency believes that this provision of the final rule will allow for a more efficient and predictable certification process for all parties.

Under the final rule, certifying authorities are not required to grant pre-filing meeting requests. The EPA has determined that certifying authorities are in the best position to determine when a pre-filing meeting is necessary to help ensure that they receive all necessary information to act on certification requests within the reasonable period of time. The Agency encourages project proponents and certifying authorities to use the pre-filing meeting to discuss the proposed project and to determine what information is needed to enable the certifying authority to act on the certification request in the reasonable period of time. Additionally, certifying authorities and project proponents may use the pre-filing meeting to discuss other appropriate water quality requirements that may be applicable to the certification request and any necessary procedural requirements (*e.g.*, ascertain whether the State or Tribe requires any fees). The EPA expects that certifying authorities may take advantage of a pre-filing meeting request for larger or more complex projects and might choose to decline the request for more routine and less complex projects.

The pre-filing meeting may be conducted in-person, or remotely (through telephone, online, or other virtual platforms), as deemed appropriate by the certifying authority.

Certifying authorities are encouraged to develop pre-filing meeting procedures tailored to identify information that may be needed to review and act on a certification request. Such procedures could vary depending on the project type, project complexity, or the triggering federal license or permit, to enable greater efficiency and predictability in the certification process. The Agency emphasizes that any pre-filing meeting procedures or pre-filing expectations developed or promulgated by certifying authorities cannot modify the requirements for a certification request established in this final rule. The EPA also notes that any new State or Tribal pre-filing meeting procedures may not be used to extend the 30-day timeline following a pre-filing meeting request for project proponents to submit a certification request, nor may pre-filing meeting procedures be used to extend or modify the reasonable period of time established by a Federal agency. The EPA believes that requiring a pre-filing meeting request too early could be an abuse of the process and result in an unreasonable extension of the reasonable period of time that Congress envisioned, which is not to exceed one year. Rather, such procedures should be focused on allowing both the project proponent and the certifying authority an opportunity to develop a common understanding and expectation of the types of information that may be necessary for a certifying authority to act on a certification request consistent with section 401 and this final rule.

Some commenters asserted that pre-filing meetings should not limit a State's ability to request additional information after a certification request has been made. Other commenters did not think that pre-filing meetings should preclude project proponents from withdrawing and resubmitting certification requests to extend the reasonable period of time, which they stated is sometimes necessary for complex projects. Under the final rule, the pre-filing meeting request requirement does not affect a certifying authority's ability to request additional information from a project proponent once the reasonable period of time has started (*see* section III.F.2.a of this notice), but such information requests cannot operate to extend the reasonable period of time (*see* section III.F for further discussion on how certifying authorities may request an extension to the reasonable period of

time from the federal agency). This requirement also does not affect the ability of project proponents to withdraw a certification request voluntarily (*see* section III.F of this notice). The Agency disagrees with commenters who asserted that the pre-filing meeting request requirement would penalize certifying authorities who choose not to avail themselves of the pre-filing meeting; accepting a pre-filing meeting is not a mandatory requirement. The Agency anticipates that certifying authorities will act in good faith when evaluating pre-filing meeting requests and identifying information they may need to review and act on a certification request. The Agency notes that early engagement and coordination, including participation in a pre-filing meeting, may help increase the quality of information that is provided by project proponents and may reduce the need for the certifying authority to make additional information requests during the reasonable period of time.

In addition to pre-filing meetings between certifying authorities and project proponents, commenters also suggested a variety of ways in which federal agencies could facilitate information-sharing prior to the certifying authority's receiving a certification request. For example, one commenter expressed support for advance coordination between States and federal agencies to streamline federal licensing and permitting actions. A couple of commenters suggested that federal agencies should notify States and Tribes of projects that require a section 401 certification as soon as possible. One of these commenters stated that the coordination between State and federal environmental review requirements and processes should be done without diminishing section 401 certification authority. Another commenter objected to federal agency use of pre-filing meetings to inform the duration of the reasonable period of time for review for certification actions, unless there were clear inputs and outcomes for such meetings.

The EPA recognizes that federal agencies are uniquely positioned to promote pre-filing coordination with certifying authorities and with project proponents, so as to harmonize project planning activities and to promote timely action on certification requests. The Agency acknowledges that other federal agencies may provide for pre-filing discussions in their regulations, *see, e.g.*, 18 CFR 5.1(d)(1) and 33 CFR 325.1(b), and recognizes that many certifying authorities and federal agencies already have coordination

memos, memoranda of agreement, or other cooperative mechanisms in place. The Agency is not finalizing specific requirements for federal agency coordination with certifying authorities (except when federal agencies are themselves seeking certification, *see* section III.M of this notice). However, if there is a pre-application process required or facilitated by the federal licensing or permitting agency and if the timing of that process would allow the project proponent to request a pre-filing meeting from the certifying authority at least 30 days before submitting a certification request, then a joint meeting among federal agencies, certifying authorities, and project proponents could also be used as the pre-filing meeting for a certification request.

In general, the EPA encourages federal agencies to notify certifying authorities as early as possible about proposed projects that may require a section 401 certification. Additionally, the EPA encourages federal agencies (1) to timely respond to requests from certifying authorities for information concerning the proposed federal license or permit, and (2) to the extent consistent with agency regulations and procedures, provide technical and procedural assistance to certifying authorities and project proponents upon request. The EPA also encourages project proponents and certifying authorities to engage in any additional pre-filing discussion opportunities that may facilitate greater communication and information sharing, and therefore a more efficient and informed certification decision.

C. Certification Request/Receipt

1. What is the Agency finalizing?

Under this final rule, a project proponent must submit a certification request to a certifying authority to initiate an action under section 401. Consistent with the text of the CWA, the final rule provides that the statutory timeline for certification review starts when the certifying authority receives a “certification request,” rather than when the certifying authority receives a “complete application” or “complete request” as determined by the certifying authority. After considering public comments, the final rule has been revised to provide a general definition of “certification request” and provide two different lists of documents and information that must be included in a certification request: One list for individual licenses and permits and a separate list for the issuance of a general license or permit. The certification request requirements, as well as other

provisions of the final rule tailored to the issuance of general licenses and permits, are described in detail in section III.M of this notice.

To better account for water quality certifications required for general licenses or permits, the definition of “project proponent” has been modified as follows pursuant to section 121.1(j) of the final rule:

Project proponent means the applicant for a license or permit or the entity seeking certification.

This final rule’s definition of “project proponent” extends all of the substantive and procedural requirements in this final rule to federal agencies seeking certification for a general license or permit.

Pursuant to section 121.1(c) of the final rule,

Certification request means a written, signed, and dated communication that satisfies the requirements of section 121.5 (b) or (c).

Section 121.5(b) of the final rule includes an enumerated list of documents and information that must be included in a certification request for an individual license or permit, including the seven components from the proposed rule and two new components. A certification request must include all components to start the statutory clock. A certification request submitted for an individual license or permit shall:

1. identify the project proponent(s) and a point of contact;
2. identify the proposed project;
3. identify the applicable federal license or permit;
4. identify the location and nature of any potential discharge that may result from the proposed project and the location of receiving waters;
5. include a description of any methods and means proposed to monitor the discharge and the equipment or measures planned to treat, control, or manage the discharge;
6. include a list of all other federal, interstate, tribal, state, territorial, or local agency authorizations required for the proposed project, including all approvals or denials already received;
7. include documentation that a pre-filing meeting request was submitted to the certifying authority at least 30 days prior to submitting the certification request;
8. contain the following statement: *‘The project proponent hereby certifies that all information contained herein is true, accurate, and complete, to the best of my knowledge and belief;’* and
9. contain the following statement: *‘The project proponent hereby requests that the certifying authority review and*

take action on this CWA 401 certification request within the applicable reasonable period of time.’

The statutory reasonable period of time for a certifying authority to act on a certification request begins when the certifying authority is in “receipt of such request.” The EPA is finalizing the definition of the term “receipt” as proposed:

Receipt means the date that a certification request is documented as received by a certifying authority in accordance with applicable submission procedures.

Together, these provisions will provide greater certainty for project proponents, certifying authorities, and federal agencies concerning when the reasonable period of time has started. Each of these provisions is discussed in greater detail below.

2. Summary of Final Rule Rationale and Public Comment

The Act places the burden on the project proponent to obtain a section 401 certification from a certifying authority in order to receive a federal license or permit. As discussed in the preamble to the proposed rule, the section 401 certification process begins on the date when the certification request is received by a certifying authority. The statute limits the time for a certifying authority to act on a request as follows:

If the State, interstate agency, or Administrator, as the case may be, fails or refuses to act on a *request for certification*, within a reasonable period of time (which shall not exceed one year) after *receipt* of such request, the certification requirements of this subsection shall be waived with respect to such Federal application.

33 U.S.C. 1341(a)(1) (emphasis added). The plain language of the Act requires that the reasonable period of time to act on certification not extend beyond one year after the receipt of the certification request. The statute, however, does not define those terms. As discussed in the preamble to the proposed rule, because they are not defined and their precise meaning is ambiguous, these terms are susceptible to different interpretations. This ambiguity has resulted in inefficiencies in the certification process; individual certification decisions that have extended beyond the statutory reasonable period of time; regulatory uncertainty; and litigation. *See* section II.F of this notice. As the Agency charged with administering the CWA, the EPA is authorized to interpret through rulemaking undefined terms, including those associated with CWA section 401 certifications. *See Chevron,*

U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 844 (1984). Given the large number of certification requests submitted each year⁵⁴ and the statutory requirement that those requests be acted on within a reasonable period of time not to exceed one year, the EPA is finalizing definitions for the terms “certification request” and “receipt” to provide project proponents, certifying authorities, and federal agencies with clear regulatory text stating when the statutory reasonable period of time begins.

The EPA is finalizing a definition for “certification request” that requires a written, signed, and dated communication that satisfies the requirements of section 121.5(b) or (c) of the final rule. A certification request that meets the requirements of the final rule begins the certifying authority’s reasonable period of time. The structure of the final rule is somewhat different than the proposal because, as described above, the final rule contains two separate lists for certification requests; however, the purpose and function of the “certification request” remains consistent with the proposal.

Commenters provided numerous recommendations for what should be included in a certification request, including but not limited to information on prior contamination at the project site, payment of applicable fees, specific project proponent contacts, specific geographic information, construction and mitigation plans, engineering plans, sediment sampling plans, aquatic resources and their condition, the characteristics of the discharge, description of all affected wetlands and waters, State-listed species information and habitat assessments, baseline data and information, and the complete federal license or permit application, as well as a statement from the project proponent that all information is true and correct. Conversely, a few commenters recommended removing the specific components of a “certification request” and argued that the proposed information was not necessary for a certifying authority to act on a request for certification. The EPA considered all of these comments and made some modifications in the final rule. The final definition of “certification request” requires that the project proponent’s written submission contain the components identified in either section 121.5(b) or (c) of the final rule.

Section 121.5(b) of the final rule addresses certification requests

submitted by project proponents, as the term is defined in the final rule, and it requires the seven components listed in the proposed definition, with a slight modification in one component, as well as two additional components: A statement that all information contained in the request is true, accurate, and complete to the best of the project proponent’s knowledge, and documentation that a pre-filing meeting request was submitted to the certifying authority at least 30 days prior to submitting the certification request. These additional components are discussed further below. The Agency has modified the fourth factor in the final rule to require project proponents to identify the location and the *nature of any potential discharge* that may result from the proposed project and the location of receiving waters. This modification clarifies that project proponents should identify the nature of the discharge, including (as appropriate) the potential volume, extent, or type of discharge associated with the proposed project. This modification is similar to the modification made in the factors to be considered by a federal agency when setting the reasonable period of time. See section III.F for further discussion. The inclusion of this information will provide the certifying authority with clear notice that the project proponent has submitted a certification request and a sufficient baseline of information to allow it to begin its evaluation in a timely manner.

The Agency requested comment on whether it should include a reference to “any applicable fees” among the components of its definition of a certification request. Many commenters stated that a certifying authority’s applicable fees should be a required element in the final rule. One commenter suggested that applicable fees for a section 401 certification might be affected by the type of federal license or permit for which they are applying. After considering all of the public comments on this issue and conducting additional research into whether and how certifying authorities may require fees for section 401 certifications, the EPA has decided not to include a reference to fees in the enumerated list of elements of a certification request. States vary in how and when they require fees in the certification process. They have different fee structures and different requirements for the timing of paying a certification-related fee. The Agency encourages the project proponent and the certifying authority to discuss during the pre-filing meeting the certifying authority’s fee structure

and the project proponent’s obligation, if any, to pay a fee related to the section 401 certification. Given the States’ differing practices in this area, the final rule does not include proof of fee payment as a required component of a certification request to trigger the statutory timeframe for State or Tribal action.

Consistent with the proposal, the final rule requires a project proponent to identify the location of any potential discharge in the certification request. To meet this requirement, the EPA recommends that the project proponent provide locational information about the extent of the project footprint and all potential discharge locations, as shown on design drawings and plans. The EPA recommends that project proponents be prepared to provide underlying geographic data such as shapefiles or geodatabases. Alternatively, the project proponent should consider identifying potential discharge locations on hard copy maps. The Agency acknowledges that the appropriate format and method to identify potential discharge locations may change with evolving technology and recommends that project proponents and certifying authorities discuss the best approach to providing the information required for the certification request.

The EPA received comments from the public and feedback from other federal agencies that the categories of information identified in the proposed definition of certification request may not be appropriate for a federal agency seeking section 401 certification for a general license or permit. For example, at the time of certification, a federal agency may not know the location of every potential discharge that may in the future be covered under a general license or permit. In response to these comments and to improve the utility and clarity of the final rule, the Agency is also finalizing in section 121.5(c) of the final rule a separate list of documents and information required for a “certification request for issuance of a general license or permit.” See section III.M of this notice for further discussion of the certification process for general licenses or permits.

The Agency received public comments emphasizing the efficiencies that can be gained by federal agencies issuing general licenses and permits, such as general NPDES permits issued by the EPA and Nationwide or Regional section 404 general permits issued by the Corps. A few commenters stated that federal agencies should follow procedures that are consistent with other project proponents when submitting certification requests and

⁵⁴ See section 2 of the Economic Analysis.

complying with other aspects of the rule. The EPA agrees with commenters that consistent procedural and substantive requirements for all water quality certifications would promote regulatory certainty for project proponents, federal agencies, and certifying authorities and has modified the final rule definition of “project proponent” to promote consistent water quality certifications. Section 121.1(j) of the final rule defines “project proponent” to mean “the applicant for a license or permit or the entity seeking certification.” With this modified definition, the final rule clarifies that federal agencies that issue general licenses or permits must comply with all of the procedural and substantive requirements of this final rule.

Consistent with the proposal, sections 121.5(b) and (c) of the final rule include the following statement—“*The project proponent hereby requests that the certifying authority review and take action on this CWA 401 certification request within the applicable reasonable period of time.*” This requirement is intended to remove any potential ambiguity on the part of the certifying authority about whether the written request before it is, in fact, a “certification request” that triggers the statutory timeline. One commenter noted that, if a project proponent is uncertain whether the certifying authority will be able to certify its project within the reasonable period of time, the project proponent could submit a non-compliant certification request that omits one or more components, which would prevent the reasonable period of time clock from starting. The Agency agrees with this commenter that if a project proponent does not submit a certification request as defined at section 121.5(b) of the final rule, then the reasonable period of time does not begin. The Agency encourages pre-filing meetings, engagement, and information sharing between project proponents and certifying authorities, but such engagement does not start the reasonable period of time unless a certification request, as defined in the final rule, is submitted to the certifying authority.

Sections 121.5(b) and (c) of the final rule include two additional provisions that were not in the proposed rule: A statement that all information contained in the certification request is true, accurate, and complete to the best of the requester’s knowledge and belief, and documentation that a pre-filing meeting request was submitted to the certifying authority at least 30 days prior to submitting the certification request. Both requirements are intended to

create additional accountability on the part of the project proponent to ensure that information submitted in a certification request accurately reflects the proposed project, and to ensure that the project proponent has complied with the requirement to request a pre-filing meeting with the certification authority. If a certification request does not include these components, it does not meet the conditions of section 121.5(b) or (c) of the final rule and it does not start the statutory clock.

Notwithstanding the text of section 401(a)(1), which refers to a “request for certification,” some commenters asserted that requiring a “certification request,” as opposed to a “complete application,” contravened congressional intent and cooperative federalism, and represented a change in the EPA’s longstanding practice. As discussed in the preamble to the proposed rule, section 401 does not use the term “complete application” or prescribe what a “certification request” would require. The reference in prior EPA guidance to a “complete application,” without explaining what an “application” must include, has led to inconsistent and subjective determinations about the sufficiency of certification request submittals. This, in turn, has caused uncertainty about when the statutory reasonable period of time begins to run. The Agency is authorized to interpret ambiguous statutory terms, *see Chevron*, 467 U.S. at 844, and is finalizing what it deems the most appropriate, reasonable interpretation of “certification request” to reduce uncertainty and enable project proponents and certifying authorities to objectively and transparently understand which submittals start the reasonable period of time.

Some commenters also asserted that a standardized definition of “certification request” cannot capture all of the kinds of information necessary for the certifying authority to make an informed decision on a certification request. They expressed concern that project proponents would be incentivized to circumvent a certifying authority’s meaningful review by not providing additional information. Additionally, some commenters suggested that certifying authorities should be given the flexibility to develop their own definition of a “request” or “application” to meet their applicable State and Tribal laws and needs. While the Agency acknowledges these commenter concerns, the EPA disagrees. As discussed above, the Agency is authorized to interpret the term “certification request” because the Act does not define the term, nor does it

prescribe the amount of information that must be included in a certification request. *See Chevron*, 467 U.S. at 844. In this final rule, the Agency is interpreting “certification request” to include components that the Agency believes are necessary to provide a certifying authority with clear notice that a request has been submitted and a sufficient baseline of information for the certifying authority to begin its review. It is important to distinguish between the amount of information appropriate to start the certifying authority’s reasonable period of time and the amount of information that may be necessary for the certifying authority to take final action on a certification request. The components of a “certification request” identified in the final rule are intended to be sufficient information to start the reasonable period of time but may not necessarily represent the totality of information a certifying authority may need to act on a certification request. Nothing in the final rule’s definition of “certification request” precludes a project proponent from submitting additional, relevant information or precludes a certifying authority from requesting and evaluating additional information within the reasonable period of time (*see* section III.H of this notice for specific procedures when the EPA is the certifying authority). Indeed, in many cases it may be in the interest of the project proponent and may provide a more efficient certification process if relevant information about the discharge and potential impacts to the receiving waters is provided to the certification authority early in the certification process.

As discussed in section III.B of this notice, the Agency is finalizing a pre-filing meeting request requirement for all project proponents, including federal agencies when they seek a section 401 certification for general licenses or permits. The Agency is including a documentation requirement for the pre-filing meeting as a component of a certification request to ensure that certifying authorities are given an opportunity to engage in early discussions with project proponents and federal agencies, if desired. The Agency encourages project proponents and certifying authorities to use the pre-filing meeting to discuss the proposed project and to determine what information (if any), in addition to that required to be submitted as part of the “certification request,” may be needed to enable the certifying authority to take final action on the certification request in the reasonable period of time. The

certifying authority may also take this opportunity to discuss any other State or Tribal permits that may be applicable or required for the proposed project.

Although some commenters requested that the Agency include more detailed certification request components, the Agency believes additional detailed information is best ascertained through pre-filing meetings and engagement during the reasonable period of time. If pre-filing meetings, discussions, and submittals during the reasonable period of time fail to produce the information necessary for a certifying authority to grant certification or grant certification with conditions, the final rule reaffirms that certifying authorities retain the ability to deny or waive a certification request. It is important to reiterate that the burden is on the project proponent to submit a certification request to the certifying authority and work cooperatively to provide additional information as appropriate to facilitate the certification process. Likewise, the burden is on the certifying authority to evaluate the certification request in good faith and to request information, documents, and materials that are within the scope of section 401 as provided in this final rule and that can be produced and evaluated within the reasonable period of time.

The Agency also disagrees with commenters who asserted that the proposed definition of “certification request” would narrow State authority, that it contradicted the goals and purpose of the CWA, and that it was contrary to the plain language of section 401. The term “request” is not defined in the Act. As discussed above, the Agency is authorized to interpret ambiguous statutory terms, and believes the final definition of “certification request” and the provisions in sections 121.5(b) and (c) of the final rule will provide needed clarity and help ensure that certifying authorities have sufficient notice and information to begin their evaluation of a certification request. The final rule does not limit the ability of a certifying authority to communicate with project proponents and to identify and request additional information necessary to take an informed action on a certification request in the reasonable period of time. Indeed, by providing greater clarity on when the statutory reasonable period of time begins and by encouraging early and constructive dialogue between project proponents and certifying authorities, the final rule facilitates a certifying authority’s efforts to protect waters of the United States within its borders within the timeframe mandated by Congress.

A number of commenters provided examples of projects that had been delayed because a certifying authority repeatedly requested additional information before a certification request would be considered “complete.” These commenters asserted that these types of repeated requests for additional information undermine the statutory requirement to act on a certification request within a reasonable period of time, not to exceed one year. Other commenters asserted that a certifying authority cannot reasonably act on a certification request based only on the information required by the proposed rule. The EPA acknowledges the desire for certifying authorities to have all necessary information as soon as possible in the certification process, but the Agency must balance that desire while remaining loyal to the statutory requirement for timely action on a request. The Agency believes that its final rule strikes the appropriate balance by identifying the kinds of information that provide a reasonable baseline about any project while recognizing the ability of certifying authorities and project proponents to request and provide additional information both before and after the review clock starts.

The Agency also sees the value in finalizing certification request components that are objective and do not require subjective determinations by a certifying authority about whether the request submittal requirements have been satisfied. A certification request must have all components listed at section 121.5(b) or (c) of the final rule to start the statutory reasonable period of time. If any of the components of section 121.5(b) or (c) of the final rule is missing from the certification request, the statutory reasonable period of time does not start. With respect to the component of a certification request for project proponents at section 121.5(b)(5) of the final rule, the EPA acknowledges that not all proposed projects may be subject to monitoring or treatment for a discharge (e.g., section 404 dredge or fill permits rarely allow for a treatment option). The final rule has been modified slightly to add the word “manage” to broaden the scope of information that may be provided by project proponents. However, if a project is not subject to monitoring, treatment, or management requirements for its discharge, the project proponent should state that in the certification request. The effect of such statement would be to make that component inapplicable to that project. Many commenters expressed concern that the proposed components of a certification

request would require subjective determination regarding the appropriate level of detail. However, the Agency believes that the final certification request components do not require a subjective inquiry into their sufficiency or any inquiry beyond whether they have been provided in the request.

The final rule requires a certification request to include a statement that, to the best of the project proponent’s knowledge and belief, all information contained in the request is true, accurate, and complete. This requirement is intended to ensure that project proponents are making a good-faith effort to provide the certifying authority with accurate information necessary to begin its evaluation of the certification request. Additionally, as discussed above, the EPA anticipates that the project proponent and the certifying authority will coordinate information needs before and throughout the reasonable period of time, if necessary. The EPA expects that the project proponent both will provide a certification request that includes the components identified in the final rule and will engage with the certifying authority, as requested, to understand and respond to appropriate and reasonable additional information requests that are within the scope of section 401 and can be generated and reviewed within the reasonable period of time. For its part, the EPA expects that the certifying authority will act within the scope of section 401, as provided in the CWA and in this final rule.

The EPA solicited comment on whether the Agency should generate a standard form for all certification requests. Most commenters did not support the development of a standard form and noted that most States have their own forms for “complete applications.” At this time, the Agency is not developing a standard form for project proponents to use to submit certification requests, but notes that States and Tribes that wish to continue using standard forms may choose to update those forms to be consistent with the final definition of “certification request.” The Agency may consider developing such forms in the future, if useful to project proponents and certifying authorities.

Some commenters asked for clarification on the practical effect on the review clock of a project proponent’s independently withdrawing a certification request by its own choice and not at the request of a certifying authority. If a project proponent withdraws a certification request because the project is no longer being

planned or if certain elements of the proposed project materially change from what was originally proposed or from what is described or analyzed in additional information submitted by the project proponent, it is the EPA's interpretation that the certifying authority no longer has an obligation to act on that request. To avoid scenarios like those presented in *Hoopa Valley* and to address the EPA's policy concern that section 401 certification delays also delay implementation of updated State and Tribal water quality standards and other requirements, the EPA expects that voluntary withdrawal by the project proponent will be done sparingly and only in response to material modifications to the project or if the project is no longer planned. In these circumstances, if the project proponent seeks to obtain a certification in the future, the project proponent must submit a new certification request. At a minimum, the project proponent would have to wait 30 days before re-submitting a certification request, because under the final rule project proponents must request a pre-filing meeting at least 30 days before submitting a certification request, and voluntary withdrawal by a project proponent of a prior certification request does not obviate this pre-filing requirement. For further discussion about project proponent withdrawal, see section III.F of this notice.

Commenters asked the Agency to clarify when a change in the proposed project would be so significant that it would require a new request. Many commenters asserted that the proposed rule would prevent extending the reasonable period of time even though the scope of the project changes during the reasonable period of time. Other commenters noted that the proposed rule did not account for project changes that may result from the federal license or permit review processes. A couple of commenters stated that the EPA should provide guidance to federal agencies on when a new certification request would be necessary based on the type and change in a project's scope, while one commenter asked the Agency to clarify whether projects that change in scope or design require a new certification.

After considering public comments on this issue, the final rule does not identify each circumstance that may warrant the submission of a new certification request because the Agency believes that such circumstances are best addressed on a case-by-case basis. However, if certain elements of the proposed project (e.g., the location of the project or the nature of any potential discharge that may result) change

materially after a project proponent submits a certification request, it may be reasonable for the project proponent to submit a new certification request. Administrative changes, such as a change in the point of contact or the list of other required permits, and minor changes to the proposed project, such as those that do not change the project footprint in a material way, should not warrant the submission of a new certification request. The EPA recognizes that complex projects that are subject to multi-year federal licensing or permitting procedures may change over time as a result of those federal procedures. From a practical standpoint, the EPA encourages project proponents to maintain close coordination and communication with certifying authorities and recommends that the project proponent provide information about any project changes to the certifying authority regardless of when the change occurred or whether a certification has already been issued by the certifying authority. As an additional measure, the Act and the final rule provide certifying authorities with the opportunity to inspect a certified project prior to initial operation to ensure the project will comply with the certification.

The Agency is finalizing the definition of "receipt" as proposed, so as to provide clarity for project proponents and certifying authorities about when the certification request is deemed received and the statutory clock begins. The CWA does not define the term "receipt of such request" in section 401(a)(1), which has led States, Tribes, and project proponents, as well as courts, to use different definitions. "Receipt of the request" has been used alternately to mean receipt by the certifying authority of the request in whatever form it was submitted by the project proponent, or receipt of a "complete application" as determined by differing regulations established by certifying authorities. The statute also does not specify how requests are to be "received" by the certifying authority—whether by mail, by electronic submission, or some other means. The EPA understands that some certifying authorities have established general submission procedures for project proponents to follow when seeking State or Tribal licenses or permits. The EPA encourages the use of consistent procedures for all submittals, including section 401 certification requests. The final rule requirement that certification requests be documented as received "in accordance with applicable submission procedures" is intended to recognize

that certifying authorities may have different procedures for submission of requests established in State or Tribal law. For instance, some certifying authorities may require hard copy paper submittals, while others may require or allow electronic submittals. If the certifying authority accepts hard copy paper submittals, the EPA recommends that the project proponents submitting a hard copy request send the request via certified mail (or similar means) to confirm receipt of the certification request. If the certifying authority allows for electronic submittals, the EPA recommends that the project proponent set up an electronic process to confirm receipt of the request. Nothing in the final rule precludes the use of electronic signatures when deemed appropriate by the certifying authority. The EPA recommends that project proponents retain a copy of any written or electronic confirmation of submission or receipt for their records.

One commenter disagreed with the suggestion that the word "receipt" is ambiguous but nonetheless agreed with the proposed rule because, this commenter asserted, states have made efforts to evade the one-year reasonable period of time. For the reasons explained above, EPA disagrees with the commenter and concludes that the word is ambiguous. Another commenter stated that section 401 does not require certifying authorities to act "upon" receipt of a request, but "after" receipt of a request. This commenter is correct that the statute requires certifying authorities to act on a certification request "within a reasonable period of time (which shall not exceed one year) after receipt of such request." As discussed above, the Agency has the authority to interpret ambiguous statutory terms, including the terms "request" and "receipt of such request." The Agency has defined "receipt" to mean "the date that a certification request is documented as received by a certifying authority in accordance with applicable submission procedures." Therefore, under the EPA's final rule, the statutory clock begins on the date when the certification request is documented as received by the certifying authority.

Some commenters recommended that "receipt" should mean the date when a certification request and all materials required by State or Tribal law are documented as received by a certifying authority in accordance with applicable submission procedures. The Agency disagrees with these commenters. The EPA is aware that some States have regulations establishing what should be in a request for certification and when

it will be considered “complete.” For instance, the California Code of Regulations states: “Upon receipt of an application, it shall be reviewed by the certifying agency to determine if it is complete. If the application is incomplete, the applicant shall be notified in writing no later than 30 days after receipt of the application, of any additional information or action needed.” Cal. Code Regs. tit. 23, 3835(a). The EPA also notes that some State regulations may require the completion of certain processes, studies, or other regulatory milestones before it will consider a certification request “complete.” Although the CWA provides flexibility for certifying authorities to follow their own administrative procedures, particularly for public notice and comment, *see* 33 U.S.C. 1341(a), these procedures cannot be implemented in such a manner as to violate the CWA. The Act requires the timeline for review to begin “after receipt” of a certification request, notwithstanding any completeness determination procedure, and it requires certifications to be processed within a “reasonable period of time (which shall not exceed one year.)”.

One principal goal of this rulemaking is to provide additional clarity and certainty about the certification process, including when the reasonable period of time begins. Establishing a consistent and objective list of information necessary to start the statutory reasonable period of time is necessary to achieve that goal. As discussed above, the Agency has defined the elements necessary to provide the certifying authority with sufficient notice and information to begin to evaluate a request for certification. If there are additional information needs aside from the finalized components provided in a certification request, the certifying authority and project proponent may discuss those needs during the pre-filing meeting (*see* section III.B of this notice) or during the reasonable period of time. The requirement that certification requests be received “in accordance with applicable submission procedures” cannot be used by certifying authorities to introduce unreasonable delay between when an agency receives a certification request and when “receipt” occurs, as this would contravene this final rule.

Many commenters expressed concern that the proposal lacked any requirement that a request be “administratively complete.” One commenter asserted that without a robust administrative record on which to rely, certifying authorities would be more vulnerable to successful

challenges of their certification determinations. The final rule establishes that a certification request is administratively complete when it contains the items set forth in section 121.5(b) or (c). The final rule requires that the project proponent request a pre-filing meeting with the certifying authority before submitting the certification request, thereby providing that certifying authority the opportunity to discuss any additional informational needs it may have. If a project proponent fails to supply the certifying authority with information necessary to assure that the discharge from the proposed project complies with the water quality requirements, the certifying authority may so specify in a denial of the certification. If the certifying authority requests information from the project proponent that is beyond the scope of section 401, the project proponent’s remedy lies with a court of competent jurisdiction. To avoid situations where the certifying authority requests information from project proponents that cannot be developed and submitted within the reasonable period of time, the EPA recommends that both the project proponent and the certifying authority work in good faith, consistent with section 401, and have early and sustained coordination and communication to streamline the overall certification process.

Some commenters asserted that under the proposed rule, the federal agency would not have a reliable way to determine whether a certifying authority has received a request because the proposed rule required only project proponents, and not certifying authorities, to alert federal agencies when a project proponent had submitted a certification request. Project proponents have the burden of requesting certification from a certifying authority and for providing federal agencies with the certification to help fulfill the requirements of a federal license or permit. After reviewing public comments, the Agency has decided not to finalize the requirement proposed at section 121.4(b) in order to provide all interested parties with greater clarity and a common understanding regarding the status of a certification request. To effectuate notice of a certification request at the earliest point in time, section 121.5(a) of the final rule requires a project proponent to submit a certification request to the appropriate certifying authority and the federal licensing or permitting agency concurrently. Including this requirement in the final

rule will provide the federal agency with notification about a certification request and sufficient information to determine the reasonable period of time for that certification request. This process will also address commenter concerns by providing federal agencies and certifying authorities with a concurrent notice when a certification request is received. As discussed above, the Agency recognizes that certifying authorities may have different submission procedures and recommends that project proponents submit copies to the federal agency in a manner consistent with the certifying authority’s submission procedures, to ensure that the request is received at the same time. The final rule requires the federal agency to communicate the reasonable period of time to the certifying authority within 15 days of receiving the certification request from the project proponent in accordance with section 121.5(a) of the final rule. The EPA expects federal licensing and permitting agencies to provide the notice required in this final rule and strongly encourages federal agencies to promulgate or update agency-specific regulations to implement CWA section 401 and this final rule. However, in the unlikely event that the federal agency does not provide the required notice, the EPA recommends that certifying authorities assume that the federal agency’s promulgated default reasonable period of time applies (*e.g.*, the Corps’ 60 days). If the federal agency fails to provide notification and has not promulgated a default or categorical reasonable period of time, the Agency recommends that certifying authorities assume the reasonable period of time expires one year from the date the certification request was received. The Agency recommends that all parties retain copies of certification requests for their records in case there is any misunderstanding about the beginning of the reasonable period of time.

EPA acknowledges that many States and Tribes have established their own requirements for section 401 certification request submittals, which may be different from or more extensive than the “certification request” requirements set forth in this final rule. However, these additional requirements should not be used to expand the certification request requirements in this final rule, which are intended to establish clear expectations for certifying authorities and project proponents, and which provide a transparent and consistent framework for when the reasonable period of time begins. The EPA notes that certifying

authorities may update their existing section 401 certification regulations to be consistent with the EPA's regulations. Additionally, the EPA observes that certifying authorities may wish to work with neighboring jurisdictions to develop regulations that are consistent from State to State. This may be particularly useful for interstate projects, like pipelines and transmission lines, requiring water quality certifications from more than one State.

Some commenters requested additional clarification about when project proponents should submit a certification request, relative to the timelines in federal licenses or permits or other federal laws. One commenter stated it would be helpful to specify a point in the federal permitting timeline when project proponents should submit a certification request. The commenter suggested that this point in time should be based on when States would have adequate information to make a certification decision. One commenter explained that if a State is required to issue section 401 certification before NEPA environmental documentation is complete and made available, the State would have to initiate state environmental review before NEPA documents are available, which is an unnecessarily burdensome approach for both the State and the applicant. Other commenters noted that the proposed rule could place an unnecessary burden on States and Tribes if an EIS results in a no action alternative being chosen, but the State or Tribe has already expended resources to complete a section 401 certification. The EPA also observes that some federal permit or license procedures can be lengthy and can result in project modifications in the early stages of the process.

The Agency is not prescribing a specific point in a federal licensing or permitting process when project proponents are required to submit a certification request. The Agency is aware that FERC's regulations already establish when during the hydropower licensing process a project proponent may request certification. Specifically, FERC's regulations require project proponents to complete a years-long process that includes environmental studies and reviews before a project proponent may request certification for that federal license. *See* 18 CFR 5.22, 5.23. The Agency encourages all federal licensing and permitting agencies to evaluate their programs and processes and to consider promulgating or updating their section 401 implementing regulations to specify when a section 401 certification request should be submitted. Providing

additional specificity and procedures for project proponents may reduce the duplication of work between federal, State and Tribal authorities and may make the certification process more efficient. In the absence of formal guidance or rulemaking from the appropriate federal licensing or permitting agency, the EPA recommends that project proponents, certifying authorities, and federal agencies coordinate and discuss the appropriate timing for a section 401 certification request in light of the federal licensing or permitting process and other project approval requirements.

D. Certification Actions

1. What is the Agency finalizing?

Consistent with the text of the CWA, under the final rule a certifying authority may take one of four actions pursuant to its section 401 authority: Grant certification, grant certification with conditions, deny certification, or waive its opportunity to provide a certification. These actions are reflected in section 121.7 of the final regulatory text. Any action by the certifying authority to grant, grant with conditions, or deny a certification request must be within the scope of certification (*see* section III.E of this notice), must be completed within the established reasonable period of time (*see* section III.F of this notice), and must otherwise be in accordance with section 401 of the CWA (*see* section III.G of this notice). Alternatively, a certifying authority may expressly waive the certification requirement. Under the final rule, certifying authorities may also implicitly waive the certification requirement by failing or refusing to act (*see* section III.G.2.d of this notice). All certification actions must be in writing, and the contents and effects of such actions are discussed below in section III.G of this notice. The final rule is consistent with the Agency's longstanding interpretation of what actions may be taken in response to a certification request.

2. Summary of Final Rule Rationale and Public Comment

Under the final rule, if the certifying authority determines that the discharge from a proposed project will comply with specific provisions enumerated in CWA section 401(a) and with other appropriate State or Tribal water quality requirements, it may grant that certification with or without conditions, as appropriate. To provide additional clarity, section 121.1(n) of the final rule defines "water quality requirements"

(*see* section III.E.2.b of this notice for further discussion of this definition). If the certifying authority cannot certify (with or without conditions) that the discharge from a proposed project will comply with "water quality requirements," it may either deny or waive certification. There may be multiple reasons why a certifying authority is unable to certify, including a lack of resources for reviewing the certification request, higher priority work that the certifying authority must attend to, or evidence that the discharge will not comply with "water quality requirements." Under the former circumstances, waiver would be appropriate; and under the latter circumstance, denial would be appropriate.

a. Grant

When a certifying authority grants a section 401 certification, it has concluded that the potential point source discharge into waters of the United States from the proposed project will be consistent with "water quality requirements." Granting certification allows the federal agency to proceed with issuing the license or permit.

b. Grant With Conditions

If the certifying authority determines that the potential discharge from a proposed project would be consistent with "water quality requirements" only if certain conditions are met, the authority may include such conditions in its certification. Where the certifying authority grants certification with conditions in accordance with section 401 and this final rule, the federal agency may proceed to issue the license or permit. Certification conditions that satisfy the requirements of this final rule must be incorporated into the federal license or permit, if issued, and become federally enforceable.

c. Deny

A certifying authority may deny certification if it is unable to certify that the potential discharge from a proposed project would be consistent with "water quality requirements" as defined in this rule. CWA section 401(a)(1) provides that "[n]o license or permit shall be granted if certification has been denied by the State, interstate agency, or the Administrator, as the case may be." 33 U.S.C. 1341(a)(1).

This final rule reaffirms the ability of a project proponent to submit a new certification request if a previous request is denied. Some commenters agreed that it would always be proper to allow project proponents to request certification again if the certifying

authority denied their previous request(s). Other commenters interpreted this provision as preventing certifying authorities from denying with prejudice and recommended that the final rule explicitly allow certifying authorities the option to deny with prejudice. These commenters asserted that denial with prejudice is a tool that preserves certifying authorities' resources in cases where they are asked to review substantially similar certification requests for the same project once it has already determined that the project cannot comply with water quality requirements. Some commenters argued that section 401 does not preclude certifying authorities from denying requests with prejudice, and that regulations that precluded certifying authorities from doing so would be inconsistent with the statute. Other commenters noted that the statute does not explicitly authorize denial with prejudice or prevent a project proponent from requesting a new section 401 certification after a request is denied. The EPA agrees that the statute is silent on this issue. The EPA is not aware that any other CWA program authorizes a permit application to be denied with prejudice or explicitly precludes a permit applicant from re-applying for a permit after an initial denial. For consistency with other CWA programs, and because nothing in section 401 prohibits a project proponent from submitting a new certification request after a denial is issued, the EPA is finalizing this provision as proposed. In the event that a denial is issued, the EPA recommends that the project proponent discuss with the certifying authority whether project plans could be altered or whether additional information could be developed to demonstrate that the discharge from the proposed project will comply with applicable water quality requirements upon submittal of a new certification request.

d. Waive

Under the final rule, a certifying authority may waive its opportunity to certify in two ways (*see* section 121.9(a) of the final regulatory text). First, the certifying authority may waive expressly by issuing a written statement that it is waiving certification. Second, the certifying authority may implicitly or constructively waive by failing or refusing to act within the reasonable period of time, failing to act in accordance with the procedural requirements of section 401, or failing to act in accordance with the requirements

in sections 121.7(c)-(e) of this rule.⁵⁵ As discussed throughout this final rule preamble, section 401 requires a certifying authority to act on a certification request within a reasonable period of time, not to exceed one year. If the certifying authority fails or refuses to act within that reasonable period, the certification requirement will be deemed waived by the federal licensing or permitting agency. *Id.* As described further in section III.G.2.d of this notice, if a certification grant, grant with conditions, or denial does not satisfy the procedural requirements of this final rule, it is waived. When a certifying authority waives the requirement for a certification, under this final rule the federal agency may proceed to issue the license or permit in accordance with its implementing regulations.

E. Appropriate Scope for Section 401 Certification Review

1. What is the Agency finalizing?

While Congress did not provide a single, clear, and unambiguous definition of the appropriate scope of section 401, the text, structure, and legislative history of the CWA (including the name of the statute itself—the Federal Water Pollution Control Act Amendments of 1972 or, more commonly, the Clean Water Act) demonstrate that section 401 appropriately focuses on addressing *water quality* impacts from *potential or actual discharges* from federally licensed or permitted projects. The EPA, as the federal entity charged with administering the CWA, has authority to reasonably resolve any ambiguity in section 401's scope through notice and comment rulemaking. To accomplish this, the Agency is finalizing as proposed section 121.3 of the regulatory text, which contains the following clear and concise statement of the scope of certification:

The scope of a Clean Water Act section 401 certification is limited to assuring that a discharge from a Federally licensed or permitted activity will comply with water quality requirements.

The Agency is also finalizing definitions of the terms “discharge” and “water quality requirements.” Together, these provisions of the final rule provide clarity on the scope of section 401. As explained in section III.A of this notice, based on the text and structure of the Act, as well as the history of modifications between the 1970 version and the 1972 amendments, the EPA has

concluded that section 401 is best interpreted as protecting water quality from federally licensed or permitted activities that may result in point source discharges into waters of the United States. The Agency is finalizing the definition of *discharge* with only one change, replacing “navigable waters” with “waters of the United States”:

Discharge for purposes of this part means a discharge from a point source into a water of the United States.

The Agency chose to use the more commonly used term “waters of the United States” to increase clarity in the final rule; however, this does not change the meaning of the definition. As described further below, the term “water quality requirements” is used throughout section 401, and the term “other appropriate requirements of State law” is used in section 401(d), but neither of these terms is defined in the CWA. As the terms are used in the CWA, the EPA interprets “other appropriate requirements of state law” to mean a subset of “water quality requirements.” To give more specific meaning to this ambiguous and undefined language, the final rule defines the term “water quality requirements” as follows:

Water quality requirements means applicable provisions of sections 301, 302, 303, 306, and 307 of the Clean Water Act, and state or tribal regulatory requirements for point source discharges into waters of the United States.

The final rule uses the term “water quality requirements” to define the universe of provisions that certifying authorities may consider under sections 401(a) and 401(d). This definition has been modified from the proposal to provide additional clarity.

The scope of certification in section 121.3 is the foundation of the final rule. The scope is based on the text, structure, and legislative history of the CWA, is informed by important policy considerations and the Agency's expertise, and informs all other provisions of the final rule. The scope of certification provides clarity to certifying authorities, federal agencies, and project proponents regarding the nature and breadth of the environmental review that is expected and the type of information that may reasonably be needed to review a certification request. The scope applies to all actions on a certification request, including a decision to grant, grant with conditions, or deny. The scope of certification also helps inform what may be a reasonable period of time for a certifying authority to review and act on a certification request.

⁵⁵ As noted elsewhere in this notice, waiver of a specific certification condition does not waive the entire certification.

To help ensure that section 401 certification actions are taken within the scope of certification, the EPA is finalizing certain requirements for certifications in section 121.7(c) of the final rule, certification conditions in section 121.7(d) of the final rule, and denials in section 121.7(e) of the final rule. For further discussion of the contents and effects of certification conditions and denials, see section III.G of this notice.

2. Summary of Final Rule Rationale and Public Comment

The Agency is finalizing as proposed the scope of certification in section 121.3 of the final rule. Consistent with the proposal, the scope of a section 401 certification in the final rule is limited to assuring that a “discharge” from a federally licensed or permitted activity—rather than the activity as a whole—“will comply” with “water quality requirements.” The definition of “water quality requirements” has been modified in the final rule to provide additional clarity.

a. Activity Versus Discharge

The Agency is finalizing the rule as proposed, focusing the scope of section 401 on the discharge from a federally licensed or permitted activity, as opposed to the activity as a whole. As described in section II.G.1.b of this notice, section 401(a) explicitly provides that the certifying authority, described as “the State in which the discharge originates or will originate,” must certify that “any such discharge will comply with the applicable provisions of sections 301, 302, 303, 306 and 307 of this Act” (emphasis added). The plain language of section 401(a) therefore directs authorities to certify that the discharge resulting from the proposed federally licensed or permitted project will comply with the CWA. Although section 401(d) authorizes a certifying authority to establish conditions to assure that the “applicant” will comply with applicable water quality requirements, the EPA does not interpret the use of “applicant” in section 401(d) as broadening the scope beyond consideration of water quality impacts from the “discharge,” as set out in section 401(a).

Some commenters asserted that the proposed scope of review for section 401 conflicts with the language of the CWA, applicable case law, and the legislative history of the CWA. These commenters asserted that the proper scope of section 401 should include all water quality impacts from the federally licensed or permitted activity or the

project as a whole. Many commenters relied on the Supreme Court’s rationale in *PUD No. 1* and argued that the plain language of section 401(d) is unambiguous and reasonably read as authorizing conditions and limitations on the activity as a whole. Commenters asserted that the plain meaning of the statutory language is clear, as is the legislative intent, and further asserted that the EPA’s reliance on *Chevron* is misplaced. Commenters claimed that the Court in *PUD No. 1* found the statutory language unambiguous and analyzed section 401 under *Chevron* step 1 and therefore, they argue, *Brand X* does not support EPA’s reanalysis of the statutory language in a manner contrary to the *PUD No. 1* opinion. These commenters asserted that even if it was not a *Chevron* step 1 analysis, the Court’s majority opinion is a reasonable, holistic reading of section 401. These commenters also asserted that the Court did not rely on the EPA’s interpretation of the statute, but relied on the plain language of the statute and therefore, they argue, *Brand X* does not support the EPA’s reanalysis of the statutory language in a manner contrary to *PUD No. 1*. Some commenters also asserted that the proposed scope of certification improperly departs from the EPA’s longstanding interpretation without providing an adequate justification.

Other commenters agreed with the EPA’s interpretation of the statutory language and case law analysis in the proposed rule preamble, including the interpretation of the scope of certification, and agreed that section 401 is a limited grant of federal authority to States and Tribes. These commenters found the EPA’s interpretation of section 401 reasonable despite their view that it was inconsistent with the majority opinion in *PUD No. 1*. These commenters also observed that the Court in *PUD No. 1* did not have the benefit of an EPA interpretation of the 1972 version of section 401.

The Agency disagrees with commenters who asserted that the proposed scope of certification conflicts with the CWA, case law, and legislative history, and disagrees with the contention that the proposed scope was not supported by adequate justification. The scope of certification in the final rule is based on the EPA’s holistic examination of section 401 and the legislative history. Congress’ change in section 401(a) from “activity” to “discharge” in the 1972 amendments reflects the “total restructuring” and “complete rewriting” of the existing statutory framework in 1972 that resulted in the core provisions of the CWA that regulate discharges into

waters of the United States. See *City of Milwaukee v. Illinois*, 451 U.S. 304, 317 (1981) (quoting legislative history of 1972 amendments). See also *County of Maui, Hawaii v. Hawaii Wildlife Fund, et al.*, No. 18–260, Op. at 2 (April 23, 2020). The final rule gives due weight to Congress’ intentional choice to change the language in section 401(a) to ensure that “discharges” from federally licensed or permitted activities, rather than the activity as a whole, comply with appropriate water quality requirements.

The Agency also disagrees with commenters who asserted that the scope of certification is expressed unambiguously in section 401. As demonstrated by the variation in public comments received, section 401 is susceptible to a multitude of interpretations. The EPA also disagrees with the suggestion that the *PUD No. 1* Court found section 401 to be unambiguous. Nowhere in the opinion does the Court conclude that section 401 is unambiguous. In fact, the Supreme Court in *PUD No. 1* offered its own interpretation of the ambiguous language in section 401 when it “reasonably read” the scope of section 401 to allow conditions and limitations on the activity as a whole. As discussed in detail in section II.F.4.a.i of this notice, although the Court did not articulate a *Chevron* step one or step two analysis in its decision, the Court did reference EPA’s 1971 certification regulations with approval and concluded that the EPA’s “reasonable interpretation” (based on those regulations) is entitled to deference. *Id.* The Court further found the EPA’s regulations to be consistent with the Court’s own reasonable reading of the language of sections 401(a) and (d). *Id.* at 712. As discussed in section II.F.4.a.i of this notice, the Court’s “reasonable reading” of a statute undercuts any argument that the statute’s text or meaning is unambiguous.

For the first time, the EPA has presented in this final rule the Agency’s interpretation and analysis of section 401. The Agency’s interpretation of the scope of section 401 as presented in section 121.3 of this final rule is not foreclosed by the holding in *PUD No. 1*. The Court’s conclusion that section 401 applied to the activity as a whole, rather than the discharge, did not follow from the unambiguous terms of the statute. *Nat’l Cable & Telecomm. Ass’n v. Brand X internet Serv.*, 545 U.S. 967, 982 (2005). The scope of certification in section 121.3 of this final rule is permissible and is based on a reasonable interpretation of the ambiguity created

by the different language Congress used in sections 401(a) and 401(d) of the Act.

Some commenters supported the alternative interpretation presented in the proposed rule to the effect that only the CWA sections enumerated in section 401(a) may be used as a basis for a water quality certification denial, while section 401(d) lists the considerations for applying conditions to a granted water quality certification. These commenters stated that this approach reflects the plain language of the CWA, and therefore that “any other appropriate requirement of State law” could be considered only when applying conditions to a water quality certification and cannot be grounds for a denial. Other commenters stated that section 401(a) and section 401(d) do not and have never been interpreted to have different scopes. After considering all public comments on this and other issues, the Agency is not finalizing the proposed alternative interpretation. The EPA believes that interpreting section 401 as establishing different standards for issuing a denial under section 401(a) and for requiring conditions under section 401(d) is likely to lead to implementation challenges, including confusion by project proponents, certifying authorities and federal licensing and permitting agencies. Moreover, if a certifying authority determines that it must add conditions under section 401(d) to justify a grant of certification under section 401(a), that is equivalent to deciding that—without those conditions—it must deny certification. The standard is therefore essentially the same. As explained above in this section and in section II.F.4.a.i of this notice, the Agency is finalizing what it has determined to be the most appropriate, reasonable interpretation of section 401 that is based on a holistic analysis of section 401, the entirety of the CWA, and the legislative history.

Some commenters argued that the focus of the CWA 1972 amendments on discharges does not override what they assert are the plain terms of section 401 and accused the EPA of selectively picking language to support a narrower scope. Some commenters disagreed with the EPA’s view that the proposed rule is necessary to update EPA’s certification regulations to conform with the 1972 CWA amendments, and they maintained that the EPA’s reading of the statute is inconsistent with Supreme Court precedent. Other commenters agreed that the proposed rule is necessary, as the existing water quality certification regulations were promulgated prior to the 1972 CWA amendments, and these commenters

agreed that the conflicting interpretations that have followed the original promulgation need to be addressed through revised regulations.

For the reasons explained in section II.F of this notice, the EPA concludes that the existing certification regulations must be updated to reflect the language of the 1972 CWA amendments. This final rule reflects the EPA’s holistic review of the CWA statutory text, the history of that text, and legislative history, and is informed by relevant case law. The EPA acknowledges that the final rule’s focus on discharges, as opposed to the activity as a whole, is not consistent with the majority opinion in *PUD No. 1*; however, the Agency’s rationale supporting its interpretation is grounded in the text of the statute, gives due weight to word choices made by Congress, and is clearly explained in the proposed and final rule preambles.

Some commenters asserted that the proposed rule was inconsistent with other holdings in *PUD No. 1*, including that (1) States could condition a certification on any limitations necessary to ensure compliance with State water quality standards or other appropriate requirements of State law; (2) a minimum flow condition was an appropriate requirement of State law; and (3) a State’s authority to impose minimum flow requirements would not be limited on the theory that it interfered with FERC’s authority to license hydroelectric projects. The EPA disagrees with these commenters. First, neither the proposed rule nor the final rule prohibits water quality-related certification conditions that are necessary to assure compliance with appropriate State or Tribal law. Rather, the rule clarifies the scope of laws that are appropriate for consideration and as the basis for certification conditions. As described in this section of the notice, the EPA made some changes in the final rule to provide additional clarity and regulatory certainty. Second, neither the proposed rule nor the final rule address minimum flow issues.

Some commenters asserted it was inappropriate for the proposed rule to rely on Justice Thomas’ “nonbinding” dissent in *PUD No. 1* instead of the holding of the majority opinion. One commenter suggested that reliance on the dissent exposes the EPA to legal challenge, injecting even more uncertainty into water quality certification programs. For the reasons explained in sections II.F.4.a.i, the EPA disagrees with these commenters. The EPA is not relying on any single judicial opinion for its interpretation of ambiguous statutory terms in this final rule. Rather, the final rule reflects the

EPA’s holistic analysis of the text, structure, and history of CWA section 401, informed by the Agency’s expertise developed over nearly 50 years of implementing the CWA.

Commenters asserted that the proposed rule would weaken the ability of States and Tribes to protect water quality, and some commenters asserted that the proposed rule would lead to negative impacts to the environment and public health. Some commenters asserted that the purpose of the rule is not consistent with the CWA’s goal of protecting and enhancing the quality of the nation’s waters. These commenters maintained that the proposed rule would not facilitate States’ and Tribes’ ability to carry out their roles and responsibilities under the CWA. Some commenters asserted that most federally licensed or permitted projects may result in water quality impacts beyond just those from a point source discharge, and argued that the appropriate scope of the certification is the activity and not only the discharge. These commenters provided examples of project impacts that they asserted may affect water quality but would be tangential to the discharge itself, including increased water withdrawals, releasing pollutants into groundwater, increased erosion and sedimentation, reduced stormwater infiltration, disconnecting ecosystems, and harming endangered species. Other commenters expressed concern that limiting the scope of section 401 to discharges would not allow States and Tribes to address indirect impacts from the project, such as impacts resulting from hydrological changes or increases in impervious surfaces that result in high-velocity runoff events that can deposit sediment or other pollutants into waterways.

The Agency recognizes the importance of protecting water quality and that aquatic resources serve a variety of important functions for protection of overall water quality. Ultimately, the Agency’s interpretation of section 401 is a legal interpretation that has been established within the overall framework and construct of the CWA, informed by important policy considerations and the Agency’s expertise. The purpose of this rulemaking is to provide a clear articulation of what is authorized by CWA section 401, including the appropriate procedures and scope of decision-making for water quality certifications, that is supported by a robust and comprehensive legal analysis of the statute. The federal licenses and permits that are subject to section 401 are also subject to additional federal agency statutory reviews, including the

National Environmental Policy Act, the Endangered Species Act, and the National Historic Preservation Act, all of which are intended to provide a comprehensive environmental evaluation of potential impacts from a proposed project. In addition, where applicable, the CWA's longstanding regulatory permitting programs, like those under sections 402 and 404, will continue to address water quality issues related to the discharge of pollutants into waters of the United States, and the CWA's non-regulatory measures, like protection of water quality from nonpoint sources of pollution under section 319, will continue to address pollution of water generally to achieve the objective of restoring and maintaining the chemical, physical, and biological integrity of the nation's waters. Section 401, on the other hand, provides specific and defined authority for States and Tribes to protect their water quality in the context of a federal licensing and permitting process, including those processes in which State or Tribal authority may otherwise be entirely preempted by federal law. The language of section 401 makes it clear that this authority is limited and does not broadly encompass all potential environmental impacts from a project.

Some commenters requested examples of what considerations would be outside the scope of certification, based on the Agency's limiting the scope of certification to discharges, rather than to the entire activity or project. Commenters mentioned specific considerations that they believed should be excluded from the scope of certification in the regulatory text, such as effects caused by the presence of pollutants in a discharge that are not attributable to the discharge from a federally licensed activity, effects attributable to features of the permitted activity besides the discharge, and effects caused by the absence or reduction of discharge. The Agency generally agrees that such considerations would be beyond the scope of certification as articulated in this final rule; however, the Agency is not modifying the regulatory text to reflect these specific considerations, as there may be unique project-specific facts or circumstances that must inform whether a particular impact is caused by the discharge, as defined in this final rule.

b. Water Quality Requirements

Under the final rule, the term "water quality requirements" means applicable effluent limitations for new and existing sources (CWA sections 301, 302, and

306), water quality standards (section 303), toxic pretreatment effluent standards (section 307), and State or Tribal regulatory requirements for point source discharges into waters of the United States, including those more stringent than federal standards. The definition in the final rule has been modified from the proposal to provide additional clarity.

The term "water quality requirements" is used throughout section 401, and the term "other appropriate requirements of State law" is used in section 401(d), but neither of these terms is defined in the CWA.⁵⁶ Because the EPA interprets "other appropriate requirements of state law" to be a subset of "water quality requirements," the final rule uses the term "water quality requirements" to define the universe of provisions that certifying authorities may consider when evaluating a certification request pursuant to CWA sections 401(a) and 401(d). The EPA's interpretation of these terms and the final definition are intended to closely align the scope and application of section 401 regulations with the text of the statute.

An interpretation of section 401 that most closely aligns with the text of the statute would limit "water quality requirements" to sections 301, 302, 303, 306 and 307 of the CWA and State and Tribal laws and regulations that are either counterparts to or that implement these enumerated sections of the Act. The EPA considered adopting this interpretation in the final rule, but recognizes that, in some cases, it may be difficult to determine whether a State or Tribal statute or regulation was adopted "to implement" sections 301, 302, 303, 306 and 307 of the CWA. In many cases, State or Tribal statutes may have been enacted prior to the 1972 CWA amendments, but updated or modified over the decades to implement or

⁵⁶ In 1971, EPA Administrator Ruckelshaus provided a written statement to the Chairman of the House Committee on Public Works concerning H.R. 11896. H.R. Rep. No. 92-911, at 147-171 (1972). The Administrator described 401(d) as it was drafted at the time as requiring certifications to "assure compliance with Sections 301 and 302 and 'any other applicable water quality requirement in such State.'" *Id.* at 166. The Administrator noted that "[t]he scope of the catchall phrase is not defined in Section 401, and the question arises as to whether certification by the State is to include certification with respect to discharges from point sources to meet the provisions of Sections 306 or 307." *Id.* The Administrator stated that 401(d) could be "more clearly expressed if the term 'applicable water quality requirement' was defined. . . ." and then offered an interpretation and a definition of the term. *Id.* The Administrator's recommendation was not adopted in the enacted bill, and this rulemaking is the first formal step the EPA has taken to clarify the meaning of the terms in section 401(d).

incorporate portions of the enumerated CWA provisions.

To avoid placing a potentially burdensome factual inquiry on States and Tribes, the final rule definition of "water quality requirements" is drafted more broadly to include those enumerated provisions of the CWA and State and Tribal regulatory requirements that pertain specifically to point source discharges into waters of the United States. This is consistent with the plain language of the statute because, with one exception, each of the enumerated CWA provisions in section 401 describes discharge-related limitations. The only exception is section 303, which addresses water quality standards, but these are primarily used to establish numeric limits in point source discharge permits. Further, and as described in section III.A of this notice, section 401 applies only to actual or potential discharges into waters of the United States. The final definition of "water quality requirements" therefore closely aligns with the text of the statute, while providing an objective test for whether a particular provision is within the scope of section 401. The Agency anticipates that this approach will increase clarity and efficiency in the certification process. Under this final rule, a State or Tribal regulatory requirement that applies to point source discharges into waters of the United States is a "water quality requirement" and is therefore within the scope of certification.

The phrase "state or tribal regulatory requirements for point source discharges into waters of the United States" in the final rule's definition includes those provisions of State or Tribal law that are more stringent than federal law, as authorized in CWA section 510. 33 U.S.C. 1370. The legislative history supports the EPA's interpretation in this final rule. *See S. Rep. No. 92-414*, at 69 (1971) ("In addition, the provision makes clear that any water quality requirements established under State law, more stringent than those requirements established under this Act, also shall through certification become conditions on any Federal license or permit."). It is important to note, however, that these more stringent provisions may not alter the scope of certification as provided in this final rule. For example, nonpoint source discharges and discharges to other non-federal waters are not within the scope of certification and are not included in the definition of "water quality requirements." Accordingly, they are not factors to be considered

when making decisions on certification requests.

Some commenters agreed that the proposed definition limiting “any other appropriate requirement of state law” to “EPA-approved state or tribal Clean Water Act regulatory program provisions” is the correct interpretation of the Act because section 401 cannot apply beyond the authority of the CWA. These commenters agreed that the principle *ejusdem generis* and the logic of Justice Thomas’s dissent in *PUD No. 1* show that the appropriate interpretation of “any other appropriate requirement of state law” extends “only to provisions that, like other provisions in the statutory list, impose discharge-related restrictions,” which are the “regulatory provisions of the CWA.” Other commenters expressed confusion regarding the meaning and scope of the phrase “EPA-approved state or tribal Clean Water Act regulatory program provisions” in the proposed rule and asked for clarification on which regulatory programs would be included in that term. Some commenters stated that this lack of clarity made the scope of the proposed rule ambiguous such that States and Tribes would not be able to implement the regulations.

The EPA has made some enhancements to the final rule definition of “water quality requirements” to provide better clarity and regulatory certainty. The final rule does not require these State and Tribal provisions to be EPA-approved. In making this change, the Agency considered that there may be State or Tribal regulatory provisions that address point source discharges into waters of the United States that only partially implement certain CWA programs or that were not submitted to the EPA for approval. The EPA also considered, as noted by some commenters, that States and Tribes may submit to the EPA CWA regulatory program provisions, including water quality standards and applications for “treatment as States” (TAS), and wait months or sometimes years for the EPA to act on those submittals. The final rule language addresses this concern by broadening the universe of State and Tribal laws that may be considered “water quality requirements” compared to the proposal.

A few commenters expressed concern that the proposed rule failed to recognize that most Tribes do not have EPA-approved water quality regulations. These commenters asserted that in areas where the EPA is the certifying authority, the Administrator would not be able to consider water quality protective ordinances or water quality

standards adopted by Tribes, leaving no protection for most Tribal waters. The EPA appreciates these comments, and under the final rule, State and Tribal regulatory provisions for point source discharges into waters of the United States are “water quality requirements” regardless of whether they have been approved by the EPA. Therefore, if a Tribe has adopted water quality standards under Tribal law that serve as a basis for effluent limitations or other requirements for point source discharges into waters of the United States, the certifying authority must consider those provisions when evaluating a certification request.

Some commenters asserted that the proposed rule would limit the ability of a Tribe to adopt water quality regulations or to obtain TAS for section 401 certifications. Neither the proposal nor the final rule affect in any way the ability of a Tribe to adopt CWA water quality standards or obtain TAS. The EPA understands there may be unique challenges with Tribal implementation of CWA statutory authorities, but reiterates that pursuant to section 401(b), the EPA is available and obligated to provide technical expertise on any matter related to section 401. In addition, the EPA actively and routinely provides financial and technical assistance to Tribes for the development of aquatic resource protection programs. Such assistance includes Tribal capacity building for new or enhanced regulatory programs, as well as development of laboratory, field, and quantitative methods, tools, and trainings for monitoring and assessing aquatic resources. With this final rule, the Agency is reaffirming its responsibilities under section 401 to serve as a resource and consultant to Tribes requesting technical assistance.

Some commenters, citing the broad interpretation of “any other appropriate requirement of State law” in EPA’s Interim Handbook, stated that the EPA has not provided an adequate explanation or rationale for departing from its prior interpretation of the CWA. The EPA disagrees with the suggestion that it has not provided sufficient or adequate explanation for the interpretation presented in the proposed rule. In any event, the final rule is based in part on the plain language of section 401, which provides that the enumerated sections of the CWA and “any other appropriate requirement of State law” must be considered in a water quality certification. The CWA does not define what is an “appropriate requirement of State law,” and the EPA reasonably interprets this term to refer to a subset of “water quality

requirements,” a term that is also used throughout section 401. The final rule, like the proposal, is informed by the principle *ejusdem generis*. Under this principle, where general words follow an enumeration of two or more things, they apply only to things of the same general kind or class specifically mentioned. See *Wash. State Dept. of Social and Health Services v. Keffeler*, 537 U.S. 371, 383–85 (2003). Given the breadth of potential interpretations of “water quality requirements” and “other appropriate requirement of State law” described throughout this notice, the Agency concludes that the most appropriate interpretation is one that remains loyal to the text of the statute. Accordingly, the final definition of “water quality requirements” includes sections 301, 302, 303, 306, and 307 of the CWA and State or Tribal statutes and regulations governing point source discharges into waters of the United States.

A few commenters stated that the EPA’s reliance on the canon of statutory interpretation *ejusdem generis* is unfounded because, if the context of a statute dictates an alternative interpretation, *ejusdem generis* should not apply, citing *N. & W. Ry. v. Train Dispatchers*, 499 U.S. 117 (1991). The EPA disagrees with these commenters who assert that the context of section 401(d) dictates a different result. The use of the word “appropriate” in section 401(d) indicates that Congress intended to limit the phrase “requirement of state law” in some meaningful manner. It is reasonable to conclude that Congress intended that limitation to be informed by the enumerated provisions of the CWA that appear in section 401, as well as other key statutory touchstones like the terms “discharge” and “navigable waters,” *i.e.*, “waters of the United States.” See *Harrison v. PPG Industries, Inc.*, 446 U.S. 578, 578–79 (1980) (rejecting application of *ejusdem generis* where—unlike the word “appropriate” in section 401(d)—the relevant statutory phrase “any other final action” did not contain limiting language that rendered its meaning uncertain and in need of further interpretation). The phrase “any other appropriate requirement of State law” in section 401(d) is not unlimited or expansive, but rather it contains limiting language (“appropriate”) that must not be read out of the statute. In short, the canon of statutory interpretation of *ejusdem generis* is a tool that the EPA reasonably and properly used to inform the interpretation of the ambiguous statutory text in section 401.

Many commenters agreed with the analysis in the proposed rule preamble

that section 401 focuses on protecting water quality and is not intended to address other environmental impacts such as air emissions, transportation effects, climate change, and other examples mentioned in the preamble to the proposed rule. These commenters stated that the proposed rule's definition of water quality requirements appropriately ensures that the scope of certification addresses water quality concerns within the scope of the CWA. A few commenters stated that the legislative history for the CWA generally supports water quality as the appropriate boundary for the scope of water quality certifications, citing 116 Cong. Reg. 8,984 (Mar. 24, 1970), and S. Rep. No. 92-414 (1971). The EPA agrees with these commenters and concludes that the final rule appropriately limits water quality certifications issued under section 401 to water quality issues.

Some commenters maintained that the proposed rule's definition of water quality requirements would allow a certifying authority only to consider numeric water quality criteria. Some commenters requested that the definition of water quality requirements be revised to explicitly include aquatic use criteria and impacts such as streamflow and water quantity. Some commenters expressed concern that the scope of water quality requirements under the proposed rule would no longer allow States and Tribes to consider water quality standards that go beyond the scope of, or are more stringent than, the CWA. Neither the proposed definition of "water quality requirements" nor the final rule would limit States to evaluating only numeric water quality criteria in a certification review. While numeric water quality criteria are a central element of a water quality certification, the final definition allows States and Tribes to evaluate narrative water quality standards and other regulatory requirements that apply to point source discharges into waters of the United States.

Some commenters requested that the final rule clarify that requiring minimum in-stream flows is beyond the scope of water quality requirements and that fish and wildlife impacts are not within the proper scope of section 401, because those impacts are more appropriately addressed under other federal statutes and regulations. The EPA agrees that, in some cases, these elements may be beyond the scope of section 401. However, neither the proposed rule nor the final rule specify whether minimum flow conditions would be appropriate certification conditions. Given the case-specific nature of such an analysis, the final rule

does not include categorical exclusions requested by these commenters.

Some commenters stated that the proposed rule would violate the broad savings clause in section 510, which applies to any pollution control or abatement requirement. These commenters asserted that nothing in section 510 excludes conditions imposed under section 401. These commenters further asserted that numerous courts have held that sections 401 and 510 evince Congress' clear intent not to preempt but to "supplement and amplify" State authority. The EPA interprets section 401 as providing an opportunity for States and Tribes to evaluate and address water quality concerns during the federal license or permit processes, which, in some cases, might otherwise preempt State authority. There is nothing in the text of section 401(d) that supports the idea that States have unbounded authority—as a result of section 510 or otherwise—to impose an unlimited universe of conditions on an applicant for a federal license or permit. Any such conditions must be—as the statute specifies—based on certain enumerated provisions of the CWA and on any other "appropriate" requirements of State law. As the Agency charged with administering the CWA, EPA is authorized to interpret "appropriate" in a way that balances the scope and focus of section 401 and State prerogative under section 510. If Congress intended for section 401 to reserve all State authorities over pollution control and abatement, as it did under section 510, Congress could have specifically referenced section 510 within section 401. Congress did not do so, and instead cited to other specific provisions of the CWA and referenced other "appropriate" requirements of State law.

In fact, the 1972 Senate Bill version of section 401(d) explicitly referenced section 510 and provided that a certification could include conditions necessary to assure that the applicant would comply with "any more stringent water quality requirements under State law as provided in section 510 of this Act . . ." S. 2770, 92nd Cong. (1972). This language was not included in the enacted bill, but the Senate Bill version demonstrates that Congress considered including a reference to section 510 within section 401, but did not do so. This is further evidence that Congress did not intend section 401 to operate as a broad savings clause for any pollution control or abatement requirement, as some commenters assert.

These commenters also fail to account for the use of the word "appropriate" in

section 401(d) as a meaningful limitation on what may be considered as part of the scope of certification under section 401. For the reasons stated above, the Agency concludes that State and Tribal regulatory requirements for point source discharges into waters of the United States properly allow States to participate in the section 401 certification process, consistent with the CWA.

As discussed throughout this section and as illustrated by public comments, the terms "water quality requirements" and "any other appropriate requirement of state law" lend themselves to a range of potential interpretations. Informed by the public comments received, the EPA considered a number of different interpretations prior to finalizing the definition of the term "water quality requirements." At one end of the spectrum, the Agency considered whether the text of section 401(d) could mean that the only State or Tribal law-based limitations allowed in a certification would be "monitoring" requirements "necessary to assure" that the applicant for a federal license or permit will "comply with" "any other appropriate requirement of State law." While this may be a permissible interpretation of section 401(d), and it may appear consistent with the directive in CWA section 304(h) that the EPA establish test procedures for the analysis of pollutants and factors that must be included in a certification, the EPA is not adopting this interpretation in the final rule. Such an interpretation would significantly limit the universe of conditions related to "appropriate requirements of State law" to only monitoring conditions and would be narrower than the interpretation set forth in both the proposed and final rule. This interpretation also would not provide any additional clarity as to the scope of State or Tribal law that could be the basis for those monitoring conditions.

At the other end of the spectrum, the EPA considered whether section 401(d) certification conditions could be based on *any* State or Tribal law, regardless of whether it is related to water quality. This interpretation reflects the current practice of some certifying authorities. The Agency rejected this broad and open-ended interpretation of section 401(d) as inconsistent with the structure and purposes of section 401 as reflected in the text of the provision, including Congress's inclusion of the limiting modifier "appropriate" in the phrase "any other appropriate requirement of State law." By including the term "appropriate," Congress placed at least some limits on the phrase "any other

. . . requirement of State law.” The EPA concludes that such an open-ended interpretation would be far more broad than the proposed rule and the final rule, would exceed the scope of authority provided under the CWA, and would further reduce regulatory certainty.

The EPA also considered another broader interpretation that would authorize certification conditions based on any State or Tribal water quality-related provision. Such an interpretation could bring in conditions that purport to address non-federal waters or that regulate nonpoint source discharges. Some commenters stated that section 401 provided a broad grant of authority to States and Tribes to protect water quality without limitations. These commenters asserted that to interpret the statute otherwise would read “any other appropriate requirement of state law” out of the statute. These commenters also cited other cases that suggest that a broad scope of State laws may be considered for a water quality certification. The EPA did not adopt this broad interpretation in the final rule because the EPA concluded that it is not required by the statute and is not the better reading of section 401(d). Although the interpretation has some superficial appeal, it errs by equating “appropriate” with “any” and thereby fails to provide meaning to the word “appropriate.” Under the familiar interpretative canon, no portion of a statute may be construed as mere surplusage. Such an interpretation would also be inconsistent with the regulatory framework of the CWA, which addresses point source discharges from waters of the United States.

Finally, the EPA considered an interpretation that would limit water quality requirements to those provisions of State or Tribal law that restore or maintain the physical, chemical, and biological integrity of the nation’s waters, consistent with CWA section 101(a). These same principles could also be applied to only waters of the United States, or narrowed to only include water quality requirements that restore or maintain the chemical integrity of waters. Although this may be a permissible interpretation of the statute, the EPA concluded that it may not provide sufficient specificity or regulatory certainty.

The EPA considered all of these public comments and the varying interpretations described above and is finalizing a definition of “water quality requirements” that strikes a balance among various competing

considerations while remaining loyal to the text of the CWA. The final rule is a reasonable interpretation of the ambiguous statutory text, is within the clear scope of the CWA, and will provide additional clarity and regulatory certainty for certifying authorities, project proponents, and federal licensing and permitting agencies.

c. Scope of Certification Conditions and Denials

The scope of certification described above is the foundation of the final rule and it informs all other provisions of the final rule, including all actions taken by a certifying authority. Under this final rule, certification conditions and denials must be within the scope of certification as provided in section 121.3 of the final rule. In other words, a condition must be necessary to assure that the discharge from a proposed federally licensed or permitted project will comply with water quality requirements, as defined at section 121.1(n) of this final rule, and a denial must be due to the inability of a certifying authority to determine that the discharge from the proposed project will comply with water quality requirements.

To promote transparency and to help assure that certifying authorities understand and consider the appropriate scope of information when developing a certification condition or issuing a denial, the final rule also requires a certifying authority to include specific information to support each condition or denial. These requirements help to build a comprehensive administrative record and to document the certifying authorities’ basis for the condition or denial. As discussed in greater detail in section III.G.2.b of this notice, this final rule requires that the following information be included in a certification to support each condition:

1. A statement explaining why the condition is necessary to assure that the discharge from the proposed project will comply with water quality requirements; and

2. A citation to federal, state, or tribal law that authorizes the condition.

Similarly, as discussed in greater detail in section III.G.2.c of this notice, the final rule requires that the following information be included in a denial of certification:

1. The specific water quality requirements with which the discharge will not comply;
2. A statement explaining why the discharge will not comply with the identified water quality requirements; and
3. If the denial is due to insufficient information, the denial must describe the

specific water quality data or information, if any, that would be needed to assure that the discharge from the proposed project will comply with water quality requirements.

These requirements are intended to increase transparency and ensure that any limitation or requirement added to a certification, and any denial, is within the scope of certification.

As discussed in section II.G.1.a of this notice, the EPA is aware that some certifying authorities may have previously interpreted the scope of section 401 to include non-water quality-related considerations. For example, the EPA understands some certifying authorities have included conditions in a certification that have nothing to do with effluent limitations, monitoring requirements, water quality, or even the CWA. Such requirements were perhaps based on other non-water quality-related federal statutory or regulatory programs (NEPA, ESA), or on concerns about environmental media other than water. Or such requirements might have been related to State, Tribal, or local laws, policies, or guidance that are unrelated to the regulation of point source discharges to waters of the United States. Similarly, the EPA is aware of circumstances in which some States have denied certifications on grounds that are unrelated to water quality requirements and that are beyond the scope of CWA section 401.⁵⁷ The EPA does not believe that such actions are authorized by section 401, because they go beyond assuring that “discharges” from federally licensed or permitted activities comply with “water quality requirements.” See also section II.G.1 of this notice for further discussion of the terms “discharge” and “water quality requirements.”

Some commenters provided comment regarding the appropriate scope of denials. These commenters asserted that the proposed scope of review would limit a certifying authority’s ability to deny certification. A few commenters asserted that states should be able to deny certification if any state requirements would not be met. Other commenters argued that the scope of denial should be limited to just those CWA provisions enumerated in section 401(a). As discussed in section III.D of this notice, the final rule provides a

⁵⁷ See Letter from Thomas Berkman, Deputy Commissioner and General Counsel, New York State Department of Environmental Conservation, to Georgia Carter, Vice President and General Counsel, Millennium Pipeline Company, and John Zimmer, Pipeline/LNG Market Director, TRC Environmental Corp. (Aug. 30, 2017) (denying section 401 certification because “FERC failed to consider or quantify the effects of downstream [greenhouse gas emissions] in its environmental review of the Project”).

certifying authority the ability to deny certification if it is unable to certify that the proposed discharge will comply with “water quality requirements” as defined in this rule. The Agency disagrees with commenters who asserted that a certifying authority should be able to deny certification if any State or Tribal requirements would not be met. As discussed above in section III.E.2.b of this notice, extending the scope of review to any State or Tribal law would be inconsistent with Congress’s inclusion of the limiting modifier “appropriate” in the phrase “any other appropriate requirement of State law,” and the Agency is not finalizing the proposed alternative interpretation that would limit the scope of denials to the CWA provisions enumerated in section 401(a). The Agency’s interpretation of the scope of certification, including the scope of denials, strikes a balance among competing considerations while remaining loyal to the text of the CWA.

Many commenters specifically addressed the appropriate scope of conditions. Some commenters urged the EPA not to use a small number of examples of conditions that did not directly relate to protecting water quality to justify narrowing the scope of certification conditions. These commenters provided additional examples of conditions that certifying authorities have included in certifications, such as building and maintaining fish passages, compensatory mitigation, temporal restrictions on activities to mitigate hazards or protect sensitive species, pre-construction monitoring and assessment of resources, habitat restoration, tree planting along waterways, spill management plans, stormwater management plans, and facilitating public access. The EPA appreciates commenters’ providing additional examples of certification conditions. The EPA agrees that in many instances, each of these examples may be beyond the scope of certification as articulated in this final rule. However, there may be unique project-specific facts or circumstances, including the nature of the discharge and applicable water quality standards and related designated uses, that must inform whether a particular condition is within the scope of certification, as defined in this final rule.

A few commenters stated that narrowing States’ and Tribes’ ability to condition licenses and permits may lead to more certification denials. The EPA disagrees with these commenters, as the scope of certification in the final rule informs the scope of appropriate

conditions and the appropriate bases for denial. In other words, if this final rule would preclude a State from requiring tree planting as a certification condition, the final rule would also preclude a State from denying certification based on a lack of trees planted in or around the project area.

Some commenters stated that limiting the proposed definition of “water quality requirements” to exclude State laws that are not EPA-approved would preclude conditions based on State-required riparian buffers, erosion and sedimentation controls, chloride monitoring, mitigation, fish and wildlife protection, drinking water protections, fish ladders, and adaptive management measures. As discussed above, the Agency is finalizing a definition of “water quality requirements” that removes the condition that State or Tribal law requirements must be “EPA-approved.” Under the final rule, the definition of “water quality requirements” includes “state or tribal regulatory requirements for point source discharges into a water of the United States,” and includes State or Tribal provisions that are more stringent than federal requirements.

One commenter suggested that instead of limiting section 401 certification conditions to water quality-related conditions, the EPA should consider having each State define the reserved authorities under section 401 that it intends to apply in a certification, as well as the types of discharges associated with those State authorities. The EPA disagrees with this commenter’s suggestion, as it would result in a greater patchwork of State regulations, with potentially every State establishing a different scope of certification and a different range of discharges that may be subject to certification in each State. One principal goal of this rulemaking is to provide greater clarity, regulatory certainty, and predictability for the water quality certification process. Finalizing a rule like the one suggested by this commenter would undercut those outcomes significantly.

The EPA recognizes that, historically, many State and Tribal certification actions have reflected an appropriately limited interpretation of the purpose and scope of section 401. However, as discussed above, the Agency is also aware that some certifications have included conditions that may be unrelated to water quality, including many of the types noted above, such as requirements for biking and hiking trails to be constructed, one-time and recurring payments to State agencies for improvements or enhancements that are

unrelated to the proposed federally licensed or permitted project, and public access for fishing and other activities along waters of the United States. Using the certification process to yield facility improvements or payments from project proponents that are unrelated to water quality impacts from the proposed federally licensed or permitted project is inconsistent with the authority provided by Congress.

Some commenters stated that the EPA should clarify in the final rule that certification conditions must be directly related to impacts to water quality requirements from the project proponent’s activity, and not water quality concerns caused by other entities. One commenter stated that the guiding principle for courts tasked with determining the propriety of section 401 certification conditions has been whether the condition was designed to directly address water quality effects caused by the licensee’s or permittee’s activity, and courts have emphasized that state agencies evaluating requests for water quality certifications may not consider the effects of activities other than those being licensed. This commenter recommended that the EPA revise section 121.5(d) of the proposed rule to state, “Any condition must directly address a water quality effect caused by the particular activity for which the applicant is seeking a license or permit.” The EPA agrees with these commenters that certification conditions must be directly related to water quality impacts from the proposed project. However, the EPA has concluded that the requirements in section 121.7(d) of the final rule accomplish the commenter’s request, and the EPA did not modify the final rule to include what EPA believes would be a redundant provision. The EPA is also aware of certification conditions that purport to require project proponents to address pollutants that are not discharged from the construction or operation of a federally licensed or permitted project. As discussed in this section, certification conditions must be necessary to assure that the discharge from a proposed federally licensed or permitted project will comply with water quality requirements, because this is the extent of authority provided in section 401.

The Agency proposed a definition for “condition” in an attempt to clarify that conditions included in a water quality certification must be within the scope of certification, as defined in this final rule. Some commenters supported the proposed definition of condition and the structure of the proposed rule. Other commenters stated that the EPA

unnecessarily defined “condition” to allow for federal review of water quality certifications. One commenter stated that the argument that Congress intended to allow the EPA to define the term “condition” under section 401 misconstrues the structure of section 401(d). This commenter stated that under the plain language of section 401(d), States impose “limitations” and “monitoring requirements” in a certification, and the certification itself then becomes “a condition” on the federal permit. This commenter further stated that there is no ambiguity in the statute, which requires that the entire certification is incorporated into the federal license or permit.

The Agency disagrees that it misinterpreted section 401(d) of the statute and further disagrees with the suggestion that there is no ambiguity in section 401(d).⁵⁸ The EPA acknowledges that interpretations other than what were presented in the proposed rule could be permissible under the statute, if adequately supported by a reasoned explanation. The EPA considered the specific interpretation advanced by this commenter and is not adopting this interpretation in the final rule. As a practical matter, courts that have considered challenges to certification conditions have routinely focused their review on those specific conditions, rather than the entire certification itself. *See PUD No. 1*, 511 U.S. at 713–14; *Deschutes River All. v. Portland Gen. Elec. Co.*, 331 F. Supp. 3d 1187, 1192, 1199–1209 (D. Or. 2018); *Airport Communities Coal. v. Graves*, 280 F. Supp. 2d 1207, 1214–17 (W.D. Wash. 2003). The EPA’s final rule is consistent with these courts’ interpretations. For these reasons and to promote clarity and regulatory certainty, the EPA is declining to adopt this particular interpretation. However, based on other enhancements in the final rule, the Agency has decided not to finalize a definition for “condition.” Together, the “scope of certification” and “water quality requirements,” as well as the rule’s language specifying the elements required in a certification with conditions, appropriately limit what can be properly considered a condition under the final rule, such that defining the term is not necessary. Moreover,

section 121.7(a) of the final rule specifically provides that any action to grant a certification with conditions must be within the scope of certification. The scope of certification extends to the scope of conditions that are appropriate for inclusion in a certification—specifically, that these conditions must be necessary to assure that the discharge from a federally licensed or permitted activity will comply with water quality requirements, as defined at section 121.1(n) of this final rule.

F. Timeframe for Certification Analysis and Decision

1. What is the Agency finalizing?

In this final rule, the EPA is reaffirming that CWA section 401 requires certifying authorities to act on a request for certification within a reasonable period of time, which shall not exceed one year. By establishing an absolute outer bound of one year following receipt of a certification request, Congress signaled that certifying authorities have the expertise and ability to evaluate potential water quality impacts from even the most complex proposals within a reasonable period of time after receipt of a request, and in all cases within one year. Under the final rule, federal agencies determine the reasonable period of time for a certifying authority to act on a certification request, and the final rule establishes procedures for setting, communicating, and (where appropriate) extending the reasonable period of time. The EPA is also reaffirming that section 401 does not include a tolling provision, and the period of time to act on a certification request does not pause or stop once the certification request has been received. The final rule provides additional clarity on what is a “reasonable period” and how the period of time is established.

2. Summary of Final Rule Rationale and Public Comment

a. Reasonable Period of Time

The EPA is finalizing the proposed rule’s provision that federal licensing and permitting agencies determine the reasonable period of time, either categorically or on a case-by-case basis. Some federal licensing and permitting agencies have appropriately exercised their authority to set the reasonable period of time through promulgated regulations, including EPA, FERC and the Corps. EPA’s regulations at 40 CFR 124.53(c)(3) provide that “the State will be deemed to have waived its right to certify unless that right is exercised

within a specified reasonable time not to exceed 60 days from the date the draft permit is mailed to the certifying State agency. . . .” FERC’s regulations at 18 CFR 5.23(b)(2) provide that “[a] certifying agency is deemed to have waived the certification requirements of section 401(a)(1) of the Clean Water Act if the certifying agency has not denied or granted certification by one year after the date the certifying agency received a written request for certification.” The Corps’ regulations at 33 CFR 325.2(b)(1)(ii) state that “[a] waiver may be explicit, or will be deemed to occur if the certifying agency fails or refuses to act on a request for certification within sixty days after receipt of such a request unless the district engineer determines a shorter or longer period is reasonable for the state to act.” The Executive Order directed all federal agencies with licenses or permits that may trigger section 401 certification to update their existing regulations to promote consistency across the federal government upon completion of this rulemaking to modernize the EPA’s certification regulations.

Public commenters provided a variety of perspectives about which entity should set the reasonable period of time. Some commenters agreed with the proposed rule that federal agencies are the appropriate entity to determine the reasonable period of time, subject to the statutory one-year limit. One commenter said the federal agencies should set the time period to maximize efficiency, increase timeliness of decision-making, and reduce uncertainty. Some commenters asserted that the reasonable period of time should be set by the certifying authority, because they believe that federal agencies lack expertise on State environmental and administrative requirements and therefore may set a reasonable period of time that is incompatible with those requirements or too short for complex projects. Other commenters asserted that federal agencies do not have authority under section 401 to determine the reasonable period of time. One commenter asserted that while federal agencies have the authority to adopt regulations setting a “reasonable time” for decisions, citing *Millennium Pipeline Co. v. Seggos*, 860 F. 3d 696, 700 (D.C. Cir. 2017), the CWA did not give federal agencies unfettered discretion to set deadlines that prevent States and Tribes from exercising their substantive authority under section 401, citing *City of Tacoma v. FERC*, 460 F.3d 53, 67 (D.C. Cir. 2006). One commenter noted that it is a conflict of interest for the federal agency to determine the

⁵⁸ The legislative history of the 1972 amendments does not provide a clear answer on this issue. *See* H.R. Rep. No. 91–911, at 124 (1972) (“the effluent limitations and other limitations and any monitoring requirements will become a condition on any Federal license or permit.”) *But see* S. Rep. No. 92–414, at 69 (1971) (“such a certification becomes an enforceable condition on the Federal license or permit.”)

“reasonable period of time” where that federal agency is both the project proponent and the agency issuing the license or permit. Other commenters believed that the EPA should determine the reasonable period of time in coordination with the certifying authority. Finally, some commenters stated that a one-year reasonable period of time should be provided without any additional federal agency discretion, which they asserted would increase regulatory certainty and ensure sufficient time to meet Tribal consultation obligations.

The EPA has considered these comments and concluded that it is reasonable and appropriate for federal agencies to set the reasonable period of time. The Agency disagrees that certifying authorities should set the reasonable period of time and disagrees that the EPA should set the reasonable period of time for all certification requests. The Agency also disagrees that certifying authorities should always have an entire year to act on a certification request, as a year may not be “reasonable” in all cases, and section 401 does not guarantee one year but rather states the action shall be taken within a reasonable period of time which “shall not exceed one year.” 33 U.S.C. 1341(a)(1). The statutory language of section 401 provides that a certification shall be waived if the certifying authority fails or refuses to act within the reasonable period of time, but the statute is silent on who should set the reasonable period of time. *Id.* The Agency is authorized to reasonably interpret the statute (see *Chevron*, 467 U.S. at 843–44) and concludes that federal licensing and permitting agencies should continue to fill this role as they have done for the past several decades. This interpretation is consistent with judicial and administrative precedent⁵⁹ and with federal regulations that were promulgated decades ago through public notice and comment rulemaking (see, e.g., 33 CFR 325.1(b)(ii) and 18

CFR 5.23(b)(1)). From a practical standpoint, federal licensing and permitting agencies have decades of experience in processing applications in accordance with their license and permit programs, and it is reasonable for the EPA to conclude that federal agencies would have the necessary knowledge and expertise to establish a reasonable period of time that is appropriate considering the applicable federal procedures.

The Agency disagrees with the commenter’s suggestion that there is a conflict of interest when the federal agency setting the reasonable period of time is also the project proponent. This final rule requires federal agencies to comply with the same requirements, including requirements concerning the reasonable period of time, as other project proponents when they require a federal permit that triggers the certification process.

In setting the reasonable period of time for a certification—either on a project-by-project basis or categorically—this final rule requires federal agencies to consider:

1. The complexity of the proposed project;
2. The nature of any potential discharge; and
3. The potential need for additional study or evaluation of water quality effects from the discharge.

With one exception discussed further below, the EPA is finalizing these factors as proposed. These factors maintain flexibility for federal agencies to consider project-specific or categorical information that should be readily available. If certifying authorities believe more time is necessary than what is established by the federal agency, they may request an extension to the reasonable period of time as described below.

A federal agency may decide that it is more efficient to establish the reasonable period of time based on common attributes of a category of licenses, permits, or potential discharges—rather than on a case-by-case basis. This type of categorical approach may be set out through rulemaking or other procedures in accordance with law. Establishing categorical reasonable periods of time may be more efficient, conserve resources, and increase regulatory transparency.

Some commenters supported the proposed three factors for determining the reasonable period of time. Other commenters recommended that a variety of additional factors be added, including but not limited to State law requirements for public participation

and procedure; State agency workload and resource constraints; substantive State law requirements for environmental review, type of permit, or timing of season-dependent field studies; time to review a certification request and any subsequent supplemental information; time for all stakeholders to provide input on a certification request; time for project proponents to provide additional information; other federal program requirements; and the extent of potential impact from a discharge. Several commenters noted that under the process set forth in the proposed rule, the federal agency could be required to set the reasonable period of time based on the three factors, but without receiving the actual certification request.

After considering these public comments, the EPA is finalizing three factors that federal agencies must consider when setting the reasonable period of time. In response to comments, the second factor has been modified to require the federal agency to consider the *nature* of any potential discharge. This modification clarifies that, in establishing the reasonable period of time, federal agencies should consider not only the potential for a discharge, but also the nature of any potential discharge, including (as appropriate) the potential volume, extent, or type of discharge associated with a particular project or particular category of license or permit. Consistent with the proposal, these factors may be used to establish a reasonable period of time on a project-by-project basis or categorically.

Many of the factors that commenters recommended would be subsumed by one of the factors that the EPA is finalizing, such as project complexity. Many of the concerns that commenters raised about the proposal—for example, that the reasonable period of time does not account for State public notice procedures—would also be a concern under the status quo 1971 certification regulations. However, over the past few decades, certifying authorities and federal agencies have formulated joint applications, memoranda of agreement, and other mechanisms to ensure that public participation requirements are met within the reasonable period of time. The EPA expects certifying authorities and federal agencies to continue these cooperative approaches to facilitate implementation of the final rule.

The EPA received a variety of comments regarding a potential default reasonable period of time of six months, including conflicting views on whether

⁵⁹ *Hoopa Valley Tribe v. FERC*, 913 F.3d 1099, 1104 (D.C. Cir. 2019) (“Thus, while a full year is the absolute maximum, it does not preclude a finding of waiver prior to the passage of a full year. Indeed, the [EPA]—the agency charged with administering the CWA—generally finds a state’s waiver after only six months. See 40 CFR 121.16.”); *Constitution Pipeline Company, LLC*, 164 FERC P 61029 (F.E.R.C.), 2018 WL 3498274 (2018) (“[T]o the extent that Congress left it to federal licensing and permitting agencies, here the Commission, to determine the reasonable period of time for action by a state certifying agency, bounded on the outside at one year, we have concluded that a period up to one year is reasonable.”). See the Economic Analysis for further discussion on the litigation posture of the *Constitution Pipeline Company, LLC* case.

six months is too long or too short, and whether a default reasonable period of time would increase or decrease clarity and regulatory certainty. Some commenters asserted that a default reasonable period of time of six months would be too short in cases in which certifying authorities have not received all necessary information from project proponents, or for project proponents requiring FERC licenses. Another commenter stated that without a default period of time, the rule would introduce regulatory uncertainty and result in inefficiencies and delays. The Agency has considered these comments and is finalizing the rule as proposed with no default or minimum reasonable period of time. The final rule thus provides federal licensing and permitting agencies the maximum flexibility to develop appropriate procedures for their permitting programs as they update their certification regulations in accordance with the Executive Order.

The final rule also clarifies the process by which federal agencies and certifying authorities communicate regarding the reasonable period of time. A clear understanding of the reasonable period of time will prevent certifying authorities from inadvertently waiving their opportunity to certify a request and will provide regulatory certainty to the project proponent. As explained in section III.C of this notice, the Agency has modified the proposed rule to respond to commenter concerns and is finalizing a requirement that the project proponent provide the certification request to the federal agency concurrently when it submits the certification request to the certifying authority. Under the final rule and consistent with the proposal, within 15 days of receiving the certification request from the project proponent, the federal agency must provide, in writing, the following information to the certifying authority: The date of receipt, the applicable reasonable period of time to act on the certification request, and the date upon which waiver will occur if the certifying authority fails or refuses to act. This provision is substantively identical to the one proposed, with minor modifications to increase clarity.

Public commenters expressed implementation concerns regarding the process for federal agencies to communicate the reasonable period of time to the certifying authority. One commenter believed that the 15-day turnaround time may not be practical, and a few commenters suggested that there is no accountability for federal agencies that fail to provide the required information within 15 days. A few commenters recommended adding a

procedure for adjudicating circumstances where the certifying authority disagrees with the reasonable period of time set by the federal agency. One commenter noted there is no requirement that the federal agency explain the chosen time period, making it more difficult to challenge the federal agency's decision or to petition for more time. One commenter said that federal agencies should be required to communicate the reasonable period of time even when agencies have promulgated time periods categorically by project type in their section 401 implementing regulations.

The EPA has considered these comments and is finalizing as proposed the process for federal agencies to communicate the reasonable period of time. The EPA understands that this process may create additional administrative burdens on federal agencies, given the number of section 401 certification requests that are submitted each year. However, the Agency expects that the benefit of clarity and transparency that this additional process will provide for all parties involved in a section 401 certification process will outweigh any additional burden on federal agencies. The EPA also expects the federal agencies will quickly routinize this process by developing and using forms, electronic notifications, or other tools to minimize the potential administrative burden associated with providing written notice of the reasonable period of time. The EPA does not anticipate that federal agencies will fail to set, or fail to notify certifying authorities of, the reasonable period of time under this final rule. The EPA expects federal agencies to communicate and act in good faith and in accordance with this final rule regarding the establishment of a reasonable period of time. Consistent with the proposal, the final rule authorizes federal agencies to establish categorical reasonable periods of time for types of licenses or permits, thereby increasing efficiency and transparency. To provide additional certainty to certifying authorities and project proponents, the EPA recommends that federal agencies promulgate in their updated certification regulations a minimum reasonable period of time that may be extended on a case-by-case basis, so long as it does not exceed one year from receipt of the certification request. To the extent that federal agencies are considering establishing additional procedures for communicating the reasonable period of time to certifying authorities (*e.g.*, directing all project proponents to a

public website to view categorically-established reasonable periods of time in federal agency regulations), the EPA supports the development of such procedures so long as they comply with the requirements in this rule. The EPA disagrees with the suggestion that a separate appeal process is necessary for certifying authorities to adjudicate the federal agency's reasonable period of time, as this final rule provides a process for the certifying authority to request an extension to the established reasonable period of time and describes clear factors for federal agencies to consider when setting the reasonable period of time in the first instance.

The EPA is clarifying that section 401 does not prohibit a federal agency from extending an established reasonable period of time, provided that the extended time period is reasonable and does not exceed one year from receipt. Some commenters stated that it would increase regulatory uncertainty for project proponents if the reasonable period of time could be modified. However, most commenters on this issue agreed that the rule should allow the flexibility to modify timeframes, and many of these commenters agreed that the rule should mirror the statute and maintain the maximum timeframe of one year. A few commenters suggested that the Agency clarify the process for modifying the time period, for instance by requiring specific information to be included in an extension request, or by providing federal agencies with a deadline to respond to extension requests. Another commenter said the rule should provide a dispute resolution process in the event the federal agency denies the State's request for an extension. A few commenters stated that federal agencies should be prohibited from shortening the reasonable period of time, and other commenters asserted that federal agencies, in the spirit of cooperative federalism, should consult with certifying authorities about when shorter timelines may be appropriate.

The EPA does not expect reasonable periods of time to be extended frequently, but the final rule is intended to provide federal agencies with additional flexibility to account for unique circumstances that may reasonably require a longer period of time than was originally established. For such cases, the EPA is finalizing as proposed the process by which the extended time period should be communicated in writing to the certifying authority and the project proponent to ensure that all parties are aware of the change. This provision is substantively identical to the proposed provision, with minor modifications to

increase clarity. The EPA finds it unnecessary to include additional timelines and procedures in the regulatory text because, as many commenters on the proposed rule pointed out, many certifying authorities and federal agencies already have established procedures in place through cooperative agreements or memoranda of agreement. The Agency intends to maintain flexibility in the final rule for federal agencies and certifying authorities to coordinate in this manner and to routinize these processes to increase efficiencies. Under the final rule, the reasonable period of time could be extended, as there may be project-specific cases when this is appropriate, so long as the period of time remains “reasonable.” Consistent with the proposal, the final rule does not authorize a reasonable period of time to be shortened once it is established. The Agency has made edits in final rule section 121.6 to clarify that the reasonable period of time can be extended, but not shortened, once it is established. This change provides flexibility in circumstances where unique or complex issues may arise, but maintains certainty for the certifying authority that the reasonable period of time, once established, cannot be made shorter.

The EPA is reaffirming in this final rule that the federal agency also determines whether waiver has occurred. Some commenters asserted that federal agencies do not have authority to determine that waiver has occurred. The EPA has considered these comments and disagrees with them. Relevant court decisions and the EPA’s 1971 certification regulations recognized the role of the federal agency to determine whether a waiver has occurred. *See Millennium Pipeline Company, L.L.C.*, 860 F.3d at 700–01 (acknowledging that a project proponent can ask the federal agency to determine whether a waiver has occurred). Consistent with the proposal, this final rule clarifies the procedures for a federal agency to notify a certifying authority and project proponent that a waiver has occurred. As discussed in section III.G.2.d of this notice below and pursuant to section 121.9 of the final rule, if the certifying authority fails or refuses to act before the date specified by the federal agency, the federal agency is required to communicate in writing to the certifying authority and the project proponent that waiver has occurred.

b. Tolling

Section 401 does not include a tolling provision. Consistent with the proposal, the EPA concludes in this final rule that

the period of time to act on a certification request does not pause or stop for any reason once the certification request has been received. One recent court decision held that withdrawing and resubmitting the same certification request for the purpose of circumventing the one-year statutory deadline does not restart the reasonable period of time. *Hoopa Valley Tribe v. FERC*, 913 F.3d 1099 (D.C. Cir. 2019) (*Hoopa Valley*). The EPA agrees with the *Hoopa Valley* court that “Section 401’s text is clear” that one year is the absolute maximum time permitted for a certification, and that the statute “does not preclude a finding of waiver prior to the passage of a full year.” *Id.* at 1103–04. The court of appeals noted that “[b]y shelving water quality certifications, the states usurp FERC’s control over whether and when a federal license will issue. Thus, if allowed, the withdrawal-and-resubmittal scheme could be used to indefinitely delay federal licensing proceedings and undermine FERC’s jurisdiction to regulate such matters.” *Id.* at 1104. The court further observed that the legislative history supports its interpretation of the statute’s plain language, because “Congress intended Section 401 to curb a state’s ‘dalliance or unreasonable delay.’” *Id.* at 1104–05 (emphasis in original).

The *Hoopa Valley* case raised another important issue: Perpetual delay of relicensing efforts (in that case for more than a decade) delays the implementation and enforcement of water quality requirements that have been updated and made more stringent in the years or decades since the last relicensing process. *See id.* at 1101.⁶⁰ This concern was also raised in stakeholder recommendations received during pre-proposal outreach. One stakeholder specifically cited the delays in the *Hoopa Valley* case as a “concrete example of how the § 401 certification process was being manipulated by a state certification agency to delay implementation of effective water quality controls and enhancement measures” and that “allowing the § 401 certification process to be used to achieve further delays in the relicensing process is in turn an abuse of

⁶⁰ This is a concern shared by the EPA. The Agency has taken steps to promote its own compliance with CWA deadlines, including acting on State and Tribal water quality standard submittals, because prior delays have created a significant backlog of state submittals awaiting an Agency action. Memorandum from David P. Ross, Assistant Administrator of the Office of Water, to Regional Administrators (June 3, 2019). These delays and backlogs prevent States and Tribes from timely implementing and enforcing updated programs and standards that could otherwise be improving water quality.

the certification process.” Letter from National Tribal Water Council to David P. Ross, Assistant Administrator of the Office of Water, EPA (Mar. 1, 2019).

Given the *Hoopa Valley* court’s plain language analysis of the statute and the potential water quality impacts from allowing certification decisions to be delayed, and the Agency’s agreement with that analysis, section 121.6(e) of the final rule provides:

The certifying authority is not authorized to request the project proponent to withdraw a certification request and is not authorized to take any action to extend the reasonable period of time other than specified in section 121.6(d).

This clear statement reflects the plain language of section 401 and, as described above, is supported by legislative history. The Agency expects this clarification to reduce delays and to help ensure that certification requests are processed within the reasonable period of time established by the federal agency, and at most, within one year from receipt of the request.

Some commenters agreed that section 401 establishes an outer bound of one year for the reasonable period of time. However, other commenters argued that the rule should allow flexibility on the timeline beyond one year. Many of these commenters argued States should not be limited to one year if they have received inadequate information and if projects are complex. One commenter asserted that section 401 allows for a State to “act on” a request within one year without reaching a final decision in that one year, and the commenter asserted that this interpretation provides a legal basis to allow extensions exceeding one year.

Some commenters supported the proposed provision to the effect that the certifying authority is not authorized to request the project proponent to withdraw a request or take other action to modify or restart the time period. Most of these commenters stated that the proposed rule makes clear the allowable time may not exceed the maximum of one year, and some of these commenters agreed that no tolling should be allowed. Some of these commenters cited the *Hoopa Valley* case, and one commenter cited the CWA legislative history. However, some commenters disagreed with the suggestion that certifying authorities should be prohibited from coordinating with project proponents to modify or restart the reasonable period of time, as they asserted this would be contrary to well-established practice. Some commenters stated that a reasonable period of time longer than one year may

be warranted for complete information to be submitted and for accommodating adequate State review and certification of projects. Most of these commenters asserted that withdrawal and resubmittal to toll the timeline is the best way to manage unforeseen issues or information gaps. A few of these commenters stated that the words “for the purpose of” in proposed rule section 121.4(f) (“[t]he certifying authority is not authorized to request the project proponent to withdraw a certification request or to take any other action for the purpose of modifying or restarting the established reasonable period of time” (emphasis added)) creates a subjective element depending on the certifying authority’s intent, and would create ambiguity in the rule if finalized as proposed.

The Agency understands that in cases where the certifying authority and project proponent are working collaboratively and in good faith, it may be desirable to allow the certification process to extend beyond the reasonable period of time and beyond the one-year statutory deadline. However, the final rule reflects the statutory language that the reasonable period of time may not exceed one year, 33 U.S.C. 1341(a)(1), and the *Hoopa Valley* holding that certifying authorities and project proponents lack discretion under the CWA to engage in a coordinated effort to extend the reasonable period of time. Additionally, the Agency disagrees with the commenter’s assertion that the term “act on” provides a legal basis to extend the reasonable period of time beyond one year. As discussed in section III.D of this notice, a certifying authority may take one of four actions on a certification request: Grant certification, grant certification with conditions, deny certification, or expressly waive certification. If a certifying authority fails or refuses to take one of these actions within the reasonable period of time, the CWA provides that the certifying authority will be deemed to have waived the certification requirement. 33 U.S.C. 1341(a)(1). The Agency agrees with public commenters that it would increase clarity to remove the words “for the purpose of” in proposed rule section 121.4(f), and the final rule has been modified accordingly. The Agency has also clarified in final rule section 121.6(e) that the certifying authority may take action to extend the reasonable period of time only in accordance with section 121.6(d). Because the final rule does not contemplate that the reasonable period of time can be tolled or “restarted,” as described below in this section, final

regulatory text section 121.6(e) was also edited from the proposal so as to increase clarity and to remove the term “restarting.”

Many commenters asked for clarification on a project proponent’s ability to withdraw and resubmit a request, noting that project proponents often voluntarily withdraw and resubmit applications. Some commenters requested that the Agency clarify what action a certifying authority should take when a project proponent withdraws a request. In response, the Agency notes that nothing in the final rule precludes project proponents from voluntarily withdrawing requests of their own accord. However, to prevent scenarios like the *Hoopa Valley* case, and to address the EPA’s policy concern about section 401 delays, the Agency expects that project proponents will rarely voluntarily withdraw requests for certification. The EPA expects that such withdrawals will take place only if the project plans have been modified such that a new certification request is required, or if the project is no longer planned. If a project proponent withdraws a certification request because the project is no longer being planned or if the project materially changes from what was originally proposed, as described above, the certifying authority no longer has an obligation to act on that request within the reasonable period of time. In all cases, project proponent withdrawals would not result in tolling or pausing the clock, but rather any resubmitted request would be subject to the pre-filing meeting request requirement. After receipt by the certifying authority, the new request would initiate a new reasonable period of time as determined by the federal agency.

Some commenters supported stopping the clock when project proponents are not responsive to requests for additional information, or do not provide adequate information to the certifying authority. Some commenters requested clarification on whether withdrawn requests that are resubmitted would restart a paused clock, or completely restart the reasonable period of time. Commenters also asked for clarification on whether the contents of the request, *i.e.*, whether it is substantially the same or a different request, would affect the restarting of the clock.

The Agency is reaffirming in this final rule that the clock does not toll for any reason. The Agency disagrees that the clock should toll while project proponents gather additional information or for any other reason, as there is no statutory basis for tolling. As described above, the reasonable period

of time begins when a certifying authority receives a certification request as defined in the final rule, and it ends when the certifying authority takes action to grant, grant with conditions, deny, or waive. The Agency is clarifying that the reasonable period of time does not continue to run after a certification decision is issued regardless of whether there is time remaining in the “reasonable period of time.” As explained in section III.L of this notice, a certifying authority cannot modify the certification after issuing a decision to the federal agency.

The EPA recognizes that there may be project-specific situations when the reasonable period of time may be extended (not to exceed one year) to account for project complexities or the need to gather additional information. Procedures for extending the reasonable period of time are explained above and included in the final rule. As discussed above, the EPA expects voluntary withdrawals of certification requests to occur only when the project has materially changed, as described above, or is no longer planned. In such a case, a new request would initiate a new reasonable period of time and would not “restart” the clock from a prior withdrawn request for certification. The EPA would not expect such a new request to be identical to a previously withdrawn request for certification.

Many commenters noted that given the proposed rule’s shortened timeframes, limitations on States and Tribes collecting additional information, and provisions allowing the reasonable period of time to begin prior to “an application being complete,” States may decide to deny certification rather than risking the possibility that a federal agency would determine that the State waived certification. These commenters noted that the process of successive State denials of certification and the resulting litigation could result in delaying projects and defeating the intent of the proposed rule to promote efficiency and certainty.

The Agency disagrees with these commenters. Neither the proposal nor the final rule shortened the timeframe for certification. The statute requires action on a certification request within a reasonable period of time not to exceed one year. The proposed rule and this final rule provide exactly the same timeframe as the statute provides. To the extent commenters view the clarifications in the rule that the statute does not authorize tolling or a “withdrawal and resubmit” scheme as “shortening the timeframe,” the Agency disagrees because these mechanisms that have previously been used to

extend the reasonable period of time are not authorized by the statute. Similarly, neither the proposal nor this final rule limits the ability of a certifying authority to collect additional information from a project proponent. The final rule provides an objective list of information that a project proponent must provide to a certifying authority to start the reasonable period of time. As described above, this is intended to provide transparency and predictability so all parties understand what information is necessary to start the reasonable period of time. The Agency encourages the parties to engage throughout the certification process to help ensure the certifying authority has the information needed to act on the certification request.

Additionally, the final rule includes a number of provisions that should reduce the need for certifying authorities to deny certification based on insufficient information. Section III.B of this notice describes a mandatory pre-filing meeting request, which will allow project proponents and certifying authorities to begin early conversations about proposed projects prior to the start of the reasonable period of time. Additionally, section III.C of this notice discusses factors that a project proponent should consider in determining when to submit a certification request, as the timing of request submission affects the information that may be available for certifying authorities to make timely decisions. Section III.C identifies opportunities for federal licensing and permitting agencies to establish by rule an appropriate point in the federal licensing or permitting process when a project proponent should request certification. Finally, this final rule establishes certain criteria that the EPA as a certifying authority must follow when making additional information requests (e.g., only requesting information that is related to the discharge; only requesting information that can be collected within the reasonable period of time). The Agency encourages all certifying authorities to consider whether similar criteria would help clarify expectations when certifying authorities seek additional information during the certification process.

G. Contents and Effects of Certification

1. What is the Agency finalizing?

Under the final rule, any action by the certifying authority to grant, grant with conditions, or deny a certification request must be within the scope of certification, must be completed within

the reasonable period of time, and must otherwise be in accordance with section 401 of the CWA. Alternatively, a certifying authority may waive the certification requirement, whether expressly or by failing to act. The Agency is finalizing the requirement that any action on a certification request must be in writing and must clearly state whether the certifying authority has chosen to grant, grant with conditions, or deny certification. This final rule also requires that any express waiver of the certification requirement by the certifying authority be in writing.

Under the final rule, a certification must include certain supporting information for each condition, including, at a minimum, a statement explaining why the condition is necessary to assure that the discharge from the proposed project will comply with water quality requirements, and a citation to the federal, State, or Tribal law that authorizes the condition. The final rule also includes slightly different information requirements to support conditions in a certification for issuance of a general license or permit. These requirements are described in section III.M below. The EPA had proposed also to require a statement of whether and to what extent a less stringent condition could satisfy applicable water quality requirements. The EPA is not including that provision in the final rule.

In circumstances where certification is denied, the EPA is finalizing the requirement that the written notification of denial state the reasons for denial, including the specific water quality requirements with which the discharge will not comply; a statement explaining why the discharge will not comply with the identified water quality requirements; and if the denial is due to insufficient information, the denial must describe the specific water quality data or information, if any, that would be needed to assure that the discharge from the proposed project will comply with water quality requirements. The Agency has made minor editorial changes to these provisions in the final rule to increase clarity, but the final rule provisions retain the same meaning as the proposed rule provisions. The final rule also includes slightly different information requirements to support a denial of a certification for issuance of a general license or permit. These requirements are described in section III.M below.

Under the final rule, if a certification or denial does not include the information requirements described further below, the certification or the denial will be considered waived by the federal licensing or permitting agency.

Likewise, if a certification condition is not supported by the required information, the condition will be considered waived under the final rule. Under the final rule, a waived condition does not result in waiver of the entire certification.

Additionally, if a certifying authority fails to follow the procedural requirements of section 401, such as the public notice provisions, or fails to complete its review within the reasonable period of time, the certification will be deemed waived.

2. Summary of Final Rule Rationale and Public Comments

The CWA does not define the term “certification” or offer a definitive list of its contents or elements. Section 304(h) of the CWA requires the EPA to promulgate factors which must be provided in any section 401 certification, and under section 501(a) the EPA may reasonably interpret the statute to add content to those terms. See 33 U.S.C. 1251(d); 33 U.S.C. 1361(a); *Chevron*, 467 U.S. at 843–44. The EPA’s 1971 certification regulations included certification requirements. In this final rule, EPA is updating those requirements for each type of certification action and is more fully addressing the effects of those actions.

a. Grant

Granting a section 401 certification demonstrates that the certifying authority has concluded that the potential discharge into waters of the United States from the proposed activity will be consistent with water quality requirements. Granting certification allows the federal agency to proceed with issuing the license or permit. Consistent with the proposal, the final rule requires all certification grants, with or without conditions, to be in writing and to include a written statement that the discharge from the proposed federally licensed or permitted project will comply with water quality requirements, as defined at section 121.1(n) of the final rule. The Agency has concluded that this is a straightforward requirement and one that promotes transparency for the public.

b. Grant With Conditions

If the certifying authority determines that the potential discharge from a proposed activity would be consistent with water quality requirements only if certain conditions are met, the authority may include such conditions in its certification. The EPA proposed that three elements be included in a certification to support each condition.

The Agency is finalizing two of those elements.

Some commenters supported the proposed requirement for certifying authorities to cite applicable State or Tribal law and to provide an explanation of the necessity for each condition. Some commenters agreed that these requirements would provide transparency, and assist the federal license or permitting agency with implementation and enforcement. Other commenters asserted that these requirements would be overly burdensome for certifying authorities. Some commenters asserted that certifying authorities already generally cite the applicable State laws and regulations on which they base their conditions, and other commenters said that these requirements would create new obligations for certifying authorities. Other commenters confirmed that the value of including this information in every certification, in terms of transparency and regulatory certainty, will far outweigh the minimal additional administrative burden of including this information in a certification. The EPA agrees that requiring an explanation for the necessity of the condition and a citation to the underlying State, Tribal, or federal laws, as appropriate, will promote transparency and consistency and is finalizing these requirements. The EPA intends this provision to require citation to the specific State or Tribal statute or regulation or the specific CWA provision, e.g., CWA section 301(b)(1)(C), that authorizes the condition, and that general citations to CWA section 401 or other general authorization or policy provisions in federal, State, or Tribal law would be insufficient to satisfy the proposed requirement.

Some commenters also supported the proposed requirement for certifying authorities to identify whether a less stringent condition could satisfy applicable water quality requirements. However, most commenters asserted that this requirement would be burdensome for certifying authorities, suggesting that States and Tribes would need to conduct two detailed analyses for the certification: One to establish appropriate conditions, and another to evaluate whether a less stringent condition would be sufficient. A commenter suggested that proposed section 121.5(d)(1) may conflict with proposed section 121.5(d)(3). This commenter recommended replacing section 121.5(d)(3) with a requirement that the certifying authority include only the least stringent conditions necessary to satisfy applicable water

quality requirements. The EPA has considered these comments. Under the final rule, certifying authorities will not have to identify whether and to what extent a less stringent condition could satisfy applicable water quality requirements. As described in the preamble for the proposed rule, this provision is included in the EPA's existing certification regulations for the NPDES permit program (see 40 CFR 124.53(e)(3)), but the EPA agrees with the commenters that asserted that it may be difficult to provide an explanation as to why a condition is necessary and to also identify a less stringent condition that could satisfy water quality requirements.

The EPA disagrees with the suggestion that the information requirements for conditions in section 121.5(d)(1) and (2) of the final rule would be burdensome for certifying authorities. Certifying authorities should already be generating this type of information to build complete and legally defensible administrative records to support their certification actions. As a general matter, if a certifying authority determines that one or more conditions are necessary for a section 401 certification, the certifying authority should clearly understand and articulate why it is necessary and should identify the legal authority for requiring such conditions. Including this information in the certification itself provides transparency for the project proponent, the federal licensing and permitting agency, and the public at large. For these reasons, the EPA has determined that these are appropriate requirements, and they are included in the final rule.

During pre-proposal stakeholder engagement, the EPA also heard from federal agencies that, because several court decisions have concluded that such agencies do not have authority to "review and reject the substance of a State certification or the conditions contained therein," *Am. Rivers, Inc.*, 129 F.3d at 106, non-water quality-related conditions are often included in federal licenses and permits. Once included in the federal license or permit, federal agencies have found it challenging to implement and enforce these non-water quality-related conditions. Additionally, stakeholders in pre-proposal engagement and in public comments expressed concern that federal agencies do not always enforce the certification conditions incorporated in their federal licenses or permits.

EPA agrees that it is important for federal agencies to have a clear understanding of the basis for certification conditions, because

conditions must be included in a federal license or permit. Several appellate courts have analyzed the plain language of the CWA and concluded that the Act "leaves no room for interpretation" and that "state conditions *must* be" included in the federal license or permit. *Sierra Club v. U.S. Army Corps of Engineers*, 909 F.3d 635, 645 (4th Cir. 2018) (emphasis in original); see also *U.S. Dep't of Interior v. FERC*, 952 F.2d 538, 548 (D.C. Cir. 1992) ("FERC may not alter or reject conditions imposed by the states through section 401 certificates."); *Am. Rivers, Inc. v. FERC*, 129 F.3d 99, 107 (2d Cir. 1997) (recognizing the "unequivocal" and "mandatory" language of section 1341(d)); *Snoqualmie Indian Tribe v. FERC*, 545 F.3d 1207, 1218 (9th Cir. 2008) (collecting cases). The EPA acknowledges commenters who asserted that federal agencies may not consistently enforce certification conditions, and also acknowledges that federal agencies can apply discretion in enforcement decisions. However, providing a citation to the legal authority underpinning a certification condition is one way to make it easier for federal agencies to enforce these conditions. Federal agencies during pre- and post-proposal engagement acknowledged that this information will help them understand how best to implement and enforce certification conditions. In addition, including this information in each certification will provide transparency for the overall certification process and allow the project proponent to understand the legal basis for each condition and to assess whether a condition is within the statute's lawful scope and what recourse may be available to challenge it in an appropriate court of competent jurisdiction. Overall, the EPA concludes that the benefits of providing this information will significantly outweigh any additional administrative burden that certifying authorities may incur because of these new requirements.

One commenter asserted that the language in proposed section 121.8(b) should be changed from "[t]he license or permit must clearly identify any conditions that are *based on* the certification" to "[t]he license or permit must clearly identify any conditions that are *from* the certification." This commenter asserted that the conditions cannot be based on the certification because federal agencies do not have authority to develop their own certification conditions or to modify a condition in a certification prior to incorporating it into the federal permit. The EPA has made this change in

section 121.10 of the final rule for clarity and to reaffirm that if a condition meets the procedural requirements of section 401 and includes the elements listed in 121.7(d) of the final rule, the condition must be incorporated into the federal license or permit in its entirety, as drafted by the certifying authority. Consistent with the proposal, under the final rule, deficient certification conditions do not invalidate the entire certification, nor do they invalidate the remaining conditions in the certification. As discussed below, the Agency has clarified in the final rule that conditions that do not meet these requirements will be deemed waived.

c. Deny

A certifying authority may choose to deny certification if it is unable to certify that the discharge from a proposed project would be consistent with applicable water quality requirements. If a certification is denied, the federal agency may not issue a license or permit for the proposed project. *Id.* at 1341(a). Consistent with the proposal, the final rule requires certification denials to be made in writing and to include three elements to support certification denials. The Agency has made minor editorial changes to these provisions in the final rule to increase clarity, but the final rule provisions retain the same meaning as the proposed rule provisions.

Some commenters agreed with the proposal to require certain information in a certification denial. One commenter asserted that when preparing denials, it would be helpful for certifying authorities to specify water quality requirements with which the proposed project will not comply, as this would assist federal agencies with their duty to determine whether a section 401 certification facially satisfies the requirements of section 401. Another commenter recommended that the final rule also require a statement that there is no certification condition which would prevent noncompliance with water quality requirements.

Other commenters opposed the proposed requirement that certification denials include “the specific water quality data or information, if any, that would be needed to assure that the discharge from the proposed project complies with water quality requirements.” These commenters asserted that this requirement was vague, unnecessary, and burdensome and further asserted that it would improperly place a new burden on certifying authorities that should be borne by project proponents to show why their project complies with water

quality requirements. A few of these commenters recommended that insufficient information should be a basis for denial.

As a general matter, the EPA disagrees with the suggestion that including this information in a denial would be overly burdensome for certifying authorities. Indeed, a number of States asserted in public comments that the primary reason why certifications cannot be issued within the reasonable period of time is that project proponents have not provided sufficient information or a “complete” certification request. If this is the case, certifying authorities should be able to identify what information is lacking that precludes a determination that the project will comply with water quality requirements, as the term is defined in the final rule. Clearly establishing a record to support the basis for a denial should already be done as a matter of course to establish a complete defensible administrative record for the certifying authority’s action. Further, any denial should be informed by the record before the certifying authority and should be issued with information sufficient to allow the project proponent to understand the basis for denial and have an opportunity to modify the project or to provide new or additional information in a new certification request.

The EPA is finalizing the requirement that a certification denial be in writing and include three elements to support the denial. The required elements will lead to more transparent decision-making and a more complete record of the administrative action. The final rule’s requirements may also facilitate discussions between certifying authorities and project proponents about what may be necessary to obtain a certification should the project proponent submit a new certification request in the future. A certifying authority’s explanation of why a discharge from a proposed project will not comply with relevant water quality requirements will also assist reviewing courts in understanding whether the denial is appropriately based on the scope of certification discussed in section III.E of this notice.

Some commenters asserted that the proposed rule would prohibit certifying authorities from denying certification based on a lack of information sufficient to grant certification. The EPA disagrees with these commenters. Indeed, by requiring that “if the denial is due to insufficient information, the denial must describe the specific water quality data or information, if any, that would be needed to assure that the discharge

from the proposed project will comply with water quality requirements,” the final rule reaffirms and clarifies that insufficient information about the proposed project can be a basis for a certification denial. If the certifying authority determines that there is no specific data or information that would allow the certifying authority to determine that the discharge will comply with water quality requirements, it should indicate as such and provide the basis for the determination in its written decision to deny certification.

As noted in the preamble to the proposed rule, the EPA is aware that some certifying authorities have requested “additional information” in the form of multi-year environmental investigations and studies, including completion of a NEPA review, before the certifying authority would act on a certification request. As discussed in section III.H of this notice, the final rule explicitly prohibits the EPA from requesting additional information that cannot be generated within the reasonable period of time. The rationale for this prohibition applies to all certifying authorities; the Agency believes that such requests for additional information, regardless of which certifying authority generates such requests, would be contrary to the plain language of the statute, which requires certifying authorities to act on a request within a reasonable period of time that does not exceed one year. While additional information requests may be a necessary part of the certification process, such requests may not result in extending the period of time beyond which the CWA requires certifying authorities to act.

d. Waiver

When a certifying authority waives the requirement for a certification, under this final rule the federal agency may proceed to issue the license or permit in accordance with its implementing regulations. A certifying authority may waive expressly by issuing a written statement that it is waiving certification, or implicitly waive by failing or refusing to act. Waiver may occur due to a failure or refusal to act in accordance with the procedural requirements of section 401 or within the reasonable period of time (*see* section III.F of this notice), or by failing or refusing to provide information required to support certifications (section 121.7(c) of the final rule) or denials (section 121.7(e) of the final rule). A condition may also be waived by failing or refusing to provide information required to support

certification conditions (section 121.7(d) of the final rule).

i. Explicit Waiver

Under the final rule, a certifying authority may waive expressly by issuing a written statement that it is waiving the requirement for certification. Some commenters supported allowing certifying authorities to explicitly waive certification. One commenter observed that doing so could allow the federal permitting authority to proceed more quickly with issuing a license or permit if it need not wait until the end of the reasonable period of time. Several commenters asserted that the statute does not provide for express waiver. A few other commenters stated that certifying authorities should be required to provide a detailed statement explaining their reasoning for waiving certification.

The EPA has determined that, although the statute does not explicitly provide for express or affirmative waiver, providing this opportunity in the final rule is not inconsistent with a certifying authority's ability to waive through failure or refusal. *See EDF v. Alexander*, 501 F. Supp. 742, 771 (N.D. Miss. 1980) (“We do not interpret [the Act] to mean that affirmative waivers are not allowed. Such a construction would be illogical and inconsistent with the purpose of this legislation.”). The EPA also agrees with the commenters who stated that allowing explicit waivers may create efficiencies in circumstances where the certifying authority knows early in the process that it will waive. The EPA is not requiring certifying authorities to provide a detailed statement explaining their reasoning for waiving, as the Agency recognizes certifying authorities may waive for a variety of reasons. Consistent with the proposal, the final rule provides that a certifying authority may expressly waive by providing written notification of waiver to the project proponent and federal agency.

An express or affirmative waiver does not reflect a determination that the discharge will comply with water quality requirements. Instead, an express or affirmative waiver indicates that the certifying authority has chosen not to act on a certification request. The EPA agrees with the commenter who noted that express or affirmative waiver enables the federal agency to proceed with issuing a license or permit where the certifying authority has stated it does not intend to act, thereby avoiding the need to wait for the reasonable period of time to lapse.

ii. Implicit Waiver

The plain language of section 401(a)(1) provides that the certification requirement is waived when a certifying authority “fails or refuses to act on a request for certification, within a reasonable period of time (which shall not exceed one year).” 33 U.S.C. 1341(a)(1). The Agency proposed to define “fails or refuses to act” with the intention of providing greater clarity for project proponents, certifying authorities, and federal agencies about when an implicit or constructive waiver could occur. The Agency is not finalizing the proposed definition of “fails or refuses to act” and is instead providing additional clarification in the final rule about specific procedural failures that could trigger a federal agency to determine that waiver has occurred.

Under the proposed rule, waiver would occur if the certifying authority actually or constructively failed or refused to act within the scope of certification or within the reasonable period of time. The proposed rule preamble explained that the phrase “fails or refuses to act” lends itself to at least two interpretations. Under one interpretation, a certifying authority that takes no action, or refuses to take action, has waived certification. Under an alternative interpretation, a certifying authority that takes action beyond the scope of section 401 has failed or refused to act in a way Congress intended and has waived certification. The proposed definition was intended to resolve this ambiguity in the statute.

Some commenters supported the proposed definition of “fail or refuse to act,” including the implicit or constructive waiver provision. A few commenters cited *City of Tacoma v. FERC*, 460 F.3d 53 (D.C. Cir. 2006), in support of the proposed rule, and these commenters agreed that it would be appropriate for federal agencies to facially review certifications. Some of these commenters said that this approach is not supported by the text of the statute or by congressional intent. Many commenters asserted that the legislative history of the waiver provision makes clear that it was intended only to prevent a State's sheer inactivity. One of these commenters noted that the legislative history acknowledges that the waiver provision cannot protect against arbitrary State agency action and that the courts are the forum to challenge a State's refusal to give a certification.⁶¹ Some commenters

stated that allowing the federal agency to review a certification denial as a failure to act is unreasonable and essentially grants the federal government veto power over State action.

The EPA disagrees with commenters who asserted that federal agencies cannot review certifications. As discussed below, some courts have concluded that federal agencies have an affirmative obligation to determine whether a certifying authority has complied with requirements related to a section 401 certification. *See City of Tacoma v. FERC*, 460 F.3d 53, 67–68 (D.C. Cir. 2006); *Keating v. FERC*, 927 F.2d 616, 622–623, 625 (D.C. Cir. 1991). The final rule affirms that it is the responsibility of the federal agency to facially review certifications to ensure that certifying authorities have complied with the procedural requirements of section 401. If a federal agency, in its review, determines that a certifying authority failed or refused to comply with the procedural requirements of the Act, including the procedural requirements of this final rule, the certification action, whether it is a grant, grant with conditions, or denial, will be waived.

After considering public comments and other enhancements in this final rule, the Agency is not finalizing the definition of “fail or refuse to act.” The Agency concludes that the key ambiguous term in this statutory phrase is “to act” and reasonably interprets this term to mean not just any act or action, but an act or action that is “in conformance with applicable statutes and regulations.” The final rule provides a clear and unambiguous list of actions that are not in conformance with section 401 and that therefore amount to waiver. The clarity in the final rule provides certifying authorities with sufficient notice that all actions on certification requests must be taken in accordance with the procedural requirements of the statute and this final

of congressional intent. The history quoted by these commenters (H.R. Rep. No. 92–911, at 121–22 (1972)) says both that a failure or refusal amounts to waiver and that a refusal must be addressed in a State court challenge brought by the project proponent. “In such situations, where there is conflicting legislative history and the statute is silent or ambiguous with respect to the specific issue, our [the court's] role is to determine ‘whether the agency's answer is based on a permissible construction of the statute.’” *Smriko v. Ashcroft*, 387 F.3d 279, 288 (3d Cir. 2004) (quoting *Chevron*); *United States v. Deardorff*, 343 F. Supp. 1033, 1037–38 (S.D.N.Y. 1971) (the canon of statutory interpretation that “legislative history not be used to interpret a statute that is clear and unambiguous on its face . . . is particularly apposite where the legislative history is itself somewhat ambiguous.”).

⁶¹ The EPA observes that some legislative history related to section 401 is internally inconsistent and should not be relied upon as a definitive statement

rule. Accordingly, the Agency has decided that a separate definition of “fail or refuse to act” is not necessary. Treatment of procedural deficiencies as waivers is consistent with the EPA’s existing regulations for the NPDES program. See 40 CFR 124.53(e)(2) (providing that for certification on a draft permit, “[f]ailure to provide such citation waives the right to certify with respect to that condition”).

The waiver provision in section 121.9 of the final rule has been expanded to provide additional clarity on the circumstances that amount to a failure or refusal to act. As discussed in section III.G.2.e of this notice, a federal agency must determine whether waiver has occurred, either expressly or implicitly through a failure or refusal to act. Section 401 provides that certifying authorities may take one of four possible actions on a certification request: Grant, grant with conditions, deny, or waive. As long as a certifying authority takes one of these four actions within the reasonable period of time and in accordance with the procedural requirements of the Act and this final rule, the certifying authority will have acted on the certification request. However, section 401 provides that where a certifying authority “fails or refuses” to act on a certification request, certification shall be waived. 33 U.S.C. 1341(a)(1). Under the final rule, a certifying authority waives certification if it fails or refuses to act on a certification request in accordance with the procedural requirements of section 401 and this final rule, including but not limited to issuing public notice, acting within the reasonable period of time, providing certification for projects that are within their jurisdiction, providing certification decisions in writing, and including the information required to support a certification or denial. The final rule also provides that a certification condition may be waived if the certifying authority fails or refuses to provide information required in section 121.7(d). Under the final rule, deficient conditions are severable from the certification. In other words, waiver of a specific certification condition does not waive the entire certification.

e. Federal Agency Review of Certifications

The proposed rule would have required federal agencies to review a certification action to determine whether it was issued in accordance with the procedural requirements of the Act and determine whether the action was taken within the “scope of certification” as provided in the rule. The EPA has considered public

comments and relevant court decisions and is retaining in the final rule the requirement that federal agencies review certification actions for compliance with the procedural requirements of section 401, including procedural requirements in this final rule. However, the final rule does not require federal agencies to substantively evaluate or determine whether a certification action was taken within the scope of certification. As a general matter, federal agencies may not readily possess the expertise or detailed knowledge concerning water quality and State or Tribal law matters that would be necessary to make such substantive determinations. The EPA has determined that other provisions of this final rule, such as the definitions of “water quality requirements,” “discharge,” and “certification,” and the information requirements for certification conditions and denials listed in section 121.7(d) and section 121.7(e), will help ensure that certifying authorities have the information and necessary tools to act on a certification request within the scope of certification as provided in this rule. The Agency is not finalizing the provisions in section 121.6(c) and section 121.8(a)(1)–(2) of the proposed rule.

i. Federal Agency Procedural Review

The final rule requires federal agencies to determine whether a certifying authority’s certification, certification condition, or denial includes the information requirements in sections 121.7(c), 121.7(d), or 121.7(e) of the final rule. This federal agency review is entirely procedural in nature and does not require any specific expertise or knowledge in water quality or State or Tribal law. Under the final rule, the federal agency’s review is limited to determining whether the certification action was taken in accordance with procedural requirements and whether the certification, condition, or denial includes all of the required information. Federal agency review under the final rule does not include a substantive evaluation of the sufficiency of that information.

A few commenters supported the proposed requirement that federal agencies substantively review water quality certifications and asserted that such reviews would bring clarity and certainty to the water quality certification process. These commenters also supported the proposed authority for federal agencies to determine that constructive waiver occurred for certifications, conditions, and denials that failed to comply with procedural requirements of the rule. Some

commenters stated that allowing federal agencies to review and reject certifications, conditions, and denials would violate the rights of States and Tribes. Some commenters stated that section 401(a)(1), which provides that “[n]o license or permit shall be granted if certification has been denied,” prohibits the federal government from vetoing denials. Some commenters stated that the EPA did not provide any legal support from the CWA or case law for its proposed approach of allowing federal review of certifications, conditions, and denials.

The Agency has made modifications in the final rule text to clarify that federal agency review of certifications, conditions, and denials is procedural in nature and does not extend to substantive evaluations. The EPA’s final regulatory text at sections 121.8 (Effect of denial of certification), 121.9 (Waiver), and 121.10 (Incorporation of certification conditions into the license or permit) contemplate that the federal licensing or permitting agency will review certifications only to ensure that certifying authorities have included certain required elements and completed certain procedural aspects of a section 401 certification. Under the final rule, federal agencies are required to determine whether certification denials include the three elements listed in section 121.7(e). If certification denials do not include these three elements, the certifying authority has “fail[ed] or refuse[d] to act” (as explained in section III.G.2.d of this notice) and therefore has waived certification. Similarly, federal agencies are required to determine whether certification conditions include the two elements listed in section 121.7(d) of the final rule. If the certification conditions do not satisfy the requirements by listing these two elements, the certifying authority has “fail[ed] or refuse[d] to act” and will waive that deficient certification condition.

In delineating such a role for federal licensing or permitting agencies, the EPA has interpreted the statute reasonably and appropriately. In *City of Tacoma, Washington v. FERC*, the Court of Appeals for the D.C. Circuit noted that “[i]f the question regarding the state’s section 401 certification is not the application of state water quality standards but compliance with the terms of section 401, then [the federal agency] must address it. This conclusion is evident from the plain language of section 401: ‘No license or permit shall be granted until the certification required by this section has been obtained or has been waived.’” 460 F.3d at 67–68 (citing 33 U.S.C.

1341(a)(1)) (emphasis in original). The court went on to explain that even though the federal agency did not need to “inquire into every nuance of the state law proceeding . . . it [did] require [the federal agency] at least to confirm that the state has facially satisfied the express requirements of section 401.” *Id.* at 68; see also *Hoopa Valley Tribe v. FERC*, 913 F.3d 1099, 1105 (D.C. Cir. 2019) (“had FERC properly interpreted Section 401 and found waiver when it first manifested more than a decade ago, decommissioning of the Project might very well be underway”); *Airport Communities Coalition v. Graves*, 280 F. Supp.2d 1207, 1217 (W.D. Wash. 2003) (holding that the Army Corps had discretion not to incorporate untimely certification conditions).

Some commenters stated that allowing federal review of water quality certifications would ignore the fact that the States and Tribes are the experts on their water resources and know what is necessary to assure that the water quality standards passed under State and Tribal law are met. Another commenter requested clarification about whether the EPA would provide any assistance or guidance to federal agencies as they review certification denials and asked for clarification about how the EPA would ensure consistency and reliability across such decisions.

As discussed below, the final rule does not require the federal agency to make a substantive inquiry into the sufficiency of the information provided in support of a certification, condition, or a denial. Rather, the final rule requires only that the federal agency confirm that the certifying authority has complied with procedural requirements of the Act and these regulations and has included the required information in a certification, condition, or denial. Although this limited review function may be new to some federal agencies, it is consistent with the EPA’s own longstanding practice under its NPDES regulations implementing section 401 that allow the EPA to make such determinations under certain circumstances. See 40 CFR 124.53(e). Under the final rule, if a certification, condition or denial meets the procedural requirements of section 401 and this final rule, the federal agency must implement the certifying authority’s action, irrespective of whether the federal agency may disagree with aspects of the certifying authority’s substantive determination.

ii. Federal Agency Review of Scope

The proposed rule would have required federal licensing and permitting agencies to review and

determine whether certifications, conditions, and denials are within the “scope of certification,” as articulated in this final rule. The final rule does not include this additional substantive federal agency review requirement.

A number of commenters supported the proposed language that would allow a federal agency to set aside certification conditions or denials that are not within the “scope of certification.” Some of these commenters agreed that conditions should not be included in licenses or permits if they do not meet the definition of “water quality requirements” under the final rule. One of these commenters stated that federal agency review of certifications would allow issues of scope to be resolved expeditiously by the federal agency through the federal licensing or permitting process, rather than by forcing the applicant to challenge the certification decision through a separate administrative or judicial appeal process, which could take months or years to resolve. The commenter also asserted that the proposal would allow the federal agency to protect the integrity of its licensing or permitting process by rejecting conditions that exceed the scope of section 401 even if the applicant chooses not to challenge the conditions. Another commenter asserted that the federal agency has an obligation to determine that a certification decision “complies with the terms of section 401,” and that this obligation is supported by case law. The commenter maintained that this obligation logically also includes the obligation to confirm that certification conditions are within the scope of section 401.

Other commenters asserted that the proposed approach would conflict with sections 401(a) and (d) because, they assert, that under section 401(a) a federal license or permit may not issue if certification is denied, and under section 401(d), federal agencies have no authority to review or veto State or Tribal conditions or certifications. These commenters stated that the proposed provision would improperly circumvent judicial review. Some commenters stated that the proposed rule’s federal agency review provision is in contravention of the legislative intent. Some commenters stated that judicial precedent prohibits the EPA from authorizing federal agencies to review the scope or grounds for State and Tribal decisions on water quality certifications. One commenter stated that the authority of federal agencies to review State section 401 certifications is narrow and limited to ensuring that the State complies with the specific

procedural requirements set forth in section 401, citing *City of Tacoma, Wash. v. FERC*, 460 F.3d 53 (D.C. Cir. 2006); *Alcoa Power Generating Inc. v. FERC*, 643 F.3d 963 (D.C. Cir. 2011); *Keating v. FERC*, 927 F.2d 616 (D.C. Cir. 1991). A few commenters stated that a federal agency’s scope of review would lead to more confusion and litigation and would make the certification process more time consuming.

The Agency has considered this diverse range of opinions. For the reasons explained above, the Agency has concluded that under the final rule, federal agencies have an affirmative obligation to review certifications to ensure that certifying authorities have complied with procedural requirements and have included the required information for certifications, conditions, and denials. But the final rule does not authorize federal agencies to substantively review certifications or conditions to determine whether they are within the scope of certification. The EPA disagrees with commenters who assert that section 401(d) unambiguously requires one approach or another. As described throughout the proposed and final rule preambles, there are widely varying views and interpretations of section 401, and relevant court decisions reflect these disparate views and interpretations. The final rule provides a framework for section 401 water quality certifications that is reasonable, is supported by the language of the CWA, and will provide greater clarity and regulatory certainty.

One commenter stated that none of the cases cited by the EPA in the proposed rule suggested that federal agencies have authority to review the substance of State-imposed section 401 conditions to determine whether they comply with the EPA’s view of the appropriate scope of the statute. The same commenter stated that the proposal’s rationale that federal agencies have struggled to enforce State certification conditions misses the point and that enforcement of certification conditions may also be initiated by the appropriate States through State law, citing *Delaware Riverkeeper Network v. Secretary of Penn. Dep’t of Env’tl Protection*, 833 F.3d 360 (3d Cir. 2016). One commenter stated that EPA Office of General Counsel opinions have previously “interpreted [401(d)] broadly to preclude federal agency review of state certifications,” citing *Roosevelt Campobello Inter. Park v. U.S. EPA*, 684 F.2d 1041, 1056 (1st Cir. 1982) (citing opinions of the EPA Office of General Counsel on the issue). Some commenters also stated that to review a condition to determine whether it falls

substantively within the scope of water quality requirements would create a substantial burden on federal agencies making these types of determinations.

Some commenters stated that the proper place for water quality certifications and their conditions to be challenged is in court, particularly State court. Some commenters stated that State courts are the appropriate venue to challenge water quality certifications because those certifications are issued under State law and State courts know how best to interpret State law. Some commenters stated that the legislative history for the 1972 amendments to the CWA repeatedly shows that Congress intended conflicts regarding the scope of section 401 to be resolved by State courts, not federal agencies.

For the reasons articulated in the proposed and final rule preambles, the EPA disagrees with the proposition that relevant case law precludes any federal review of certification conditions. The EPA also disagrees with one commenter's assertion that, as a general matter, States may independently enforce certification conditions through State law. See section III.K.2.a of this notice for further discussion on the enforcement of certification conditions within federal licenses or permits. Although the proposed requirement was consistent with the principle that federal agencies have the authority to reject certifications or conditions that are inconsistent with the requirements and limitations of section 401 itself (see *City of Tacoma, Wash. v. FERC*), the final rule reflects the EPA's conclusion that courts of competent jurisdiction are better suited to evaluate the underlying State or Tribal law to determine whether a specific certification condition or the basis for a denial is within the scope of certification. The EPA also acknowledges that existing lower court case law on this topic is mixed, and that requiring federal agencies to conduct a substantive review to determine whether conditions or denials are within the scope of certification could create new litigation risk (including litigation-related staffing and cost burdens) for those federal agencies and further complexity and uncertainty concerning the appropriate path for remedying a substantively unlawful certification condition or denial. The final rule's scope of certification, requiring that "conditions" be within that scope, and requiring certifying authorities to provide specific information in support of a condition or a denial, will help provide reviewing courts with the information and tools necessary to conduct a proper

evaluation of certification conditions and denials.

iii. Remedying Deficient Conditions and Denials

The proposed rule would have allowed federal agencies to provide certifying authorities with the opportunity to remedy deficient conditions and denials. However, in response to public comments and to increase clarity in the final rule, the Agency is not finalizing these provisions.

Commenters expressed a variety of viewpoints about whether federal agencies can or should provide certifying authorities with the opportunity to remedy deficient conditions and denials. One commenter did not support providing certifying authorities with the opportunity to remedy conditions that are not related to water quality, while other commenters asserted that the ability to remedy deficient conditions should be mandatory rather than discretionary. Some commenters expressed concern regarding timeframes for federal review, notification to States and Tribes, and opportunity for States and Tribes to remedy water quality certifications and suggested that the opportunity to cure a deficient condition could effectively shorten the reasonable period of time. Commenters also requested that certifying authorities should be able to remedy deficient conditions regardless of whether the reasonable period of time has expired, or at least up until the one-year maximum reasonable period of time specified in the CWA. Some commenters expressed concern that the proposal did not provide an administrative appeal process for a certifying authority to dispute that conditions and denials are in fact "deficient."

The Agency has considered these comments and determined not to include in the final rule an express allowance for certifying authorities to remedy deficient conditions after the certification action is taken. The Agency recognizes and agrees with many of the implementation and process-related concerns raised by commenters, including concerns that there may not be sufficient time to remedy deficient conditions during the established reasonable period of time. The EPA disagrees with the commenters who asserted that the certifying authority must be given an opportunity to remedy deficient conditions even after the reasonable period of time has expired. The final rule contains additional clarification on procedural and substantive requirements. These

clarifications should provide certifying authorities with the information and tools necessary to act on certification requests consistent with section 401 and within the scope of certification provided in this final rule, reducing the need to remedy deficient conditions or denials. The EPA has concluded in the final rule that if a federal licensing or permitting agency wishes to create procedures whereby certifying authorities may remedy deficient conditions or denials, it may do so in its own water quality certification regulations. Such procedures may not be used to exceed the one-year statutory limit on the reasonable period of time. The approach in the final rule provides sufficient flexibility to those federal agencies should they wish to update their water quality certification regulations to provide additional procedures for remedying deficient certification conditions or denials.

H. Certification by the Administrator

1. What is the Agency finalizing?

In the final rule, the Agency is establishing specific procedures regarding public notice and requests for additional information that apply only when the EPA is the certifying authority. As discussed in section III.B of this notice, the Agency proposed to require pre-filing meeting procedures only when the EPA is the certifying authority, but the final rule expands the requirement for pre-filing meeting requests to all project proponents, including federal agencies when they seek certification for general licenses or permits, regardless of the certifying authority. The rationale for expanding this practice to all section 401 certifying authorities as a best practice for all certification actions is more fully explained in section III.B of this notice.

2. Summary of Final Rule Rationale and Public Comments

Section 401(a)(1) of the CWA provides that "[i]n any case where a State or interstate agency has no authority to give such a certification, such certification shall be from the Administrator." 33 U.S.C. 1341(a)(1). Currently, all States have authority to implement section 401 certification programs. However, the EPA acts as the certifying authority in two scenarios: (1) On behalf of federally recognized Indian Tribes that have not received TAS for section 401, and (2) on lands of exclusive federal jurisdiction, such as Denali National Park. When acting as a certifying authority, the EPA is subject to the same timeframes and section 401 certification requirements as other

certifying authorities. This section outlines additional procedures that apply only when the EPA is the certifying authority.

The first scenario arises when Tribes do not obtain TAS authorization for section 401 certifications. As discussed in section II.F.1 of this notice, Tribes may obtain TAS authorization for purposes of issuing CWA section 401 certifications. If a Tribe does not obtain TAS for section 401 certifications, the EPA is responsible to act as the certifying authority for projects resulting in a potential discharge into waters of the United States on Tribal land.

The second scenario arises when the federal government has exclusive federal jurisdiction over land. The federal government may obtain exclusive federal jurisdiction in multiple ways, including where the federal government purchases land with State consent to jurisdiction, consistent with article 1, section 8, clause 17 of the U.S. Constitution; where a State chooses to cede jurisdiction to the federal government; and where the federal government reserved jurisdiction upon granting statehood. See *Collins v. Yosemite Park Co.*, 304 U.S. 518, 529–30 (1938); *James v. Dravo Contracting Co.*, 302 U.S. 134, 141–42 (1937); *Surplus Trading Company v. Cook*, 281 U.S. 647, 650–52 (1930); *Fort Leavenworth Railroad Company v. Lowe*, 114 U.S. 525, 527 (1895). For example, the federal government retained exclusive jurisdiction over Denali National Park in Alaska's Statehood Act. Alaska Statehood Act, Public Law 85–508, 72 Stat. 339 (1958).

The EPA's 1971 certification regulations identified circumstances where the Administrator certifies instead of a State, Tribe, or interstate authority, and limited the Administrator's certification to certifying that a potential discharge "will not violate applicable water quality standards." 40 CFR 121.21. However, this language reflects the language of section 21(b) of the FWPCA (1970) and is not consistent with the statutory language of section 401(a), which requires authorities to certify that the potential discharge will comply with the applicable provisions of CWA sections 301, 302, 303, 306, and 307. In this final rule, the Agency is modernizing and clarifying its regulations by finalizing the following text in section 121.13(a):

Certification by the Administrator that the discharge from a proposed project will comply with water quality requirements is required where no state, tribe, or interstate agency has authority to give such a certification.

In circumstances where the EPA is the certifying authority and the water body impacted by the proposed discharge does not have any applicable water quality standards, the EPA's 1971 certification regulations provided the EPA with an advisory role. 40 CFR 121.24. The statute does not explicitly provide for this advisory role, and therefore, this final rule does not include a similar provision. However, the Agency believes that the technical advisory role provided in section 401(b) and discussed in section III.J of this notice is sufficient to authorize the EPA to play an advisory role in such circumstances. As a result, omitting this text in the final rule is unlikely to change the Agency's existing practice. 33 U.S.C. 1341(b).

Commenters provided feedback on a few general aspects of this topic. Several commenters expressed the importance of the Administrator's certification authority where a Tribe or interstate authority lacks such authority. Some of these commenters stressed that the EPA has a trust obligation to protect water quality for those Tribes that lack TAS and a responsibility to provide Tribes with an opportunity for meaningful input. One commenter stated that the EPA had not provided a list or map of the geographic areas in which it intends to assert certification authority and requested that the EPA explicitly identify all lands within its jurisdiction and the basis for EPA's jurisdictional assertion.

The EPA has a statutory obligation to act as a certifying authority, pursuant to CWA section 401(a)(1). Separately, pursuant to the Agency's 1984 Indian Policy (EPA Policy for the Administration of Environmental Programs on Indian Reservations, see <https://www.epa.gov/tribal/epa-policy-administration-environmental-programs-indian-reservations-1984-indian-policy>), the EPA has a responsibility to coordinate with Tribes when making decisions and managing environmental programs that affect reservation lands. The EPA takes these obligations and responsibilities seriously. Consistent with the CWA, the final rule directs the EPA to act as the certifying authority on behalf of Tribes that do not have TAS for CWA section 401. Under the final rule, the EPA does this by determining whether the potential discharge from a proposed project will comply with water quality requirements, as defined and explained in section III.E.2.b of this notice. As provided in section 401(a)(1) and in section 121.7(f) of the final rule, if there are no water quality requirements applicable to the waters receiving the

discharge from the proposed project, the EPA will grant certification. The Agency will continue to comply with the EPA Policy on Consultation and Coordination with Indian Tribes when certifying on behalf of Tribes and disagrees with commenters who suggested that this rule would preclude Tribes from contributing meaningful input.

The EPA does not maintain a national map of lands for which the Agency serves as the certifying authority, as such borders may on occasion change as Tribes continue to annex and cede lands. Rather, it is the duty of the project proponent to determine the appropriate certifying authority when seeking a section 401 certification. The EPA acknowledges that there may be potential for jurisdictional overlap between certifying authorities at certain project sites (e.g., at the boundaries of Tribal lands), and the Agency believes that the requirement for project proponents to request a pre-filing meeting with certifying authorities will provide an opportunity for clarifying discussions about which agency or organization is the proper certifying authority.

Some commenters expressed confusion about whether the "EPA as the certifying authority requirements" in the proposed rule applied to just the EPA, or to all certifying authorities, and one commenter asserted that subpart D of the proposed regulatory text should not use the term "certifying authority" to define those instances in which the EPA is taking action. The Agency disagrees that using the term "certifying authority" in subpart D of the proposed regulatory text is unclear, as subpart D of the proposed rule is titled "Certification by the Administrator" and section 121.11(c) of the proposed rule explained that for purposes of this subpart the Administrator is the certifying authority. However, to avoid any potential for confusion, the EPA has replaced the word "certifying authority" with "the Administrator" throughout subpart D of the final rule. As noted above, when the EPA is the certifying authority, it must comply with all of the requirements in the final rule, not just subpart D.

This final rule includes two sets of procedural requirements that would apply only when the Administrator is the certifying authority: (1) Clarified public notice procedures, and (2) specific timelines and requirements for the EPA to request additional information to support a certification request. These requirements are discussed below and are included in final rule sections 121.15 and 121.14.

The EPA also proposed a third set of procedural requirements that would have applied only when the Administrator is the certifying authority: Pre-filing meeting request requirements. As explained in section III.B of this notice, the EPA is finalizing a requirement that all project proponents, including federal agencies when they seek certification for general licenses or permits, submit a pre-filing meeting request to the certifying authority, regardless of whether the Administrator is the certifying authority. This requirement is now in section 121.4 of final rule subpart B, rather than in subpart D.

Some commenters recommended extending all three of these sets of proposed requirements to all certifying authorities. Other commenters recommended that none of the proposed requirements should apply to all certifying authorities. The EPA has considered the conflicting perspectives in these comments and has concluded in this final rule that only the pre-filing meeting request requirements will apply to all certifying authorities, as described in section III.B of this notice.

a. Public Notice Procedure

Section 401 requires a certifying authority to provide procedures for public notice, and a public hearing where necessary, on a certification request. Some courts have held that this includes a requirement for public notice itself. *City of Tacoma*, 460 F.3d at 68. The 1971 certification regulations at 40 CFR part 121.23 described the EPA's procedures for public notice after receiving a request for certification. The EPA is updating its regulations to provide greater clarity to project proponents, federal agencies, and other interested parties concerning the EPA's procedures for public notice when the Administrator is the certifying authority.

Under the final rule, when the Administrator is the certifying authority, the Agency will provide appropriate public notice, within 20 days of receipt of a certification request, to parties known to be interested. If the EPA in its discretion determines that a public hearing is appropriate or necessary, the Agency will, to the extent practicable, give all interested and affected parties the opportunity to present evidence or testimony at a public hearing.

One commenter stated that the public should be kept informed of the section 401 process and proposed project plans, especially for large projects. Another commenter suggested that public participation requirements in the

section 401 certification review process should be expanded, which they maintained would lead to better identification of projects that should be denied certification because of adverse effects on water quality. A few commenters disagreed with the proposition that public notice should be limited to parties known to be interested and asserted that notice should be provided to the general public. One commenter suggested that the public should receive a minimum of 30-days' notice prior to a hearing, or another timeframe tied to the date when information is made available for public review.

The EPA appreciates the public commenters who provided feedback on the public notice process for when the EPA is the certifying authority. The public notice and hearing process in the final rule will ensure that the Agency keeps the public informed about the section 401 certification process and proposed project plans. The proposed rule included a list of potentially interested parties, such as Tribal, State, county, and municipal authorities, heads of State agencies responsible for water quality, adjacent property owners, and conservation organizations. To avoid artificially or unintentionally narrowing the universe of potentially interested parties, this list is not included in the final rule. The procedures in the final rule, including providing notice to interested parties, will provide sufficient public notice, as required in section 401, and will provide the public with an opportunity to inform the EPA's certification decision through public comments. Under the final rule, the Agency may also, at its discretion, determine whether a public hearing is appropriate and necessary. In such cases, all interested and affected parties would be given the opportunity to present evidence or testimony at a public hearing. The Agency is not prescribing a single timeframe for the length of public notice under the final rule. The appropriate timeframe for notice and comment is more appropriately determined on a case-by-case basis, considering project-specific characteristics as well as the length of the established reasonable period of time. In general, the EPA anticipates that public notices will provide for a 30-day comment period; however, comment periods as short as 15 days or as long as 60 days may be warranted in some cases, based on the nature of the project and the reasonable period of time. The public hearing may be conducted in-person, or remotely

(through telephone, online, or other virtual platforms), as deemed appropriate by the Agency.

b. Requests for Additional Information

The definition of a certification request in this final rule identifies the information that project proponents are required to provide to certifying authorities when they submit a certification request. However, in some cases, the EPA may conclude that additional information is necessary to determine that the potential discharge will comply with water quality requirements (as defined at section 121.1(n) of the final rule). Section 401 does not expressly address the issue of whether and under what circumstances a certifying authority may request additional information to review and act on a certification request. The EPA concluded that it is reasonable and consistent with the CWA's statutory framework that when the Administrator is the certifying authority, the Agency be afforded the opportunity to seek additional information necessary to do its job. However, consistent with the statute's firm timeline to act on a certification request, it is also reasonable to assume that Congress intended some appropriate limits be placed on the timing and nature of such requests. This final rule fills the statutory gap and provides a structure for the Administrator as the certifying authority to request additional information and for project proponents to timely respond. Consistent with the proposal, this final rule includes procedural requirements and timeframes for action that will provide transparency and regulatory certainty for the Agency and project proponents. However, in response to public comments and to increase clarity, the Agency has provided enhancements to the final rule text.

Some commenters stated that the procedures proposed for when the EPA is the certifying authority would inhibit the EPA from seeking additional information on water quality effects relevant to making a certification decision. Some of these commenters stated that this would lead to unnecessary denials of certification where, had better information been developed, a certification may have been granted. The Agency disagrees with the suggestion that the procedures proposed for when the EPA is the certifying authority would lead to certification decisions based on incomplete information. Consistent with the proposal, the EPA must request information within 30 days of receipt. The final rule includes additional

clarifications that if the EPA finds it necessary to request additional information, then the EPA must make an *initial request* within 30 days of receipt. Nothing in the regulation precludes the EPA from making additional information requests at a later point in the process after an initial request is made, so long as that information can be developed by the project proponent and considered by the EPA within the reasonable period of time. This final rule acknowledges that certifying authorities like the EPA need relevant information as early as possible to review and act on section 401 certification requests within the reasonable period of time. As discussed in section III.B of this notice, the pre-filing meeting request requirement under this final rule is intended to ensure that the EPA has an opportunity to engage with the project proponent early, learn about the proposed project, and consider what, if any, additional information might be needed from the project proponent.

Under the final rule, if the Agency needs additional information, an initial request for information must be made to the project proponent within 30 days after the receipt of a certification request. Additional information may include, for example, more detail about the contents of the potential discharge from the proposed project or specific information about treatment or waste management plans or additional details about discharges associated with the operation of the facility. The final rule does not preclude the Agency from making additional requests for information, but such requests for information must still comply with the requirements outlined below in this section of the final rule preamble.

The EPA is finalizing a provision that when the Administrator is the certifying authority, the Agency can request only additional information that is within the scope of certification and is directly related to a potential discharge from the proposed project and its potential effect on the receiving waters. Some commenters supported the proposal to limit additional information requests to information within the scope of the section 401 certification, while other commenters disagreed with the limitation. The Agency considered these and other comments and is finalizing this provision with minor modifications to provide clarity and certainty when the EPA is the certifying authority.

Several commenters stated that the proposal would not distinguish between complex and simple projects and noted that the type of information needed to develop a certification for a complex

project, such as a 30- or 50-year FERC license, would not be the same as that needed for a shorter-term or simpler project. The EPA agrees with commenters that information needs may differ depending on the complexity of the proposed project and other project-specific factors. The final rule provides sufficient flexibility for the Administrator to request project-specific information to help inform the certification decision. To ensure that the Agency's action remains within the scope of certification, the EPA has determined that any additional information requested must be within the scope of certification and must be directly related to the discharge from the proposed project and its potential effect on receiving waters. In addition to ensuring that the Agency acts within the scope of certification, limiting the type of information that the EPA may request as the certifying authority eliminates unnecessary and burdensome requests. Doing so also limits EPA review of information irrelevant to the Agency's decision-making process.

The EPA is also finalizing a provision that when the Administrator is serving as the certifying authority, the Agency can request only additional information that can be collected or generated within the established reasonable period of time. Some commenters disagreed with this provision, and one commenter asserted that this provision would contravene the CWA and the statute's emphasis on protecting human health and the environment. Several commenters stated that the proposal defers to a project proponent to determine what information may reasonably be developed during the "reasonable period of time," because the project proponent could claim that it would take too long to collect or generate the information.

The Agency disagrees with commenters that suggested that this provision defers to project proponents to determine what information may be developed during the reasonable period of time. In most cases, it should be objectively known whether certain information can be generated or collected within the reasonable period of time. For example, a multi-year study cannot be conducted within a 12-month reasonable period of time. Similarly, a 180-day study cannot be conducted within a 60-day reasonable period of time. In the event of disputes between the EPA and the project proponent about whether certain new information can be collected or generated within the reasonable period of time, the EPA will engage directly and in good faith with

the project proponent to resolve the dispute.

This final rule is also intended to address issues that have caused delays in certifications and project development and that have resulted in protracted litigation. Although these provisions apply only when the EPA is the certifying authority, they may serve as models for other certifying authorities. For example, the Agency is aware that some certifying authorities have requested "additional information" in the form of multi-year environmental investigations and studies, including completion of a NEPA review, before the authority would even begin review of the certification request.⁶² Consistent with the plain language of section 401, under this final rule, when the Administrator is acting as the certifying authority, such requests from the EPA would not be authorized because they would extend the statutory reasonable period of time, which is not to exceed one year. This final rule provides clarity that, while additional information requests may be a necessary part of the certification process, such requests may not result in extending the period of time beyond which the CWA requires the Agency to act.

Under this final rule, when the Administrator is acting as the certifying authority, in any request for additional information, the EPA must include a deadline for the project proponent to respond. The deadline must allow sufficient time for the Agency to review

⁶² Some stakeholders have suggested that it may be challenging for a state to act on a certification request without the benefit of review under NEPA or a similar state authority. *See, e.g.,* Cal. Pub. Res. Code Section 21000 *et seq.*; Wash. Rev. Code Section 43.21C.150. Consistent with the EPA's 2019 Guidance, the EPA recommends that certifying authorities do not need to delay action on a certification request until a NEPA review is complete. The environmental review required by NEPA has a broader scope than that required by section 401. For example, the NEPA review evaluates potential impacts to all environmental media, as well as potential impacts from alternative proposals that may not be the subject of a federal license or permit application. By comparison, a section 401 certification review is far more narrow and is focused on assessing potential water quality impacts from the proposed federally licensed or permitted project. Additionally, many NEPA reviews have taken more than one year to complete. Waiting for a NEPA process to conclude may result in waiver of the certification requirement for failure to act within a reasonable period of time. To the extent that State or Tribal implementing regulations may have required a NEPA review to be completed as part of a section 401 certification review, the EPA encourages certifying authorities to update those regulations to incorporate deadlines consistent with the reasonable period of time established under the CWA, or to decouple the NEPA review from the section 401 process, so as to ensure timely action on section 401 certification requests and to avoid waiver by the certifying authority.

the additional information once it is received, and to act on the certification request within the established reasonable period of time.

Many commenters asserted that the proposed rule would not require project proponents to timely respond to requests for additional information. Some commenters requested that the EPA clearly state that failure by the project proponent to complete a section 401 certification request or provide requested additional information within a specified time period should be grounds for denial of certification.

The Agency disagrees with the suggestion that the project proponent would not be required to timely respond to requests for additional information. Under the final rule, when the Administrator is the certifying authority, project proponents must submit requested information by the EPA's deadline. The Agency has clarified in section 121.14(e) that a project proponent's failure to provide additional information does not prevent the Administrator from taking action on a certification request. If the project proponent fails to submit the requested information, the Agency may conclude that it does not have sufficient information to certify that a potential discharge will comply with applicable water quality requirements and may therefore deny the certification request. The EPA may also use its expertise to evaluate the potential risk associated with the remaining information or data gap and to consider granting certification within the reasonable period of time with conditions to address those potential risks. The EPA expects that when the Administrator is the certifying authority, these procedures will provide clarity and regulatory certainty to the EPA and project proponents. The EPA notes that States and Tribes may choose to adopt similar provisions to ensure that all certifying authorities are working effectively and in good faith to act on certification requests within the reasonable period of time, and that denials based on a lack of information are not done simply for administrative purposes but because additional information is needed to assure that the discharge from the proposed project will comply with water quality requirements and the lack of information cannot be addressed by appropriate certification conditions. The EPA further notes that under the proposal and this final rule, certifying authorities are not obligated to act on incomplete certification requests. If a certification request is not complete as required by this final rule,

the reasonable period of time does not begin.

I. Determination of Effect on Neighboring Jurisdictions

1. What is the Agency finalizing?

Consistent with the proposal, under the final rule, if the EPA in its discretion determines that a neighboring jurisdiction may be affected by a discharge from a federally licensed or permitted project, the EPA must notify the affected jurisdiction, the certifying authority, and the federal agency within 30 days of receiving the notice of the certification from the federal agency. The final rule includes certain enhancements to the proposed rule to increase clarity and regulatory certainty, as explained below in this section of the final rule preamble.

2. Summary of Final Rule Rationale and Public Comment

Section 401(a)(2) requires federal agencies to immediately notify the EPA when a certification is issued by a certifying authority for a federal licensing or permitting application. Section 401(a)(2) also provides a mechanism for the EPA to notify States and authorized Tribes where the EPA has determined the discharge from a proposed federally licensed or permitted project subject to section 401 may affect the quality of their waters. The EPA's 1971 certification regulations established procedural requirements for this process but required updating to align with CWA section 401 and to establish additional clarity. The EPA recognizes that federal agencies may have different processes to satisfy this requirement and will continue to work with these agencies to ensure that the Agency is notified of all certifications. The final rule does not contain a standardized process for federal agencies to immediately notify the EPA when certifications are issued. The EPA expects federal agencies to develop notification processes as they update their certification regulations in accordance with the Executive Order. The final rule provides flexibility for federal agencies to develop processes and procedures that work best within their licensing or permitting programs. Additionally, the Agency has made minor, non-substantive modifications to the regulatory text at section 121.12(a) to clarify that the federal agency's statutory obligation to notify the EPA is triggered when the federal agency receives a federal license or permit application and the related certification. The text of section 401(a)(2) provides that the federal agency must

"immediately" notify the EPA of such application and certification. To aid in clarity and implementation, the Agency reasonably interprets "immediately" to mean within five days of the Federal agency's receiving notice of the certification. 33 U.S.C. 1341(a)(2). The EPA believes that, in the context of section 401(a)(2), five days is a reasonable interpretation of the statutory term "immediately." The federal agency needs some amount of time to process receipt of the license application and certification from the project proponent or certifying authority, review the received materials (which might be substantial), and then transmit notice to the appropriate EPA office. Allowing for five days is a prompt yet reasonable period of time to complete this process. Moreover, unlike emergency response or notifications provisions in environmental statutes, the provisions in CWA 401 governing certifications do not appear to require an emergency response that might—in other contexts—justify interpreting "immediately" to require a shorter period of time to act. As provided in section 121.9(c) of the final rule, the federal agency must provide a separate written notification of any waiver determination; this notification need not occur prior to transmitting the certification to EPA under section 121.12(a) of the final rule.

This final rule affirms the EPA's interpretation that section 401(a)(2) establishes authority for the Agency to determine in its discretion whether the discharge from a certified project may affect the water quality in a neighboring jurisdiction. One public commenter agreed with the EPA's interpretation and discretion concerning the determination whether a project may affect downstream States under CWA section 401(a)(2). Other commenters stated that even if the EPA's discretion is supported by the language of the CWA, the unbounded scope of the discretion is not consistent with the statute and would not provide accountability to neighboring States, the project proponent, or the public without additional clarification. Some commenters stated that the EPA should provide notice to neighboring jurisdictions in every instance, thereby allowing neighboring jurisdictions who are best situated to understand their own water quality concerns to make a determination as to whether there would be an effect on water quality. Some commenters stated that the rule should set forth specific factors that the EPA would consider in making a determination or that the EPA's

determination should be made in consultation with neighboring jurisdictions. Other commenters requested that the EPA develop regulations or guidance that would explain when the EPA would exercise its authority to notify downstream jurisdictions.

The EPA appreciates these comments and recognizes the desire for more prescriptive and specific provisions concerning the determination of potential effects on neighboring jurisdictions. As a general matter, the EPA intends to use its technical expertise from administering the CWA over nearly fifty years to evaluate whether a certified project may affect a neighboring jurisdiction. At this time, the EPA is not establishing specific provisions in the final rule, but the EPA may in the future take action to further clarify this provision via either additional rulemaking or guidance.

The final rule modifies the EPA's 1971 certification regulations to mirror the CWA in describing the EPA's procedural duties regarding neighboring jurisdictions. The statute provides that, following notice of a section 401 certification, the Administrator shall within 30 days notify a potentially affected downstream State or authorized Tribe "[w]henver such a discharge *may affect, as determined by the Administrator*, the quality of the waters of any other State." 33 U.S.C. 1341(a)(2) (emphasis added). Because the EPA's duty to notify is triggered only when the EPA has made a determination that a discharge "may affect" a downstream State or Tribe, the section 401(a)(2) notification requirement is contingent. It is not a duty that applies to the EPA with respect to all certifications, rather it applies where—exercising its discretion—the EPA has determined that the certified discharge "may affect" a neighboring jurisdiction's waters. This provision is being finalized with minor modifications to increase clarity regarding the EPA's discretionary determination. The Agency has made minor, non-substantive modifications to the regulatory text at section 121.12(b) to clarify that the 30-day review period is triggered after the Administrator receives notice from the federal agency.

The EPA is also clarifying the section 401(a)(2) notification process in this final rule, as such procedures were not described in sufficient detail in the 1971 certification regulations. If, as described above, the EPA determines that a neighboring jurisdiction may be affected by a certified discharge from a federally licensed or permitted project, the EPA must notify the affected jurisdiction, certifying authority, federal agency, and

project proponent within 30 days of receiving the notice that certification was issued for a proposed project. If the Agency does not provide the required notification within 30 days of receiving notification from a federal agency, the federal agency may resume processing the federal license or permit. The EPA need not wait the full 30 days, but may notify the federal agency at any time so that it may continue processing the license or permit.

Some public commenters requested changes to the proposed procedures, such as different timelines for neighboring jurisdictions to make a decision. One commenter requested that timelines be flexible and incorporate the same factors that the federal agencies would consider for determining the reasonable period of time. Other commenters stated that neighboring jurisdictions should be able to request additional information to make a determination. The EPA is finalizing notification procedures substantively as proposed, because they are consistent with the text of section 401(a)(2).

The final rule also provides a predictable framework for determinations by neighboring jurisdictions. The final rule requires that the EPA's notification to neighboring jurisdictions be in writing, dated, and state that the neighboring jurisdiction has 60 days to notify the EPA and the federal agency, in writing, whether or not the discharge will violate any of its water quality requirements (as defined at section 121.1(n) of the final rule) and whether the jurisdiction will object to the issuance of the federal license or permit and request a public hearing from the federal agency. The final rule also requires that, if the neighboring jurisdiction requests a hearing, the federal agency must forward the hearing notice to the EPA at least 30 days before the hearing takes place. The public hearing may be conducted in-person or remotely through telephone, online, or other virtual platforms, as deemed appropriate by the Agency. Under the final rule, the EPA must provide its recommendations on the federal license or permit at the hearing. After considering the EPA's and the neighboring jurisdiction's input, the federal agency is required to condition the license or permit as necessary to assure that the discharge from the certified project will comply with the neighboring jurisdiction's water quality requirements, as the term is defined in the final rule. Consistent with section 401(a)(2), under the final rule, if additional conditions cannot assure that the discharge from the certified project will comply with the neighboring

jurisdiction's water quality requirements, the federal agency cannot issue the license or permit. The final rule further clarifies that the federal agency may not issue the license or permit pending the conclusion of the determination of effects on a neighboring jurisdiction.

One commenter asserted that the EPA should consider all Tribes as neighboring jurisdictions for purposes of section 401(a)(2), irrespective of whether they have TAS. The commenter argued that limiting the application of the neighboring jurisdiction provision to those Tribes with TAS would subject Tribes without TAS to a lesser standard of review and ultimately resource protection. The Agency has determined that only States or authorized Tribes are considered to be "neighboring jurisdictions" under the final rule. As explained in section II.F.1 of this notice, section 518 of the CWA authorizes the EPA to treat eligible Tribes with reservations "as a State" within the meaning of that provision, but the CWA does not authorize the EPA to treat all Tribes in that manner. 33 U.S.C. 1377(e).⁶³

J. The EPA's Role in Review and Advice

The final rule reaffirms the EPA's important role in providing advice and technical assistance as requested through the certification process. The final rule provision in section 121.16 has been modified from the proposal to better align with the text of section 401 and the scope of certification in this final rule.

As described in the proposal, the EPA's 1971 regulations limited the provision of technical assistance to concerns regarding "water quality standards." To be consistent with the 1972 amendments, the final rule replaces this term with the broader "water quality requirements" which, as defined in the final rule, includes water quality standards. The proposed rule included a provision specifically authorizing a certifying authority, federal agency, or project proponent to request assistance from EPA to evaluate whether a certification condition was intended to address water quality effects

⁶³This final rule does not change the regulations under which federally recognized Indian Tribes obtain authorization to be treated in the same manner as states. 40 CFR 131.4(c) expressly states that where the EPA determines that a Tribe is eligible for TAS for purposes of water quality standards, the Tribe is likewise eligible to the same extent as a State for purposes of section 401 certifications. The regulations also establish criteria, application requirements, and application processing procedures for Tribes to obtain TAS authorization for purposes of CWA water quality standards. See 40 CFR 131.8.

from the discharge. The Agency is not finalizing that provision because it concluded that the final rule section 121.16 is broad enough to capture all technical advice that may be requested by certifying authorities, federal agencies, and project proponents.

Some commenters expressed concern that the proposed rule's description of the EPA's review and advice role goes beyond the authority provided in section 401(b). Other commenters supported the EPA's providing assistance upon request. Other commenters asked whether the EPA would be the "decision maker" or a party to litigation challenging a certification if a project proponent, certifying authority, or federal agency relied on the EPA's technical advice at any point during the certification process.

Under the final rule, federal agencies, certifying authorities, and project proponents may seek the EPA's technical expertise at any point during the section 401 water quality certification process. The Agency disagrees with commenters who asserted that the proposed regulation exceeded the authority provided in section 401(b). The Agency is not asserting independent or expanded authority in this role, but rather will provide assistance upon request. The legislative history for the Act provides further support for the Agency's technical role under section 401(b). *See* H.R. Rep. No. 92-911, at 124 (1972) ("The Administrator may perform services of a technical nature, such as furnishing information or commenting on methods to comply with limitations, standards, regulations, requirements or criteria, but only upon request of a State, interstate agency or Federal agency."). Under the final rule section 121.16, a certifying authority, federal agency, or project proponent may request assistance from the Administrator to provide relevant information and assistance regarding the meaning of, content of, application of, and methods to comply with water quality requirements. This provision of the final rule is not intended to give the EPA authority to make certification decisions, or to independently review certifications or certification requests. Nor does this provision authorize the EPA to interpret a State or Tribal water quality standard or designated use in a manner that is inconsistent with the State or Tribe's interpretation or implementation of that standard. This provision is merely intended to implement a provision of the statute that has been in effect since 1972. The provision of technical advice to project

proponents, certifying authorities, or federal agencies is not a final agency action, and it does not render the EPA a decision maker for purposes of the certification action or subsequent action of the federal agency.

K. Enforcement

1. What is the Agency finalizing?

Under the final rule, the federal agency issuing the applicable federal license or permit is responsible for enforcing certification conditions that are incorporated into a federal license or permit. Once the certifying authority acts on a certification request, the CWA does not provide independent authority for certifying authorities to enforce the conditions that are included in a certification under federal law. Under the final rule, the EPA is interpreting the CWA to clarify that this enforcement role is reserved to the federal agency issuing the federal license or permit.

Consistent with section 401, the final rule also expands the post-certification inspection function from the 1971 certification regulations to all certifying authorities. Under the final rule, certifying authorities are provided the opportunity to inspect the facility or activity prior to initial operations, in order to determine whether the discharge from the certified project will violate the certification. After an inspection, the certifying authority is required to notify the project proponent and federal agency in writing if it determines that the discharge from the certified project will violate the certification. The certifying authority is also required to specify recommendations concerning measures that may be necessary to bring the certified project into compliance with the certification.

2. Summary of Final Rule Rationale and Public Comment

The CWA expressly notes that all certification conditions "shall become a condition on any Federal license or permit" subject to section 401.33 U.S.C. 1341(d). The EPA's 1971 certification regulations did not discuss the federal agency's responsibility to enforce certification conditions after they are incorporated into the permit. Under the final rule and consistent with the Act, the federal agency is responsible for enforcing certification conditions that are incorporated into a federal license or permit. In limited circumstances, the EPA's 1971 certification regulations required the Agency to provide notice of a violation and to allow six months for a project proponent to return to compliance before pursuing further

enforcement. *See* 40 CFR 121.25. The EPA finds no support for that provision in CWA section 401, and such a provision is not included in the final rule.

a. Federal Agency Enforcement of Certification Conditions

The CWA does not provide an independent regulatory enforcement role for certifying authorities. The role of the certifying authority is to review the proposed project and to either grant certification, grant certification with conditions, deny certification, or waive certification. Once the certifying authority acts on a certification request, section 401 does not provide an additional or ongoing role for certifying authorities to enforce certification conditions under federal law. Rather, federal agencies typically have enforcement authority in accordance with the enabling statutes that provide such agencies with permitting and licensing authority.

Many commenters agreed with the proposal that the enforcement of section 401 conditions in a federal license or permit is the sole responsibility of the federal agency that issues the license or permit. A few commenters asserted that nothing in the CWA provides States with the authority to enforce or implement conditions of a section 401 certification. Another commenter stated that if certification conditions were enforceable independent of the federal license or permit, there would have been no need for Congress to require conditions to become part of the federal license or permit under section 401(d). Another commenter requested that the final rule unequivocally provide that section 401 certification conditions may be enforced only after they are incorporated into the federal license or permit and only in the same manner as the other conditions of the federal license or permit, and that such conditions may not be independently enforced pursuant to the CWA. As reflected in the final rule regulatory text, the EPA generally agrees with these commenters.

Other commenters asserted that the rule should allow States and Tribes to independently enforce their section 401 certification conditions. Some commenters asserted that providing federal agencies with exclusive authority to enforce section 401 certification conditions, and limiting State enforcement, is contrary to the language of the CWA, legislative history, and case law, citing *Deschutes River Alliance v. PGE Co.*, 249 F.Supp.3d 1182 (D. Or. 2017); *S.D. Warren*, 547 U.S. at 386. Another commenter

asserted that the Agency failed to cite any legal authority for prohibiting States from enforcing their own certifications. One commenter asserted that section 401 does not override State enforcement authority under State law, in those States that have provided for it. A few commenters referenced the savings clause in section 510 as explicitly preserving State authority to enforce State laws and requirements and suggested that reservation includes enforcement of section 401 certifications.

The EPA has considered these comments and has concluded that some of them reflect a misunderstanding of the proposed rule. The Agency recognizes that some States have enacted State laws authorizing State enforcement of certifications or certification conditions in State court. State enforcement under State authorities may be lawful where State authority is not preempted by federal law.⁶⁴ Nothing in this final rule prohibits States from exercising their enforcement authority under enacted State laws; however, the legality of such enforcement actions may be subject to review by a court of competent jurisdiction. Therefore, today's rule does not implicate, let alone violate, the reservation of state authority contained in section 510 of the Act.

Rather, the EPA concludes that section 401 of the CWA does not authorize States and Tribes to independently enforce section 401 certification conditions under federal law. The CWA expressly authorizes the certifying authority to review the proposed project and to either grant certification, grant certification with conditions, deny certification, or waive certification. Once the certifying authority acts on a certification request, the CWA does not authorize certifying authorities to enforce certification conditions under federal law; rather, a federal agency may enforce its license or permit, including section 401 certification conditions. The EPA has reviewed and considered legislative history from the 1972 amendments and concludes that, on this point, the

legislative history is either silent or lacks a definitive statement of congressional intent.⁶⁵ The Agency agrees with the commenter who noted that if certification conditions were enforceable independent of the federal license or permit, there would have been no need for Congress to require conditions to be included in the federal license or permit under section 401(d).

A few commenters asserted that without State enforcement, project proponents will be less likely to comply with the State conditions, to the detriment of the environment. Some commenters asserted that the certifying authority, not the federal agency, often has the technical knowledge, organizational structure, and staffing capacity to conduct inspections and to enforce section 401 certification conditions. One commenter noted that the proposal creates regulatory uncertainty if States cannot enforce certifications and conditions. Other commenters suggested that enforcement of section 401 certifications should be done jointly by federal agencies and certifying authorities. One commenter asserted that the proposed rule should be revised to allow federal agencies and States to determine their appropriate roles in enforcing water quality certifications. Another commenter asserted that federal agencies are not precluded from consulting with certifying authorities if additional substantive expertise is needed, but argued that it was important for project proponents to know to whom they are accountable and to eliminate the potential for any conflicting obligations.

The Agency disagrees with commenters' suggestion that water quality will be compromised if States cannot independently enforce certifications under federal law. The federal licensing or permitting agency remains responsible for exercising its

enforcement authority for all provisions of the federally issued license or permit, including any conditions incorporated from a certification. The Agency also disagrees with commenters who requested that the EPA include authority in the final rule for States and Tribes to independently enforce or to jointly enforce certification conditions. The EPA cannot create via rulemaking federal or state enforcement authority that is not expressly authorized in the statute. However, the EPA always encourages coordination and cooperation between certifying authorities and federal agencies, particularly if such coordination can result in greater accountability and compliance with certification conditions. This final rule is intended to promote efficient permitting processes and regulatory certainty by clarifying that section 401 does not provide an additional or ongoing role for certifying authorities to enforce certification conditions under federal law. This final rule provides clarification on who holds project proponents accountable under federal law and eliminates any confusion about which entity is responsible for enforcing specific certification conditions in the federal license or permit. This final rule also eliminates the possibility of inconsistent interpretation and enforcement of the certification conditions in the federal license or permit, increasing the likelihood that project proponents will be able to comply with the certification conditions. Additionally, as discussed above, the final rule does not preclude States from pursuing enforcement actions where authorized under State law and not preempted by other federal statutory provisions. Importantly, the Agency agrees that federal agencies are not precluded from consulting with certifying authorities or the EPA when exercising their enforcement authority under CWA section 401.

The Agency received feedback during stakeholder outreach, both pre-proposal and post-proposal, expressing concern that federal agencies may not consistently or sufficiently enforce certification conditions incorporated into their federal licenses or permits. The Agency has also received feedback from other federal agencies noting the potential challenge with enforcing certain certification conditions, particularly those that are ill-defined, that lack clarity, or that are beyond the scope of certification as outlined in section III.E of this notice. The Agency anticipates the clarity provided in this final rule with respect to the scope of a certification, the scope of the conditions

⁶⁴ Examples of situations where State authority would be preempted by federal law include FERC's sole authority to approve the construction of interstate natural gas pipelines and to regulate the transportation of natural gas for resale on these interstate pipelines under the Natural Gas Act (5 U.S.C. 717 *et seq.*; see also *Schneidewind v. ANR Pipeline Co.*, 485 U.S. 293 (1988); *Dominion Transmission, Inc. v. Summers*, 723 F.3d 238 (D.C. Cir. 2013)) and FERC's exclusive authority to license nonfederal hydropower projects under the Federal Power Act (16 U.S.C. 797(e), 817(1); see also *California v. Federal Energy Regulatory Comm'n*, 495 U.S. 490 (1990); *First Iowa Hydro-Electric Cooperative v. FPC*, 328 U.S. 152 (1946)).

⁶⁵ Most of the legislative history simply repeats the language from section 401 that certification conditions "will become a condition on any Federal license or permit" (H.R. Rep. No. 92-911, at 124 (1972) or that the certification becomes an "enforceable condition on the Federal license or permit" (S. Rep. No. 92-414, at 69 (1971)). However, the Senate's consideration of the Conference report states that "If a State establishes more stringent limitations and/or time schedules pursuant to Section 303, they should be set forth in a certification under Section 401. Of course, any more stringent requirements imposed by a State pursuant to this section shall be enforced by the Administrator." Sen. Consideration of Conf. Rep. No. 92-1236 (Exhibit 1), at 171 (1972) (emphasis added) As discussed in sections III.H, III.I, and III.J of this notice, the text of section 401 provides specific roles for EPA as a certifying authority, protecting waters in neighboring jurisdictions, and providing technical assistance, but section 401 does not provide an enforcement role for EPA when it is not the federal licensing or permitting agency.

of a certification (see section III.E.2.c of this notice), and the requirements for a certification with conditions (see section III.G.2.b of this notice) will provide federal agencies with sufficient information to enable them to effectively enforce certification conditions.

Enforcement plays an essential role in maintaining robust compliance with the CWA, and a critical part of any strong enforcement program is the appropriate use of enforcement discretion. See, e.g., *Heckler v. Chaney*, 470 U.S. 821, 831 (1985). Enforcement programs exercise discretion and make careful and informed choices about where to conduct investigations, identifying the most serious violations and reserving limited enforcement resources for the cases that can make the most difference. See *Sierra Club v. Whitman*, 268 F.3d 898, 902–03 (9th Cir. 2001). It is important for enforcement programs to retain their enforcement discretion because federal agencies are in the best position to (1) determine whether a particular action is likely to succeed, (2) assess whether the action fits agency policies, and (3) determine whether there are enough agency resources to undertake and effectively prosecute the action, taking account of all other agency constraints and priorities. See *Heckler*, 470 U.S. at 831.

A couple of commenters asserted that section 401 is not included in the CWA enforcement provision, CWA section 309, and that the CWA citizen suit provision, CWA section 505, does not authorize a citizen suit to enforce certification conditions. One commenter noted that although *Dombeck* held that a citizen suit could be used to challenge the issuance of a permit without a certification, the court did not make reference to the enforcement of certification conditions. A few other commenters asserted that enforcement of section 401 certification conditions is authorized under the CWA citizen suit provision, citing CWA section 505, *Oregon Natural Desert Ass'n v. Dombeck*, 172 F.3d 1092 (9th Cir. 1998), and *Deschutes River Alliance v. PGE Co.*, 249 F.Supp.3d 1182 (D. Or. 2017).

The EPA considered these public comments and the varying interpretations described above and is declining to adopt a particular interpretation in this final rule. The EPA did not propose an interpretation of the CWA section 505 citizen suit provision and did not solicit comment on its applicability to section 401 certifications or certification conditions, and EPA is therefore declining to finalize an interpretation of these provisions in this final rule.

Section 401(a)(4) and the EPA's 1971 certification regulations at 40 CFR part 121.26 through 121.28 describe circumstances in which the certifying authority may inspect a facility that has received certification prior to operation⁶⁶ and may notify the federal agency so that the agency may determine whether the facility will violate applicable water quality requirements. 33 U.S.C. 1341(a)(4). The Agency is updating these regulations to reflect the scope of certification review under the modern CWA. See section 121.11 of the final rule and section III.E of this notice. The Agency has made minor, non-substantive modifications to section 121.11(a) from proposal to match the language of section 121.11(b) and section 401(a)(4). Additionally, consistent with section 401, the EPA is expanding this inspection function to all certifying authorities and is clarifying the process by which certifying authorities should notify the federal agency and project proponent of any concerns arising from inspections.

Consistent with section 401, this final rule provides certifying authorities the opportunity to inspect the facility or activity prior to initial operation in order to determine whether the discharge from the certified project will violate the certification. The EPA notes that section 401(a)(4) authorizes certifying authorities to “review the manner in which the facility or activity shall be operated . . .” for purposes of assuring that water quality requirements will not be violated. 33 U.S.C. 1341(a)(4). The final rule uses the terms “inspect” and “inspection” because these are well understood terms that provide additional clarity in the final rule. The Agency does not expect these terms to change the meaning of section 401(a)(4), as implemented through section 121.11 of the final rule. After an inspection, the certifying authority is required to notify the project proponent and the federal agency responsible for issuing the federal license or permit in writing if the discharge from the certified project will violate the certification. The certifying authority is also required to specify recommendations concerning measures that may be necessary to bring the certified project into compliance with the certification.

Some commenters asserted that a certifying authority's compliance assurance and enforcement role should not be limited to one pre-operational inspection and asserted that the certifying authority must be allowed to

inspect the project both before and during operation in order to ensure the project is compliant with any certification conditions. One commenter explained that the certifying authority would not always be able to determine compliance with all conditions of the certification prior to operation. Another commenter asserted that it would be unacceptable for the State (rather than the project proponent) to identify the measures necessary to correct identified violations of certification conditions. Another commenter stated that it is unclear whether States have jurisdiction over post-license maintenance and repair projects that have an impact on water quality.

The EPA disagrees with commenters who suggested that the final rule should expand the inspection and enforcement authority provided in section 401. As finalized, this rule is consistent with the breadth of inspection and enforcement authority provided in section 401. This provision in the final rule is intended to allow the certifying authority the opportunity to inspect the facility or activity to determine whether the discharge will violate the certification issued. This final rule clarifies that after commencement of operations, enforcement of certification conditions incorporated into the federal license or permit is reserved to the federal agency that issued the federal license or permit under federal law. Accordingly, after commencement of operations, all inspections and enforcement will be conducted by the federal agencies. As discussed above, federal agencies are not precluded from consulting with certifying authorities or the EPA when exercising their enforcement authority under section 401.

b. Reasonable Assurance vs. Will Comply

The proposed rule replaced the language from the existing regulations requiring a “reasonable assurance that the proposed activity will not result in a violation of applicable water quality standards” with language requiring “that a discharge from a Federally licensed or permitted activity will comply with water quality requirements.” The Agency received comments expressing concerns about this proposed change. According to these commenters, the “will comply” language could result in States' including certification conditions that are difficult or impossible to comply with, resulting in greater non-compliance by project proponents. A few commenters expressed concern that “will comply” would impose a stricter standard on States than “reasonable

⁶⁶ The Agency notes that operation may include implementation of a certified project.

assurance,” such that they would be unable to develop conditions that include adaptive management provisions. These commenters maintained that the “reasonable assurance” standard currently allows for adaptive future decision-making despite present uncertainties. Other commenters stated that, in some cases, certifying authorities may be unable to demonstrate that a proposed project will be in compliance with water quality requirements at all times in the future, potentially resulting in more denials. Another commenter stated that the language in the final rule should include a “reasonable assurance” standard that a discharge would meet water quality requirements, rather than the “will comply” standard in the proposal. Several commenters noted that sections 401(a)(3) and (a)(4) retained the “reasonable assurance” language and asserted that Congress inadvertently changed the language in (a)(1) and (d). Another commenter argued that the ambiguity throughout 401(a) and (d) suggests that the competing provisions cannot be harmonized based on a plain language reading of the statute alone.

The Agency disagrees with the suggestion that the “reasonable assurance” language should be retained in the final rule. The “reasonable assurance” language in the EPA’s 1971 certification regulations was an artifact from the pre-1972 version of section 21(b), which provided that the certifying authority would certify “that there is reasonable assurance . . . that such activity will be conducted in a manner which will not violate applicable water quality standards.” Public Law 91–224, 21(b)(1), 84 Stat. 91 (1970). The Agency acknowledges that the inclusion of the phrase “reasonable assurance” in section 401(a)(3) and (a)(4) creates some ambiguity. The legislative history does not explain why Congress retained the term in sections 401(a)(3) and (a)(4) but not in sections 401(a) and (d).

Under basic canons of statutory construction, the EPA begins with the presumption that Congress chose its words intentionally. *See, e.g., Stone v. INS*, 514 U.S. 386, 397 (1995) (“When Congress acts to amend a statute, we presume it intends its amendment to have real and substantial effect.”). The Agency presumes that Congress chose to use the phrase “will comply” in sections 401(a)(1) and (d), while retaining the phrase “reasonable assurance” in 401(a)(3) and (a)(4). As such, the scope under this final rule and the “will comply” language are consistent with the 1972 CWA amendments to section 401(a)(1) and

(d), which require certifying authorities to conclude that a discharge “will comply” with water quality requirements (as defined in section 121.1(n) of this final rule).

The Agency disagrees with the suggestion that using “will comply” will place an impossible standard on certifying authorities. The Agency does not intend or believe that the statutory language requires States to ensure that a project will maintain strict compliance, in every respect, throughout its entire existence. The inclusion of the statutory language “will comply” does not require certifying authorities to provide absolute certainty that applicants for a federal license or permit will never violate water quality requirements. Indeed, future compliance depends on many factors besides just facility design and operation, and it would not be reasonable for an authority to certify that no unknown future event could ever result in a violation of the certification. The use of the language comparable to “will comply” is not uncommon in CWA regulatory programs. For example, CWA section 402 contemplates that an NPDES permits may issue only upon a showing that discharge “will meet” various enumerated provisions. 33 U.S.C. 1342(a). This standard has not precluded States, Tribes, or the EPA from routinely issuing NPDES permits for a variety of discharges; nor has it resulted in NPDES permits that are impossible for permittees to comply with. The Agency concludes that use of the statutory language “will comply” in the final rule remains loyal to the words that Congress chose when it enacted section 401. The Agency has no theoretical or empirical basis to conclude that the language in the final rule will materially change the way in which certifying authorities, including the EPA, process certification requests, so long as certifying authorities act in good faith and in accordance with CWA section 401.

L. Modifications

1. What is the Agency finalizing?

The EPA is finalizing the rule as proposed and is removing EPA’s oversight role for modifications to an existing certification. Additionally, the final rule does not authorize or include any procedure for certifying authorities to modify certifications after issuance. As discussed below, there are other established procedures that certifying authorities may rely on to address modifications, should the need arise.

2. Summary of Final Rule Rationale and Public Comment

a. The EPA’s Role in Modifications

Section 401 does not provide an express oversight role for the EPA with respect to the issuance or modification of section 401 certifications. The EPA’s role under section 401 consists of providing a common framework for the program through rulemaking, providing technical assistance under section 401(b), ensuring the protection of other States’ waters under section 401(a)(2), and acting as the certifying authority in some circumstances. However, the EPA’s 1971 certification regulations provided the Agency an oversight role in the unique context of modifications to existing water quality certifications. 40 CFR 121.2(b). The final rule removes this oversight role from the regulatory text, as it is inconsistent with the statute.

The Agency solicited comment generally on the appropriate scope of the EPA’s oversight role under section 401, and specifically whether the EPA should play any role in oversight of State or Tribal certifications or modifications, and, if so, what that role should be. The Agency received a considerable number of public comments on this issue, most of which supported removing the EPA’s oversight role for modifications to certifications. Some commenters agreed with the proposal that there is no statutory basis for section 121.2(b) of the 1971 certification regulations, nor is there any indication that Congress intended for the EPA to have an oversight role for modifications to certifications. Another commenter suggested that the EPA could follow the process described in the proposed rule section 121.10 to meet its obligation under section 401(a)(2) regarding neighboring States with respect to a modification to a section 401 certification.

The EPA agrees with commenters that there is no statutory basis in section 401 for the Agency to have an oversight role for modifications to certifications. The Agency disagrees with the commenter who asserted that it would be appropriate to expand the EPA’s authority provided under section 401(a)(2) to grant the Agency a more formal oversight role. The EPA’s role under section 401(a)(2) is plainly limited to (1) notifying a State or authorized Tribe if the Agency makes a discretionary determination that a discharge from a certified project may affect the waters of that jurisdiction, and (2) subsequently providing recommendations to the federal agency if the affected neighboring jurisdiction

requests a hearing. See section III.I of this notice.

b. Modifications by Certifying Authorities

In light of the statute's one-year time limit for a certifying authority to act on a section 401 certification, the EPA solicited comment on whether and to what extent States or Tribes should be able to modify a previously issued certification, either before or after the reasonable period of time expires, before or after the license or permit is issued, or to correct an aspect of a certification or its conditions if remanded or found unlawful by a federal or State court or administrative body.

Certain commenters were in favor of retaining the ability for States and Tribes to modify certifications. One commenter asserted that other CWA sections, such as sections 402 and 404, also do not explicitly allow for modifications, yet the EPA and the Corps assume authority to modify permits issued under those sections as long as they follow their own processes to do so. However, many commenters suggested that certain parameters should be applied to modifications, such as restrictions on "unilateral" modifications and "reopener" clauses. The EPA disagrees with commenters who argued in favor of allowing modifications to certifications. As described throughout this final rule preamble, section 401 certifications are unique in that they are not subject to ongoing enforcement by certifying authorities or oversight by the EPA, as section 402 and 404 permits may be. Indeed, once a certification is issued, the conditions therein are incorporated into a *different* document, a federal license or permit, for implementation and enforcement. Allowing certifications to be modified after issuance could create significant confusion and regulatory uncertainty within those federal license and permit programs.

Some commenters argued that "unilateral" modifications by the certifying authority should not be allowed, whereas other commenters favored a broad ability for States and Tribes to modify certifications. The commenters who disfavored unilateral modifications argued that it would effectively void the maximum reasonable period of time of one year and would lead to economic uncertainty for the project and possibly lengthy and expensive litigation. One commenter stated that unilateral modifications should be allowed in certain circumstances, such as before the reasonable period of time has expired.

Some commenters encouraged the EPA to provide clarity on the process by which a certification can be modified and the timeframe for that modification, so as to help avoid future regulatory uncertainty and litigation. A few commenters asked the EPA to clarify the process by which federal agencies must respond to any requested revisions to certifications beyond the reasonable period of time. As discussed in more detail below, the final rule does not authorize certifications to be modified after they have been issued. Section 401 does not grant States the authority either to unilaterally modify a certification after it is issued or to include "reopener" clauses in a certification. However, other established procedures are available to address situations that necessitate a modification after a certification has been issued.

Some commenters distinguished between modifications made within the reasonable period of time and those outside of that timeframe. A few of these commenters suggested various scenarios in which a modification should be allowed, including scenarios in which a court remands a certification or condition, the project proponent wants to correct an error, or the discharge in the federal license or permit changes. Another commenter asserted that State modification of certification conditions outside of the one-year review period should not automatically become part of the license or permit, citing *Airport Communities Coalition v. Graves*, 280 F. Supp. 2d 1207, 1217 (W.D. Wash. 2003).

The EPA has determined that section 401 does not provide authority for a certifying authority to unilaterally modify a certification, either through certification conditions that purport to authorize the certifying authority to reopen the certification in the future or through any other mechanism. The Agency also notes that the ability to unilaterally modify a certification after issuance is unnecessary, because circumstances that may necessitate modifications often will be linked to other actions that have established procedures. For example, if a federal license or permit is modified or the underlying project is changed such that the federal license or permit requires modification, it may trigger the requirement for a new certification, depending on the federal agency's procedures. See, e.g., 18 CFR 5.23 (requiring project proponents to submit a new certification request when the project proponent submits an application to FERC to amend an existing hydropower license or to amend a pending application for a hydropower license). Similarly, if a

court vacates or remands a certification or condition thereof, the certifying authority may need to modify the certification, depending on the specifics of the court's decision, and the federal agency may need to modify the license or permit accordingly. To reduce uncertainty, federal agencies may establish procedures in their regulations to clarify how modifications would be handled in these specific scenarios. For example, the EPA's existing regulations regarding certification in the NPDES program, located at 40 CFR 124.55(b), provide procedures for modification in certain circumstances ("If there is a change in the State law or regulation upon which a certification is based, or if a court of competent jurisdiction or appropriate State board or agency stays, vacates, or remands a certification, a State which has issued a certification under [section] 124.53 may issue a modified certification or notice of waiver and forward it to EPA.").

Additionally, the need to unilaterally modify a certification to address a change in the proposed project should be unnecessary under this final rule. As discussed in section III.C of this notice, if certain elements of the proposed project change materially after a certification is issued, it may be reasonable for the project proponent to submit a new certification request. The clock stops after a certifying authority issues a certification decision, and therefore the Agency disagrees with the suggestion that modifications should be allowed to occur after that point but within the reasonable period of time.

The EPA requested comment on whether EPA should expressly prohibit certification conditions that may create regulatory uncertainty, including conditions that extend the effective date of a certification beyond the reasonable period of time and conditions that authorize certifications to be reopened. Some commenters opposed certification conditions that enable a State or Tribe to "reopen" or revisit the certification at a specific time or upon certain triggering events. A few commenters argued that reopeners could effectively eliminate the one-year time limit in the statute and transform section 401's grant of State authority into an ongoing regulatory role. Another commenter, stating that reopener clauses allowing a State or Tribe to unilaterally modify a certification are contrary to law, noted that a regulation prohibiting such clauses would be consistent with judicial precedent, citing *Triska v. Dept of Health & Env'tl. Control*, 355 SE2d 531, 533–34 (S.C. 1987). Other commenters maintained that States and Tribes should retain their authority to

modify certifications whenever circumstances warrant, and that no federal agency should have authority over conditions issued by a State or Tribe or future modifications to those conditions. A few commenters noted that the broad authority granted in section 401(d) of the CWA also provides authority for a State or Tribe to include a “reopener” clause to ensure that their waters are protected, especially given the long timeframes for some projects.

The EPA has considered these comments and concludes that reopener clauses are inconsistent with section 401. The final rule does not include an explicit prohibition on reopener clauses because the EPA has concluded that such conditions are already proscribed by section 121.6(e) of the final rule. By including a reopener condition in a certification, the certifying authority intends to take an action to reconsider or otherwise modify a previously issued certification at some unknown point in the future. As described in section III.F above, the reasonable period of time to act on a certification request begins when a certifying authority receives the request, and ends when the certifying authority takes action to grant, grant with conditions, deny, or waive. The reasonable period of time does not continue to run after a certification decision is issued. A reopener condition, if allowed under this final rule, would effectively extend the established reasonable period of time into the future, potentially indefinitely. The Agency acknowledges that projects may change after a certification is issued; but, as discussed above, there are other procedures in this final rule and in other federal agency regulations that can address project changes that would necessitate a new or modified certification or federal license or permit. Reopener conditions are not authorized under this final rule because such actions by the certifying authority would modify the reasonable period of time, contrary to section 121.6(e) of the final rule.

As discussed above, section 401 does not provide certifying authorities with the authority to modify certifications after they are issued. The Agency disagrees with commenters who assert that section 401(d) provides certifying authorities with authority to include reopener clauses as a condition on a federal license or permit. As a general matter, administrative agencies possess the inherent authority to reconsider prior decisions;⁶⁷ however, section 401

provides express statutory language (e.g., specifying the time period in which a certifying authority must act on a certification request or waive its right to act; requiring certification conditions to be incorporated into a separate federal permit) that displaces the general principle, and thus Congress has precluded the certifying authority from reconsidering or modifying a certification. For the reasons explained above, unilateral modifications, including certification conditions that would reopen the certification in the future, are not authorized in section 401.

The Agency also disagrees with commenters that assert that the federal agency should not have authority over certification conditions or modifications. As discussed in section III.G.2.b of this notice, consistent with section 401(d), certification conditions that meet the requirements of final rule section 121.7(d) shall be incorporated into the federal license or permit. Accordingly, the federal agency is the appropriate party to address any modifications to the license or permit, including those certification conditions incorporated into the license or permit.

M. General Licenses and Permits

1. What is the Agency finalizing?

In response to comments received, the Agency is finalizing several provisions specific for certifications for the issuance of general licenses or permits. Section 121.5(c) of the final rule specifically defines elements of a “certification request” that must be submitted for the issuance of general licenses or permits. The Agency is also including additional provisions in section 121.7 of the final rule to address certification conditions and denials for general licenses and permits.

This final rule preamble also reaffirms that a federal agency seeking certification for a general license or permit must comply with all provisions of this final rule, including the pre-filing meeting request requirement in section 121.4. This final rule preamble also clarifies a federal agency’s obligation under section 401(a)(2) to notify the EPA when it receives certification for a general license or permit.

2. Summary of Final Rule Rationale and Public Comment

The majority of certifications are issued for projects that require an individual federal license or permit. However, certifications are also required prior to the issuance or establishment of

a general license or permit. General licenses and permits are vital to the effective operation of several federal programs such as the CWA section 402 and section 404 programs, producing efficiencies that save time and money for project proponents and regulators. General licenses and permits provide streamlined procedures for project proponents by authorizing categories of discharges or simplified review procedures when the discharges comply with specified requirements. Federal licensing and permitting agencies must obtain a section 401 certification when issuing general licenses or permits, and the final rule accounts for the potential variation of future projects or activities that may be covered under the general license or permit. The final rule provides slightly modified requirements to account for differences between individual and general licenses and permits in the water quality certification context.

a. Certification Request for a General License or Permit

The Agency took comment on whether federal agencies seeking certification for a general license or permit should be subject to the same or different “certification request” submittal requirements as other project proponents seeking certification for an individual license or permit. A few commenters stated that federal agencies should follow the same procedures as other project proponents for submitting certification requests. Another commenter encouraged the EPA to revise the elements of a certification request to provide flexibility for general licenses or permits, because the type, means, and methods used to monitor the future discharges that may be authorized in the future may not be known. The final rule includes specific requirements for certification requests for the issuance of general licenses or permits.

Where a federal agency is seeking to issue a general license or permit, the EPA expects the federal agency to follow the requirements of section 121.5(c) of the final rule. Section 121.5(c) of the final rule includes a list of documents and information required for “certification request for issuance of a general license or permit,” similar to the list that was included in the proposed rule as an alternative approach:

1. Identify the project proponent(s) and a point of contact;
2. identify the proposed categories of activities to be authorized by the general license or permit for which certification is requested;

⁶⁷ See e.g., *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42 (1983); *FCC v. Fox Television Studios*, 556 U.S. 502, 514–

15 (2009); *Belville Mining Co. v. United States*, 999 F.2d 989, 997 (6th Cir. 1993).

3. include the draft or proposed general license or permit;

4. estimate the number of discharges expected to be authorized by the proposed general license or permit each year;

5. include documentation that a pre-filing meeting request was submitted to the certifying authority at least 30 days prior to submitting the certification request;

6. contain the following statement: *‘The project proponent hereby certifies that all information contained herein is true, accurate, and complete to the best of my knowledge and belief’*; and

7. contain the following statement: *‘The project proponent hereby requests that the certifying authority review and take action on this CWA 401 certification request within the applicable reasonable period of time.’*

The list in section 121.5(c) is similar to the list in section 121.5(b) of the final rule, including the two new requirements (a statement that all information contained in the request is true, accurate, and complete to the best of the project proponent’s knowledge, and documentation that a pre-filing meeting request was submitted to the certifying authority at least 30 days prior to submitting the certification request), but with some differences to account for the distinctions between issuing a general license or permit and issuing a license or permit for a specific project, with respect to the available information at the time of certification. The Agency has made these changes regarding how general licenses and permits are handled under this final rule to improve clarity and for consistent administration of section 401 for all general licenses and permits.

b. Information Requirements for General License or Permit Certification Conditions and Denials

Consistent with commenters and other federal agency concerns regarding the need to account for the differences between individual and general license and permits, the final rule contains additional language in sections 121.7(d) and 121.7(e) to ensure that the rule can be consistently and appropriately applied to certifications issued for the issuance of general licenses and permits. Section 121.7(d)(1) of the final rule provides the information requirements for certification conditions that apply when a project proponent has requested certification for an individual license or permit that may result in a specific discharge or set of discharges into waters of the United States. See section III.C of this notice. The final rule includes a new section 121.7(d)(2), which provides slightly different information requirements for certification conditions for issuance of general licenses and permits.

Certifications for issuance of general permits and licenses must include the information requirements in section 121.7(d)(2) of the final rule.

For each certification condition on issuance of a general license or permit, section 121.7(d)(2) of the final rule requires:

(i) A statement explaining why the condition is necessary to assure that any discharge authorized under the general license or permit will comply with water quality requirements; and

(ii) A citation to federal, state, or tribal law that authorizes the condition.

Similarly, section 121.7(e)(1) of the final rule provides the information requirements for certification denials that apply when a project proponent has requested certification for an individual license or permit that may result in a specific discharge or set of discharges into waters of the United States. See section III.G.2.c of this notice. The final rule also includes a new section 121.7(e)(2), which provides slightly different information requirements for denials for general licenses and permits. For each certification denial for issuance of a general license or permit, section 121.7(e)(2) of the final rule requires:

(i) The specific water quality requirements with which discharges that could be authorized by the general license or permit will not comply;

(ii) A statement explaining why discharges that could be authorized by the general license or permit will not comply with the identified water quality requirements; and

(iii) If the denial is due to insufficient information, the denial must describe the types of water quality data or information, if any, that would be needed to assure that the range of discharges from potential projects will comply with water quality requirements.

Although these are both new provisions in the final rule, the substance of these information requirements is very similar to the information requirements for certification conditions and denials for individual licenses and permits that were included in the proposed rule. The EPA made only slight changes to these proposed provisions to facilitate their application in the general licensing and permitting context. Certification denials for a general license or permit must contain the information in section 121.7(e)(2) of the final rule.

c. Other Provisions of the Final Rule Also Apply to Certifications for General Licenses or Permits

As mentioned in sections III.B and III.I of this notice, the EPA expects that all of the procedural and substantive requirements in this final rule will

apply to entities seeking certification for a general license or permit. As discussed in section III.I of this notice, section 401(a)(2) provides a mechanism for the EPA to notify a State or an authorized Tribe where the EPA has determined that the discharge from a certified project may affect the quality of that State’s or Tribe’s waters. The Act requires federal agencies to notify the EPA of certifications and associated federal licensing or permitting applications. 33 U.S.C. 1341(a)(2). This statutory obligation extends to any circumstance where a federal agency receives a certification, including where the federal agency receives certification for issuance of a general license or permit.

The EPA is finalizing a pre-filing meeting requirement that requires all project proponents, including federal agencies when they seek certification for general licenses or permits, to request a meeting with a certifying authority at least 30 days prior to submitting a certification request, as discussed in section III.B of this notice.

IV. Economic Analysis

Pursuant to Executive Orders 12866 and 13563, the Agency conducted an economic analysis to better understand the potential effects of this final rule on certifying authorities and project proponents. While the economic analysis is informative in the rulemaking context, the EPA is not relying on the analysis as a basis for this final rule. See, e.g., *Nat’l. Assn. of Homebuilders v. EPA*, 682 F.3d 1032, 1039–40 (D.C. Cir. 2012). The analysis is contained and described more fully in the document *Economic Analysis for the Clean Water Act Section 401 Certification Rule* (“the Economic Analysis”). A copy of this document is available in the docket for this action.

Section 401 certification decisions have varying effects on certifying authorities and project proponents. The Agency has limited data regarding the number of certification requests submitted and the outcome of those certifications. To make the best use of limited information to assess the potential impacts of this final rule on project proponents and certifying authorities, the Economic Analysis provides a qualitative analysis of the section 401 certification process under the 1971 certification regulations and under the final rule. In particular, the Economic Analysis focuses on the revisions to the time period for review, the scope of review, and the pre-filing meeting request requirement.

This final rule will help certifying authorities, federal agencies, and project

proponents understand what is required and expected during the section 401 certification process, thereby increasing transparency and reducing regulatory uncertainty. The EPA concludes that improved clarity concerning the time period for review and the scope of review may make the certification process more efficient for project proponents and certifying authorities.

V. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at <https://www.epa.gov/laws-regulations/laws-and-executive-orders>.

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

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review. Any changes made in response to OMB recommendations have been documented in the docket for this action. In addition, the Agency prepared an analysis of potential costs and benefits associated with this action. This analysis is contained in the Economic Analysis, which is available in the docket and is briefly summarized in Section IV of this notice. While economic analyses are informative in the rulemaking context, the Agency is not relying on the economic analysis performed pursuant to Executive Orders 12866 and 13563 and related procedural requirements as a basis for this final rule.

B. Executive Order 13771: Reducing Regulation and Controlling Regulatory Costs

Pursuant to Executive Order 13771 (82 FR 9339, February 3, 2017), this final rule is a deregulatory action. See the Economic Analysis for further discussion about the potential effects of this rule.

C. Paperwork Reduction Act

The information collection activities in this final rule have been submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA). The Information Collection Request (ICR) document that the EPA prepared has been assigned EPA ICR number 2603.05 (OMB Control No. 2040-0295). You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here. The information collection requirements are not enforceable until they are approved by OMB.

The information collected under this ICR is used by certifying authorities for reviewing proposed projects for potential water quality impacts from discharges from an activity that requires a federal license or permit, and by the EPA to evaluate potential effects on downstream or neighboring jurisdictions. Except for when the EPA is the certifying authority, information collected under section 401 is not directly collected by or managed by the EPA. The primary collection of information is performed by States and Tribes acting as certifying authorities. Information collected directly by the EPA under section 401 in support of the section 402 program is already captured under existing EPA ICR No. 0229.22 (OMB Control No. 2040-0295).

The final rule clarifies the information that project proponents must provide to request a section 401 certification and introduces a pre-filing meeting request requirement for all project proponents. The final rule also removes information requirements related to certification modifications and section 401(a)(2) procedures for neighboring jurisdictions, and provides additional transparency by identifying, unambiguously, information necessary to support certification actions. The EPA expects this final rule will provide greater clarity on section 401 requirements, reduce the overall preparation time spent by a project proponent on certification requests, and reduce the review time for certifying authorities.

In the interest of transparency and public understanding, the EPA has provided here relevant portions of the burden assessment of the final rule. More information about the burden assessment can be found in the supporting statement for the ICR.

Respondents/affected entities: Project proponents, State and Tribal reviewers (certifying authorities).

Respondent's obligation to respond: required to obtain 401 certification (33 U.S.C. 1341(a)(1)).

Estimated number of respondents: 97,119 per year.

Frequency of response: one per federal application.

Total estimated burden: 931,000 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: \$58 Million (per year), includes \$8 Million annualized capital or operation & maintenance costs.

The final rule results in an estimated marginal burden decrease of 136,000 hours. This marginal decrease is associated with the reduction of information requirements in the final

rule and a projected decrease in certifying authority review times associated with the clearer scope of certification in section 121.3 of the final rule. A full description of the analysis is available in the supporting statement accompanying this information collection request.

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

D. Regulatory Flexibility Act

I certify that this action will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (RFA). In making this determination, the impact of concern is any significant adverse economic impact on small entities. An agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, has no net burden, or otherwise has a positive economic effect on the small entities subject to the rule.

Under section 401, a federal agency may not issue a license or permit to conduct any activity that may result in any discharge into waters of the United States, unless the State or authorized Tribe where the discharge would originate (or the EPA, in certain circumstances described above) either (1) issues a section 401 water quality certification finding compliance with applicable water quality requirements or (2) waives certification. Under section 401 and this final rule, the applicant for the federal license or permit (the project proponent) is required to request and obtain a water quality certification. This action provides project proponents with greater clarity and regulatory certainty on the substantive and procedural requirements for obtaining a water quality certification. This action also provides procedural clarity to certifying authorities and Federal licensing and permitting agencies. The Agency anticipates this action will result in faster, more efficient and more transparent decision-making by certifying authorities. As discussed in the Economic Analysis accompanying this final rule, the Agency concludes

that improved clarity concerning the scope and reasonable period of time for certification review may make the certification process more efficient for project proponents, including small entities, and does not expect the cost of the rule to result in a significant economic impact on a substantial number of small entities.

E. Unfunded Mandates Reform Act

This action does not contain an unfunded mandate of \$100 million or more as described in the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1531–1538, and does not contain any regulatory requirements that significantly or uniquely affect small governments. While this action creates enforceable duties for the private sector, the cost does not exceed \$100 million or more. This action does not create enforceable duties for State and Tribal governments. See Section IV of this notice for further discussion on the Economic Analysis.

F. Executive Order 13132: Federalism

Executive Order 13132, titled “Federalism” (64 FR 43255, August 10, 1999), requires federal agencies to develop an accountable process to ensure “meaningful and timely input by state and local officials in the development of regulatory policies that have federalism implications.” The Executive Order defines “policies that have federalism implications” to include regulations that have “substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.” The Agency concludes that the final rule may have federalism implications because it may impact how some States have historically implemented water quality certification programs. This final rule makes the EPA’s CWA section 401 regulation consistent with the statutory language, and acknowledges that States may modify their practices to be consistent with this regulation. The EPA provides the following federalism summary impact statement.

The Agency consulted with State and local government officials, or their representative national organizations, during the development of this action as required under the terms of Executive Order 13132 to permit them to have meaningful and timely input into the proposed rule’s development. On April 24, 2019, the Agency initiated a 30-day Federalism consultation period prior to proposing this rule to allow for meaningful input from State and local

governments. The kickoff Federalism consultation meeting occurred on April 23, 2019; attendees included representatives of intergovernmental associations and other associations representing State and local governments. Organizations in attendance included: National Governors Association, U.S. Conference of Mayors, National Conference of State Legislatures, the Environmental Council of the States, National League of Cities, Council of State Governments, National Association of Counties, National Association of Towns and Townships, Association of Clean Water Administrators, Western States Water Council, Conference of Western Attorneys General, Association of State Wetland Managers, and Western Governors’ Association. Additionally, one in-person meeting was held with the National Governors Association on May 7, 2019. The Agency also held an informational webinar for States and Tribes on May 8, 2019. At these webinars and meetings, the EPA provided a presentation and sought input on areas of section 401 that may require clarification, including timeframe, scope of certification review, and coordination among project proponents, certifying authorities, and federal licensing or permitting agencies. See section II.C of this notice for more information on outreach with States prior to Federalism consultation.

Letters and webinar attendee feedback received by the Agency before and during Federalism consultation may be found on the pre-proposal recommendations docket (Docket ID No. EPA–HQ–OW–2018–0855, available at <https://www.regulations.gov/docket?D=EPA-HQ-OW-2018-0855>). These webinars, meetings, and letters provided a wide and diverse range of interests, positions, and recommendations to the Agency. Following publication of the proposed rule, the Agency held two additional in-person meetings with State representatives to answer clarifying questions about the proposal and to discuss implementation considerations. The Agency has prepared a report summarizing its consultation and additional outreach to state and local governments and the results of this outreach. A copy of the final report is available in the docket (Docket ID No. EPA–HQ–OW–2019–0405) for this final rule. Correspondence received from State and local governments and their representative national associations during the public comment period can be found in Docket ID No. EPA–HQ–OW–2019–0405, available at [https://](https://www.regulations.gov/docket?D=EPA-HQ-OW-2019-0405)

www.regulations.gov/docket?D=EPA-HQ-OW-2019-0405.

During Federalism consultation and engagement efforts and in the State and local government comments on the proposed rule, many States expressed concern that the proposed rule would adversely impact State authority and States’ ability to protect state waters. Commenters raised several concerns, including concerns about the federal agency review role in the certification process; constraints on the certification review process, including the scope, timeframe, and information to start the statutory review clock; information requirements to act on a certification request; State enforcement role in certification; and the potential impact on existing State regulations and law.

The Agency acknowledges that the final rule may change how States administer the section 401 program, but has made adjustments in the final rule to account for many of the concerns raised by states. The Agency has made certain changes in response to comments, including comments from States and local governments. The final rule preserves the robust State role in the certification process in a manner consistent with the CWA. As discussed in section III.G of this notice, the final rule does not provide federal agencies with a role in substantively reviewing State certification decisions. Additionally, the final rule expands the pre-filing meeting requirement to all project proponents and allows States, in their discretion, to meet with project proponents to discuss information needs and concerns prior to starting the reasonable period of time. The final rule notice also clarifies that certifying authorities may request additional information during the reasonable period of time, and the final rule preserves certifying authorities’ ability to deny certification requests if they have inadequate information to determine whether a discharge complies with water quality requirements. The final rule definition of “water quality requirements” no longer limits other appropriate requirements of State law to requirements that are EPA-approved; rather, the definition captures State or Tribal regulatory requirements for point source discharges into waters of the United States. The final rule also removes the requirement for certifying authorities to provide a statement of whether and to what extent a less stringent condition could satisfy applicable water quality requirements.

As required by Section 8(a) of Executive Order 13132, the EPA included a certification from its Federalism Official stating that the EPA

had met the Executive Order's requirements in a meaningful and timely manner. A copy of this certification is included in the official record for this final action.

G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, Nov. 9, 2000), requires agencies to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." This action has Tribal implications. However, it will neither impose substantial direct compliance costs on federally recognized Tribal governments nor preempt Tribal law.

During Tribal consultation and engagement efforts and in Tribal comments on the proposed rule, many Tribes expressed concern that the proposed rule would adversely impact Tribal waters. The final rule may affect how Tribes with treatment in a similar manner as a state (TAS) for CWA section 401 administer their section 401 program, but will not have an administrative impact on Tribes for whom the EPA certifies on their behalf. The Agency has made changes in the final rule in response to comments, including comments from Tribes. The final rule maintains the ability for Tribes to provide input in the certification process and preserves the robust Tribal role in the certification process in a manner consistent with the CWA.

The Agency consulted with Tribal officials at the beginning of rule development to permit meaningful and timely input, consistent with the EPA Policy on Consultation and Coordination with Indian Tribes. The EPA initiated a Tribal consultation and coordination process before proposing this rule by sending a "Notification of Consultation and Coordination" letter dated April 22, 2019, to all 573 Federally recognized Tribes. The letter invited Tribal leaders and designated consultation representatives to participate in the Tribal consultation and coordination process. The Agency held two identical webinars on this action for Tribal representatives on May 7 and May 15, 2019. The Agency also presented on this action at the Region 9 Regional Tribal Operations Committee Spring meeting on May 22, 2019.

Additionally, Tribes were invited to two webinars for States, Tribes, and local governments on April 17, 2019 and May 8, 2019. Tribes and Tribal organizations

sent 15 pre-proposal recommendation letters to the Agency as part of the consultation process. All Tribal and Tribal organization letters and webinar feedback may be found on the pre-proposal recommendations docket (Docket ID No. EPA-HQ-OW-2018-0855). The Agency met with four Tribes at the staff-level.

The Agency continued engagement with Tribes after the end of the formal consultation period. Following the publication of the proposed rule, the Agency held two in-person meetings with Tribal representatives to answer clarifying questions about the proposal, and to discuss implementation considerations and Tribal interest in the section 401 water quality certification process. In addition, the Agency continued to meet with individual Tribes requesting consultation or engagement following publication of the proposed rule, holding staff-level meetings with 11 Tribes and leader-to-leader level meetings with two Tribes post-proposal. In total, the Agency met with 14 individual Tribes requesting consultation, holding leader-to-leader level consultation meetings with two individual Tribes and staff-level meetings with 13 individual Tribes (the Agency met with some Tribes more than once). The Agency has prepared a report summarizing the consultation and further engagement with Tribal nations. This report, *Summary Report of Tribal Consultation and Engagement for the Clean Water Act Section 401 Certification Rule* (Docket ID No. EPA-HQ-OW-2019-0405), is available in the docket for this final rule.

As required by section 7(a), the EPA's Tribal Consultation Official has certified that the requirements of the executive order have been met in a meaningful and timely manner. A copy of the certification is included in the docket for this action.

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

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because the environmental health or safety risks addressed by this action do not present a disproportionate risk to children.

I. 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.

J. National Technology Transfer and Advancement Act

This action is not subject to the National Technology Transfer and Advancement Act of 1995 because the rule does not involve technical standards.

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

This action is not subject to Executive Order 12898 (59 FR 7629, February 11, 1994) because there is no significant evidence of disproportionately high and adverse human health or environmental effects on minority populations, low income populations, and/or indigenous populations, as specified in Executive Order 12898.

L. Congressional Review Act

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

List of Subjects in 40 CFR Part 121

Environmental protection, Administrative practice and procedure, Intergovernmental relations, Water pollution control.

Andrew Wheeler,
Administrator.

For the reasons set forth in the preamble, EPA is revising 40 CFR part 121 as follows:

PART 121—STATE CERTIFICATION OF ACTIVITIES REQUIRING A FEDERAL LICENSE OR PERMIT

Sec.

Subpart A—General

121.1 Definitions.

Subpart B—Certification Procedures

121.2 When certification is required.

121.3 Scope of certification.

121.4 Pre-filing meeting request.

121.5 Certification request.

121.6 Establishing the reasonable period of time.

121.7 Action on a certification request.

121.8 Effect of denial of certification.

121.9 Waiver.

121.10 Incorporation of certification conditions into the license or permit.

121.11 Enforcement and compliance of certification conditions.

Subpart C—Other Jurisdictions

121.12 Determination of effects on neighboring jurisdictions.

Subpart D—Certification by the Administrator

- 121.13 When the Administrator certifies.
 121.14 Request for additional information.
 121.15 Notice and hearing.

Subpart E—Consultations

- 121.16 Review and advice.

Authority: 33 U.S.C. 1251 *et seq.*

Subpart A—General**§ 121.1 Definitions.**

(a) *Administrator* means the Administrator of the Environmental Protection Agency or an authorized representative.

(b) *Certification* means a water quality certification issued in accordance with Clean Water Act section 401 and this part.

(c) *Certification request* means a written, signed, and dated communication that satisfies the requirements of § 121.5(b) or (c).

(d) *Certified project* means a proposed project that has received a certification or for which the certification requirement has been waived.

(e) *Certifying authority* means the agency responsible for certifying compliance with applicable water quality requirements in accordance with Clean Water Act section 401.

(f) *Discharge* for purposes of this part means a discharge from a point source into a water of the United States.

(g) *Federal agency* means any agency of the Federal Government to which application is made for a license or permit that is subject to Clean Water Act section 401.

(h) *License or permit* means any license or permit granted by an agency of the Federal Government to conduct any activity which may result in a discharge.

(i) *Neighboring jurisdiction* means any other state or authorized tribe whose water quality the Administrator determines may be affected by a discharge for which a certification is granted pursuant to Clean Water Act section 401 and this part.

(j) *Project proponent* means the applicant for a license or permit or the entity seeking certification.

(k) *Proposed project* means the activity or facility for which the project proponent has applied for a license or permit.

(l) *Reasonable period of time* means the time period during which a certifying authority may act on a certification request, established in accordance with § 121.6 of this part.

(m) *Receipt* means the date that a certification request is documented as received by a certifying authority in

accordance with applicable submission procedures.

(n) *Water quality requirements* means applicable provisions of §§ 301, 302, 303, 306, and 307 of the Clean Water Act, and state or tribal regulatory requirements for point source discharges into waters of the United States.

Subpart B—Certification Procedures**§ 121.2 When certification is required.**

Certification is required for any license or permit that authorizes an activity that may result in a discharge.

§ 121.3 Scope of certification.

The scope of a Clean Water Act section 401 certification is limited to assuring that a discharge from a Federally licensed or permitted activity will comply with water quality requirements.

§ 121.4 Pre-filing meeting request.

(a) At least 30 days prior to submitting a certification request, the project proponent shall request a pre-filing meeting with the certifying authority.

(b) The certifying authority is not obligated to grant or respond to the pre-filing meeting request.

(c) If the certifying authority grants the pre-filing meeting request, the project proponent and the certifying authority are encouraged to discuss the nature of the proposed project and potential water quality effects. The project proponent is encouraged to provide a list of other required state, interstate, tribal, territorial, and federal authorizations and to describe the anticipated timeline for construction and operation.

(d) After receiving the pre-filing meeting request, the certifying authority is encouraged to contact the Federal agency and to identify points of contact to facilitate information sharing between the certifying authority and Federal agency throughout the certification process.

§ 121.5 Certification request.

(a) A certification request shall be submitted to the certifying authority and to the Federal agency concurrently.

(b) A certification request for an individual license or permit shall:

(1) Identify the project proponent(s) and a point of contact;

(2) Identify the proposed project;

(3) Identify the applicable federal license or permit;

(4) Identify the location and nature of any potential discharge that may result from the proposed project and the location of receiving waters;

(5) Include a description of any methods and means proposed to monitor the discharge and the equipment or measures planned to treat, control, or manage the discharge;

(6) Include a list of all other federal, interstate, tribal, state, territorial, or local agency authorizations required for the proposed project, including all approvals or denials already received;

(7) Include documentation that a pre-filing meeting request was submitted to the certifying authority at least 30 days prior to submitting the certification request;

(8) Contain the following statement: *‘The project proponent hereby certifies that all information contained herein is true, accurate, and complete to the best of my knowledge and belief’*; and

(9) Contain the following statement: *‘The project proponent hereby requests that the certifying authority review and take action on this CWA 401 certification request within the applicable reasonable period of time.’*

(c) A certification request for issuance of a general license or permit shall:

(1) Identify the project proponent(s) and a point of contact;

(2) Identify the proposed categories of activities to be authorized by the general license or permit for which certification is requested;

(3) Include the draft or proposed general license or permit;

(4) Estimate the number of discharges expected to be authorized by the proposed general license or permit each year;

(5) Include documentation that a pre-filing meeting request was submitted to the certifying authority at least 30 days prior to submitting the certification request;

(6) Contain the following statement: *‘The project proponent hereby certifies that all information contained herein is true, accurate, and complete to the best of my knowledge and belief’*; and

(7) Contain the following statement: *‘The project proponent hereby requests that the certifying authority review and take action on this CWA 401 certification request within the applicable reasonable period of time.’*

§ 121.6 Establishing the reasonable period of time.

(a) The Federal agency shall establish the reasonable period of time either categorically or on a case-by-case basis. In either event, the reasonable period of time shall not exceed one year from receipt.

(b) Within 15 days of receiving notice of the certification request from the project proponent, the Federal agency shall provide, in writing, the following information to the certifying authority:

(1) The date of receipt;
 (2) The applicable reasonable period of time to act on the certification request; and

(3) The date upon which waiver will occur if the certifying authority fails or refuses to act on the certification request.

(c) In establishing the reasonable period of time, the Federal agency shall consider:

(1) The complexity of the proposed project;

(2) The nature of any potential discharge; and

(3) The potential need for additional study or evaluation of water quality effects from the discharge.

(d) The Federal agency may extend the reasonable period of time at the request of a certifying authority or a project proponent, but in no case shall the reasonable period of time exceed one year from receipt.

(1) Any request by a certifying authority or project proponent to the Federal agency to extend the reasonable period of time shall be in writing.

(2) If the Federal agency agrees to extend the reasonable period of time, the Federal agency shall notify the certifying authority and project proponent in writing.

(e) The certifying authority is not authorized to request the project proponent to withdraw a certification request and is not authorized to take any action to extend the reasonable period of time other than specified in § 121.6(d).

§ 121.7 Action on a certification request.

(a) Any action by the certifying authority to grant, grant with conditions, or deny a certification request must be within the scope of certification, must be completed within the reasonable period of time, and must otherwise be in accordance with section 401 of the Clean Water Act. Alternatively, a certifying authority may expressly waive certification.

(b) If the certifying authority determines that a discharge from a proposed project will comply with water quality requirements, it may issue or waive certification. If the certifying authority cannot certify that the discharge from a proposed project will comply with water quality requirements, it may deny or waive certification.

(c) Any grant of certification shall be in writing and shall include a statement that the discharge from the proposed project will comply with water quality requirements.

(d) Any grant of certification with conditions shall be in writing and shall

for each condition include, at a minimum:

(1) For certification conditions on an individual license or permit,

(i) A statement explaining why the condition is necessary to assure that the discharge from the proposed project will comply with water quality requirements; and

(ii) A citation to federal, state, or tribal law that authorizes the condition.

(2) For certification conditions on issuance of a general license or permit,

(i) A statement explaining why the condition is necessary to assure that any discharge authorized under the general license or permit will comply with water quality requirements; and

(ii) A citation to federal, state, or tribal law that authorizes the condition.

(e) Any denial of certification shall be in writing and shall include:

(1) For denial of certification for an individual license or permit,

(i) The specific water quality requirements with which the discharge will not comply;

(ii) A statement explaining why the discharge will not comply with the identified water quality requirements; and

(iii) If the denial is due to insufficient information, the denial must describe the specific water quality data or information, if any, that would be needed to assure that the discharge from the proposed project will comply with water quality requirements.

(2) For denial of certification for issuance of a general license or permit,

(i) The specific water quality requirements with which discharges that could be authorized by the general license or permit will not comply;

(ii) A statement explaining why discharges that could be authorized by the general license or permit will not comply with the identified water quality requirements; and

(iii) If the denial is due to insufficient information, the denial must describe the types of water quality data or information, if any, that would be needed to assure that the range of discharges from potential projects will comply with water quality requirements.

(f) If the certifying authority determines that no water quality requirements are applicable to the waters receiving the discharge from the proposed project, the certifying authority shall grant certification.

§ 121.8 Effect of denial of certification.

(a) A certification denial shall not preclude a project proponent from submitting a new certification request, in accordance with the substantive and procedural requirements of this part.

(b) Where a Federal agency determines that a certifying authority's denial satisfies the requirements of § 121.7(e), the Federal agency must provide written notice of such determination to the certifying authority and project proponent, and the license or permit shall not be granted.

§ 121.9 Waiver.

(a) The certification requirement for a license or permit shall be waived upon:

(1) Written notification from the certifying authority to the project proponent and the Federal agency that the certifying authority expressly waives its authority to act on a certification request; or

(2) The certifying authority's failure or refusal to act on a certification request, including:

(i) Failure or refusal to act on a certification request within the reasonable period of time;

(ii) Failure or refusal to satisfy the requirements of § 121.7(c);

(iii) Failure or refusal to satisfy the requirements of § 121.7(e); or

(iv) Failure or refusal to comply with other procedural requirements of section 401.

(b) A condition for a license or permit shall be waived upon the certifying authority's failure or refusal to satisfy the requirements of § 121.7(d).

(c) If the certifying authority fails or refuses to act, as provided in this section, the Federal agency shall provide written notice to the Administrator, certifying authority, and project proponent that waiver of the certification requirement or condition has occurred. This notice must be in writing and include the notice that the Federal agency provided to the certifying authority pursuant to § 121.6(b).

(d) A written notice of waiver from the Federal agency shall satisfy the project proponent's requirement to obtain certification.

(e) Upon issuance of a written notice of waiver, the Federal agency may issue the license or permit.

§ 121.10 Incorporation of certification conditions into the license or permit.

(a) All certification conditions that satisfy the requirements of § 121.7(d) shall be incorporated into the license or permit.

(b) The license or permit must clearly identify any certification conditions.

§ 121.11 Enforcement of and compliance with certification conditions.

(a) The certifying authority, prior to the initial operation of a certified project, shall be afforded the

opportunity to inspect the facility or activity for the purpose of determining whether the discharge from the certified project will violate the certification.

(b) If the certifying authority, after an inspection pursuant to subsection (a), determines that the discharge from the certified project will violate the certification, the certifying authority shall notify the project proponent and the Federal agency in writing, and recommend remedial measures necessary to bring the certified project into compliance with the certification.

(c) The Federal agency shall be responsible for enforcing certification conditions that are incorporated into a federal license or permit.

Subpart C—Other Jurisdictions

§ 121.12 Determination of effects on neighboring jurisdictions.

(a) A Federal agency shall within 5 days notify the Administrator when it receives a license or permit application and the related certification.

(b) Within 30 days after the Administrator receives notice in accordance with § 121.12(a), the Administrator at his or her discretion may determine that the discharge from the certified project may affect water quality in a neighboring jurisdiction. In making this determination and in accordance with applicable law, the Administrator may request copies of the certification and the federal license or permit application.

(c) If the Administrator determines that the discharge from the certified project may affect water quality in a neighboring jurisdiction, the Administrator, within 30 days after receiving notice in accordance with § 121.12(a), shall notify that neighboring jurisdiction, the certifying authority, the Federal agency, and the project proponent. The federal license or permit may not be issued pending the conclusion of the processes in this paragraph.

(1) Notification from the Administrator shall: Be in writing, be dated, and identify the materials provided by the Federal agency. The notification shall inform the neighboring jurisdiction that it has 60 days to notify the Administrator and the Federal agency, in writing, whether it has determined that the discharge will violate any of its water quality requirements, to object to the issuance of the federal license or permit, and to

request a public hearing from the Federal agency.

(2) Notification of objection and request for a hearing from the neighboring jurisdiction shall: Be in writing; identify the receiving waters it determined will be affected by the discharge; and identify the specific water quality requirements it determines will be violated by the certified project.

(3) If the neighboring jurisdiction requests a hearing in accordance with § 121.12(c)(2), the Federal agency shall hold a public hearing on the neighboring jurisdiction's objection to the license or permit.

(i) The Federal agency shall provide the hearing notice to the Administrator at least 30 days before the hearing takes place.

(ii) At the hearing, the Administrator shall submit to the Federal agency his or her evaluation and recommendation(s) concerning the objection.

(iii) The Federal agency shall: Consider recommendations from the neighboring jurisdiction and the Administrator, and any additional evidence presented to the Federal agency at the hearing; and determine whether additional certification conditions are necessary to assure that the discharge from the certified project will comply with the neighboring jurisdiction's water quality requirements.

(iv) If additional certification conditions cannot assure that the discharge from the certified project will comply with the neighboring jurisdiction's water quality requirements, the Federal agency shall not issue the license or permit.

Subpart D—Certification by the Administrator

§ 121.13 When the Administrator certifies.

(a) Certification by the Administrator that the discharge from a proposed project will comply with water quality requirements is required where no state, tribe, or interstate agency has authority to give such a certification.

(b) In taking action pursuant to this paragraph, the Administrator shall comply with the requirements of Clean Water Act section 401 and 40 CFR part 121.

§ 121.14 Request for additional information.

(a) If necessary, the Administrator may request additional information

from the project proponent, provided that the initial request is made within 30 days of receipt.

(b) The Administrator shall request only additional information that is within the scope of certification and is directly related to the discharge from the proposed project and its potential effect on receiving waters.

(c) The Administrator shall request only information that can be collected or generated within the reasonable period of time.

(d) In any request for additional information, the Administrator shall include a deadline for the project proponent to respond.

(1) The project proponent shall comply with the deadline established by the Administrator.

(2) The deadline must allow sufficient time for the Administrator to review the additional information and to act on the certification request within the reasonable period of time.

(e) Failure of a project proponent to timely provide the Administrator with additional information does not extend the reasonable period of time or prevent the Administrator from taking action on a certification request.

§ 121.15 Notice and hearing.

(a) Within 20 days of receipt, the Administrator shall provide appropriate public notice of receipt, including to parties known to be interested in the proposed project or in the receiving waters into which the discharge may occur.

(b) If the Administrator in his or her discretion determines that a public hearing is appropriate or necessary, the EPA shall: Schedule such hearing at an appropriate time and place; and, to the extent practicable, give all interested and affected parties the opportunity to present evidence or testimony in person or by other means at the hearing.

Subpart E—Consultations

§ 121.16 Review and advice.

The Administrator may, and upon request shall, provide Federal agencies, certifying authorities, and project proponents with relevant information and assistance regarding the meaning of, content of, application of, and methods to comply with water quality requirements.

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Part V

Department of Justice

Drug Enforcement Administration

21 CFR Part 1308

Schedules of Controlled Substances: Placement of NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA in Schedule I; Proposed Rule and Temporary Rule

DEPARTMENT OF JUSTICE**Drug Enforcement Administration****21 CFR Part 1308**

[Docket No. DEA-479]

Schedules of Controlled Substances: Placement of NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA in Schedule I**AGENCY:** Drug Enforcement Administration, Department of Justice.**ACTION:** Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration (DEA) proposes placing naphthalen-1-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate (trivial names: NM2201; CBL2201), N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide (trivial name: 5F-AB-PINACA), 1-(4-cyanobutyl)-N-(2-phenylpropan-2-yl)-1H-indazole-3-carboxamide (trivial names: 4-CN-CUMYL-BUTINACA; 4-cyano-CUMYL-BUTINACA; 4-CN-CUMYL BINACA; CUMYL-4CN-BINACA, SGT-78), methyl 2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3-methylbutanoate (trivial names: MMB-CHMICA, AMB-CHMICA), and 1-(5-fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-pyrrolo[2,3-b]pyridine-3-carboxamide (trivial name: 5F-CUMYL-P7AICA), including their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, in schedule I of the Controlled Substances Act. If finalized, this action would make permanent the existing regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, import, export, engage in research, conduct instructional activities or chemical analysis with, or possess) or propose to handle NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA.

DATES: Comments must be submitted electronically or postmarked on or before August 12, 2020.

Interested persons may file written comments on this proposal in accordance with 21 CFR 1308.43(g). Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

Interested persons may file a request for hearing or waiver of hearing

pursuant to 21 CFR 1308.44 and in accordance with 21 CFR 1316.45 and/or 1316.47, as applicable. Requests for hearing and waivers of an opportunity for a hearing or to participate in a hearing must be received on or before August 12, 2020.

ADDRESSES: Interested persons may file written comments on this proposal in accordance with 21 CFR 1308.43(g). Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period. To ensure proper handling of comments, please reference "Docket No. DEA-479" on all electronic and written correspondence, including any attachments.

- **Electronic comments:** The Drug Enforcement Administration (DEA) encourages that all comments be submitted electronically through the Federal eRulemaking Portal which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to <http://www.regulations.gov> and follow the online instructions at that site for submitting comments. Upon completion of your submission you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on *Regulations.gov*. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

- **Paper comments:** Paper comments that duplicate the electronic submission are not necessary. Should you wish to mail a paper comment, *in lieu of* an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152.

- **Hearing requests:** All requests for a hearing and waivers of participation must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for hearing and waivers of participation should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/LJ, 8701 Morrisette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/ODW, 8701 Morrisette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Regulatory Drafting and

Policy Support Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (571) 362-3261.

SUPPLEMENTARY INFORMATION:**Posting of Public Comments**

Please note that all comments received in response to this docket are considered part of the public record. They will, unless reasonable cause is given, be made available by the Drug Enforcement Administration (DEA) for public inspection online at <http://www.regulations.gov>. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter. The Freedom of Information Act applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be made publicly available, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You must also place all of the personal identifying information you do not want made publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your comment. You must also prominently identify the confidential business information to be redacted within the comment.

Comments containing personal identifying information or confidential business information identified as directed above will be made publicly available in redacted form. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments posted to <http://www.regulations.gov> may include any personal identifying information (such as name, address, and phone number) included in the text of your electronic submission that is not identified as directed above as confidential.

An electronic copy of this document and supplemental information to this proposed rule are available at <http://www.regulations.gov> for easy reference.

Request for Hearing or Waiver of Participation in a Hearing

Pursuant to 21 U.S.C. 811(a), this action is a formal rulemaking "on the

record after opportunity for a hearing.” Such proceedings are conducted pursuant to the provisions of the Administrative Procedure Act, 5 U.S.C. 551–559. 21 CFR 1308.41–1308.45; 21 CFR part 1316, subpart D. Such requests or notices must conform to the requirements of 21 CFR 1308.44(a) or (b), as applicable, and include a statement of the person’s interests in the proceeding and the objections or issues, if any, concerning which the person desires to be heard. Any waiver must conform to the requirements of 21 CFR 1308.44(c) and may include a written statement regarding the interested person’s position on the matters of fact and law involved in any hearing.

All requests for hearing and waivers of participation must be sent to DEA using the address information provided above.

Legal Authority

The Controlled Substances Act (CSA) provides that proceedings for the issuance, amendment, or repeal of the scheduling of any drug or other substance may be initiated by the Attorney General (1) on his own motion; (2) at the request of the Secretary of the Department of Health and Human Services (HHS);¹ or (3) on the petition of any interested party. 21 U.S.C. 811(a). This proposed action is supported by a recommendation from the Assistant Secretary for Health of HHS (Assistant Secretary) and an evaluation of all other relevant data by DEA. If finalized, this action would make permanent the existing temporary regulatory controls and administrative, civil, and criminal sanctions of schedule I controlled substances on any person who handles or proposes to handle NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA.

Background

On July 10, 2018, DEA published an order in the **Federal Register** amending 21 CFR 1308.11(h) to temporarily place naphthalen-1-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate (trivial name: NM2201; CBL2201), *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide (trivial name: 5F-AB-

PINACA), 1-(4-cyanobutyl)-*N*-(2-phenylpropan-2-yl)-1H-indazole-3-carboxamide (trivial name: 4-CN-CUMYL-BUTINACA; 4-cyano-CUMYL-BUTINACA; 4-CN-CUMYL BINACA; CUMYL-4CN-BINACA, SGT-78), methyl 2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3-methylbutanoate (trivial name: MMB-CHMICA, AMB-CHMICA), and 1-(5-fluoropentyl)-*N*-(2-phenylpropan-2-yl)-1H-pyrrolo[2,3-*b*]pyridine-3-carboxamide (trivial name: 5F-CUMYL-P7AICA) in schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). 83 FR 31877. That temporary scheduling order was effective on the date of publication, and was based on findings by the former Acting Administrator of DEA (Acting Administrator) that the temporary scheduling of these five synthetic cannabinoids (SCs) was necessary to avoid an imminent hazard to the public safety pursuant to 21 U.S.C. 811(h)(1). Subsection 811(h)(2) requires that the temporary control of these substances expire two years from the effective date of the scheduling order, which for these five substances had an effective date of July 10, 2018. However, this same subsection also provides that during the pendency of proceedings under 21 U.S.C. 811(a)(1) with respect to a substance, the temporary scheduling of that substance may be extended for up to one year. Proceedings for the scheduling of a substance under 21 U.S.C. 811(a) may be initiated by the Attorney General (delegated to the Administrator of DEA pursuant to 28 CFR 0.100) on his own motion, at the request of the Secretary of HHS,² or on the petition of any interested party. An extension of the existing temporary order is being ordered by the Acting Administrator in a separate action, and is being simultaneously published elsewhere in this issue of the **Federal Register**.

The Acting Administrator, on his own motion, is initiating proceedings under 21 U.S.C. 811(a)(1) to permanently schedule NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA. DEA has gathered and reviewed the available information regarding the pharmacology, chemistry, trafficking, actual abuse, pattern of abuse, and the relative potential for abuse for these five SCs. On February 4, 2019, the Acting Administrator submitted a request to the

Assistant Secretary to provide DEA with a scientific and medical evaluation of available information and a scheduling recommendation for NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA, in accordance with 21 U.S.C. 811(b) and (c). Upon evaluating the scientific and medical evidence, on May 29, 2020, the Assistant Secretary submitted HHS’s scientific and medical evaluation and scheduling recommendation for these five substances to the Acting Administrator. Upon receipt of the scientific and medical evaluation and scheduling recommendation from HHS, DEA reviewed the documents and all other relevant data, and conducted its own eight-factor analysis of the abuse potential of NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA, in accordance with 21 U.S.C. 811(c).

Proposed Determination to Schedule NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA

As discussed in the background section, the Acting Administrator is initiating proceedings, pursuant to 21 U.S.C. 811(a)(1), to add NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA permanently to schedule I of the CSA. DEA has reviewed the scientific and medical evaluation and scheduling recommendation received from HHS, and all other relevant data, and conducted its own eight-factor analysis of the abuse potential of NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA, pursuant to 21 U.S.C. 811(c). Included below is a brief summary of each factor as analyzed by HHS and DEA, and as considered by DEA in its proposed scheduling action. Please note that both DEA Eight-Factor and HHS Eight-Factor analyses and the Assistant Secretary’s May 29, 2020, letter are available in their entirety under the tab “Supporting Documents” of the public docket of this action at <http://www.regulations.gov>, under Docket Number “DEA-479.”

1. *The Drug’s Actual or Relative Potential for Abuse:* The term “abuse” is not defined in the CSA. However, the legislative history of the CSA suggests that DEA consider the following criteria in determining whether a particular

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

² Because the Secretary of HHS has delegated to the Assistant Secretary the authority to make domestic drug scheduling recommendations, for purposes of this proposed scheduling action, all subsequent references to “Secretary” have been replaced with “Assistant Secretary.”

drug or substance has a potential for abuse:³

(a) *There is evidence that individuals are taking the drug or drugs containing such a substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or to the community; or*

(b) *There is significant diversion of the drug or drugs containing such a substance from legitimate drug channels; or*

(c) *Individuals are taking the drug or drugs containing such a substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs in the course of his professional practice; or*

(d) *The drug or drugs containing such a substance are new drugs so related in their action to a drug or drugs already listed as having a potential for abuse to make it likely that the drug will have the same potentiality for abuse as such drugs, thus making it reasonable to assume that there may be significant diversions from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community.*

In its recommendation, HHS noted that abuse of NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA has a substantial capability to create a hazard to the health of the individual users and the safety of others within the community. Adverse effects observed following the ingestion of NM2201, 5F-AB-PINACA, or 4-CN-CUMYL-BUTINACA included diaphoresis, tachycardia, hypertension, seizures, agitation, violence, nausea, and memory impairment (see factor 6). SCs, including NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA, have been generally found to be easily accessible and difficult to detect in standard urine drug screens, which contributes to their popularity and high rates of abuse.

As stated by HHS, there are no Food and Drug Administration (FDA)-approved drug products containing NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA for treatment in the United States, and there appear to be no legitimate sources for these substances as marketed drugs. In addition, HHS stated that the human use of NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA is assumed to be on an individual's own initiative, rather than on the basis of medical

advice from a practitioner licensed by law to administer drugs, since these SCs are not approved for medical use and are not formulated or available for clinical use. As noted by HHS, individuals may be using these five SCs on their own initiative, possibly because they are seeking the same cannabinoid-like effects as other schedule I cannabinoids while avoiding the criminal penalties associated with those substances. Further, published scientific and medical literature and law enforcement reports indicate that individuals are taking these SCs on their own initiative, rather than on the basis of medical advice of a licensed practitioner.

As stated by HHS, the pharmacological data for NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA show that these substances, similar to other schedule I SCs, bind to and activate the CB1 cannabinoid receptors. In drug discrimination studies either sponsored by the National Institute on Drug Abuse or conducted by FDA's National Center for Toxicological Research under an Interagency Agreement, NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA, similar to other schedule I SCs (e.g., JWH-018, AM2201, ADB-PINACA, AB-FUBINACA), fully substitute for delta-9-tetrahydrocannabinol (THC) in animals trained to discriminate THC from vehicle control. Documented adverse effects associated with NM2201, 5F-AB-PINACA, and 4-CN-CUMYL-BUTINACA in the United States and abroad, and 5F-CUMYL-P7AICA in Europe, similar to other schedule I SCs, include tachycardia, aggressive or violent behavior, confusion, depressed mental status, severe agitation, psychosis, and/or death in some instances (see factors 4 and 6). HHS stated that because of the psychological and cognitive disturbances associated with such responses, it is reasonable to assume that these five SCs have a substantial capability to be a hazard to the health of the user and to the safety of the community.

The above information collectively indicates that the relative potential for abuse of NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA is similar to other schedule I CB1 receptor agonists.

2. *Scientific Evidence of the Drug's Pharmacological Effects, if Known:* Within its recommendation, HHS described *in vitro* receptor binding and functional assays that were conducted

with NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA. These results indicate that NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA, similar to other schedule I SCs, bind to CB1 receptors and act as full cannabinoid agonists at CB1 receptors. Drug discrimination studies were conducted in animals to evaluate whether the five SCs have cannabinoid characteristics similar to substances in schedule I of the CSA. Each of the five SCs were shown to fully substitute for the discriminative stimulus effects produced by THC, a schedule I substance.

3. *The State of Current Scientific Knowledge Regarding the Drug or Other Substance:*

NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA are all potent cannabinoid agonists that are pharmacologically similar to THC and several schedule I SCs.

As stated by HHS, when FDA approves a drug under the Federal Food, Drug, and Cosmetic Act for human or animal medical use, such drug is considered to have a currently accepted medical use in the United States. In the absence of such approval by FDA, a drug may be considered to have a currently accepted medical use in the United States if DEA concludes that the drug satisfies all of the following five elements:⁴

a. *The drug's chemistry is known and reproducible;*
 b. *There are adequate safety studies;*
 c. *There are adequate and well-controlled studies proving efficacy;*
 d. *The drug is accepted by qualified experts; and*
 e. *The scientific evidence is widely available.*

According to HHS, NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA have not been approved by FDA as a human or animal drug product in the United States or, to FDA's knowledge, been approved for medical use in any other country. Moreover, there are no well-controlled clinical studies showing safety or efficacy for any of these cannabinoids. In addition, there is no evidence by qualified experts that the five cannabinoids are accepted as having therapeutic uses. Therefore, NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA have no

3 Comprehensive Drug Abuse Prevention and Control Act of 1970, H.R. Rep. No. 91-1444, 91st Cong., Sess. 1 (1970); reprinted in 1970 U.S.C.A.N. 4566, 4603.

⁴ 57 FR 10492 (1992), *pet. for rev. denied*, *Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131, 1135 (D.C. Cir. 1994).

currently accepted medical use for treatment in the United States.

4. *Its History and Current Pattern of Abuse:* NM2201 was first identified in the United States in November 2012 in seized drug evidence, followed by 5F-AB-PINACA (August 2013), MMB-CHMICA (December 2015), 4-CN-CUMYL BUTINACA (January 2016), and most recently 5F-CUMYL-P7AICA (February 2018). The European Monitoring Centre for Drugs and Drug Addiction reported a seizure of 50 kg of 4-CN-CUMYL-BUTINACA in Europe in 2016. According to the National Forensic Laboratory Information System⁵ (NFLIS), although the first encounter of 4-CN-CUMYL-BUTINACA in the United States occurred in January 2016, the increase in encounters did not occur until later in 2017. Similarly, prior to the first encounter of 5F-CUMYL-P7AICA in the United States in February 2018, two deaths related to the use of this substance had already been documented in Europe in November and December 2016 (see factor 6). The data also show that SCs originate in China and these substances are often abused in Europe and other countries before being trafficked in the United States.

HHS stated that compared to cannabis, acute fatal poisoning appears to be more prevalent with SCs. As demonstrated by NFLIS, law enforcement encounters of these five SCs have decreased following their placement in schedule I (see Factor 5).

5. *The Scope, Duration, and Significance of Abuse:* Following multiple scheduling actions controlling SCs, law enforcement and health care professionals have encountered novel SCs, including NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA, that differ from previously scheduled SCs and one another only by small structural modifications intended to avoid prosecution while maintaining the pharmacological effects. NFLIS detailed 5,259 reports from forensic laboratories for these five substances as follows: 2,938 reports of NM2201, 1,200 reports of 5F-AB-PINACA, 797 reports of 4-CN-CUMYL-BUTINACA, 323 reports of MMB-CHMICA, and 1 report of 5F-CUMYL-P7AICA for a period from November 2012 through June 2020.⁶

⁵ NFLIS is a DEA program and a national forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by state and local forensic laboratories in the United States. The NFLIS database also contains Federal data from U.S. Customs and Border Protection (CBP). NFLIS only includes drug chemistry results from completed analyses.

⁶ Query date June 3, 2020.

Reports peaked for NM2201 and 5F-AB-PINACA in 2015, for MMB-CHMICA in 2017, and for 4-CN-CUMYL-BUTINACA in 2018. The report of 5F-CUMYL-P7AICA also occurred in 2018. In addition, the System to Retrieve Drug Evidence (STRIDE)⁷ and STARLiMS⁸ have 644 reports involving NM2201 (311 reports), 5F-AB-PINACA (202 reports), 4-CN-CUMYL-BUTINACA (13 reports), and MMB-CHMICA (118 reports) from 2013 through June 2020. A full presentation of the NFLIS and STRIDE/STARLiMS reports by substance and by year are available in the Supporting Documents of the public docket available at <http://www.regulations.gov>.

6. *What, if Any, Risk There is to the Public Health:* HHS and DEA documented multiple cases where NM2201, 5F-AB-PINACA, and 4-CN-CUMYL-BUTINACA have been identified in overdoses and/or cases involving death attributed to their abuse in the United States and abroad. In addition, HHS and DEA reported exposure to 5F-CUMYL-P7AICA resulted in two deaths in November and December 2016 in Europe. Adverse health effects reported from these incidents involving NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, and 5F-CUMYL-P7AICA included diaphoresis, tachycardia, hypertension, seizures, agitation, violence, nausea, and memory impairment, and/or death. By sharing pharmacological similarities with schedule I substances (THC, JWH-018, and other temporarily and permanently controlled schedule I SCs), NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA are SCs with no approved medical use that pose serious risk to the abuser. While no adverse event information is currently available for MMB-CHMICA, substantial law enforcement seizures and the pharmacological similarity of MMB-CHMICA to other currently controlled schedule I SCs with known risks to public health (*i.e.*, AB-CHMINACA, AB-FUBINACA, JWH-018) demonstrate an imminent hazard to public safety (see factor 5).

7. *Its Psychic or Physiological Dependence Liability:* As stated by HHS, NM2201, 5F-AB-PINACA, 4-CN-

⁷ STRIDE is a database of drug exhibits sent to DEA laboratories for analysis. Exhibits from the database are from DEA, other federal agencies, and some local law enforcement agencies.

⁸ STARLiMS is a laboratory information management system that systematically collects results from drug chemistry analyses conducted by DEA laboratories. On October 1, 2014, STARLiMS replaced STRIDE as DEA's laboratory drug evidence data system of record.

CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA have pharmacological profiles that are similar to other schedule I SCs. There are no clinical studies evaluating dependence liabilities specific to NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA. HHS noted that while the five SCs are pharmacologically related to several current schedule I SCs such as JWH-018, XLR11, and AKB-48, there are still no specific studies examining their respective psychic or dependence liability. HHS stated that it is reasonable to assume, given the pharmacology of the five SCs, the likelihood of such a withdrawal effect being associated with the use of these cannabinoids as well.

8. *Whether the Substance is an Immediate Precursor of a Substance Already Controlled Under the CSA:* As noted by HHS, NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA are not immediate precursors of any controlled substance of the CSA as defined by 21 U.S.C. 802(23).

Conclusion: After considering the scientific and medical evaluation conducted by HHS, HHS's recommendation, and DEA's own eight-factor analysis, DEA finds that the facts and all relevant data constitute substantial evidence of the potential for abuse of NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA. As such, DEA hereby proposes to permanently schedule NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA as controlled substances under the CSA.

Proposed Determination of Appropriate Schedule

The CSA establishes five schedules of controlled substances known as schedules I, II, III, IV, and V. The CSA also outlines the findings required to place a drug or other substance in any particular schedule. 21 U.S.C. 812(b). After consideration of the analysis and recommendation of the Assistant Secretary for Health of HHS and review of all other available data, the Acting Administrator of DEA, pursuant to 21 U.S.C. 811(a) and 812(b)(1), finds that:

1. NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA have a high potential for abuse that is comparable to other schedule I substances such as THC and JWH-018;

2. NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA have no

currently accepted medical use in treatment in the United States; and

3. There is a lack of accepted safety for use of NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA under medical supervision.

Based on these findings, the Acting Administrator of DEA concludes that naphthalen-1-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate (trivial names: NM2201; CBL2201); N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide (trivial name: 5F-AB-PINACA); 1-(4-cyanobutyl)-N-(2-phenylpropan-2-yl)-1H-indazole-3-carboxamide (trivial names: 4-CN-CUMYL-BUTINACA; 4-cyano-CUMYL-BUTINACA; 4-CN-CUMYL BINACA; CUMYL-4CN-BINACA, SGT-78); methyl 2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3-methylbutanoate (trivial names: MMB-CHMICA, AMB-CHMICA), and 1-(5-fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-pyrrolo[2,3-b]pyridine-3-carboxamide (trivial name: 5F-CUMYL-P7AICA), including their salts, isomers and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible, warrant control in schedule I of the CSA. 21 U.S.C. 812(b)(1).

Requirements for Handling NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA

If this rule is finalized as proposed, NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA would continue⁹ to be subject to the CSA's schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, dispensing, importing, exporting, research, and conduct of instructional activities, including the following:

1. *Registration.* Any person who handles (manufactures, distributes, dispenses, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA, or who desires to handle NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA, is required to be registered with DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and

958 and in accordance with 21 CFR parts 1301 and 1312.

2. *Security.* NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA are subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 821, 823 and in accordance with 21 CFR 1301.71–1301.93. Non-practitioners handling these five substances must also comply with the employee screening requirements of 21 CFR 1301.90–1301.93.

3. *Labeling and Packaging.* All labels and labeling for commercial containers of NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA must be in compliance with 21 U.S.C. 825 and 958(e), and be in accordance with 21 CFR part 1302.

4. *Quota.* Only registered manufacturers are permitted to manufacture NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303.

5. *Inventory.* Any person registered with DEA to handle NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA must have an initial inventory of all stocks of controlled substances (including NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA) on hand on the date the registrant first engages in the handling of controlled substances pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

After the initial inventory, every DEA registrant must take a new inventory of all stocks of controlled substances (including NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA) on hand every two years, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

6. *Records and Reports.* Every DEA registrant is required to maintain records and submit reports with respect to NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR parts 1304 and 1312.

7. *Order Forms.* Every DEA registrant who distributes NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA is required to comply with the

order form requirements, pursuant to 21 U.S.C. 828, and 21 CFR part 1305.

8. *Importation and Exportation.* All importation and exportation of NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA must be in compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

9. *Liability.* Any activity involving NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA not authorized by, or in violation of, the CSA or its implementing regulations is unlawful, and could subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Executive Orders 12866, 13563, and 13771, Regulatory Planning and Review, Improving Regulation and Regulatory Review, and Reducing Regulation and Controlling Regulatory Costs

In accordance with 21 U.S.C. 811(a), this proposed scheduling action is subject to formal rulemaking procedures performed “on the record after opportunity for a hearing,” which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget (OMB) pursuant to section 3(d)(1) of Executive Order (E.O.) 12866 and the principles reaffirmed in E.O. 13563.

This proposed rule does not meet the definition of an E.O. 13771 regulatory action, and the repeal and cost offset requirements of E.O. 13771 have not been triggered. OMB has previously determined that formal rulemaking actions concerning the scheduling of controlled substances, such as this rule, are not significant regulatory actions under Section 3(f) of E.O. 12866.

Executive Order 12988, Civil Justice Reform

This proposed regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 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 13132, Federalism

This proposed rulemaking does not have federalism implications warranting the application of E.O. 13132. The proposed rule does not have substantial direct effects on the States, on the

⁹NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA are currently subject to schedule I controls on a temporary basis, pursuant to 21 U.S.C. 811(h). 83 FR 31877, July 10, 2018.

relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This proposed rule does not have tribal implications warranting the application of E.O. 13175. 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.

Regulatory Flexibility Act

The Acting Administrator, in accordance with the Regulatory Flexibility Act (RFA), 5 U.S.C. 601–602, has reviewed this proposed rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities. On July 10, 2018, DEA published an order to temporarily place NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA in schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). DEA estimates that all entities handling or planning to handle NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA have already established and implemented the systems and processes required to handle these substances. There are currently 28 unique registrations authorized to specifically handle NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, or 5F-CUMYL-P7AICA, as well as a number of registered analytical labs that are authorized to handle schedule I controlled substances generally. From a review of entity names, DEA estimates these 28 registrations represent 22 entities. Some of these entities are likely to be large entities. However, since DEA does not have information of registrant size and the majority of DEA registrants

are small entities or are employed by small entities, DEA estimates a maximum of 22 entities are small entities. Therefore, DEA conservatively estimates as many as 22 small entities are affected by this proposed rule.

A review of the 28 registrations indicates that all entities that currently handle NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA also handle other schedule I controlled substances, and have established and implemented (or maintain) the systems and processes required to handle NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA. Therefore, DEA anticipates that this proposed rule will impose minimal or no economic impact on any affected entities; and thus, will not have a significant economic impact on any of the 22 affected small entities. Therefore, DEA has concluded that this proposed rule will not have a significant effect on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.*, DEA has determined and certifies that this action would not result in any Federal 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 1 year * * *.” Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521. This action would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. 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.

List of Subjects in 21 CFR Part 1308

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

For the reasons set out above, DEA proposes to amend 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for 21 CFR Part 1308 continues to read as follows:

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

- 2. In § 1308.11,
- a. Add paragraphs (d)(81) through (85); and
- b. Remove and reserve paragraphs (h)(31) through (35);

The additions read as follows:

§ 1308.11 Schedule I.

* * * * *		
(d) * * *		
(81)	Naphthalen-1-yl 1-(5-fluoropentyl)-1 <i>H</i> -indole-3-carboxylate (NM2201; CBL2201)	7221
(82)	<i>N</i> -(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-1 <i>H</i> -indazole-3-carboxamide (5F-AB-PINACA)	7025
(83)	1-(4-cyanobutyl)- <i>N</i> -(2-phenylpropan-2-yl)-1 <i>H</i> -indazole-3-carboxamide (4-CN-CUMYL-BUTINACA; 4-cyano-CUMYL-BUTINACA; 4-CN-CUMYL BINACA; CUMYL-4CN-BINACA; SGT-78)	7089
(84)	methyl 2-(1-(cyclohexylmethyl)-1 <i>H</i> -indole-3-carboxamido)-3-methylbutanoate (MMB-CHMICA, AMB-CHMICA)	7044
(85)	1-(5-fluoropentyl)- <i>N</i> -(2-phenylpropan-2-yl)-1 <i>H</i> -pyrrolo[2,3- <i>b</i>]pyridine-3-carboxamide (5F-CUMYL-P7AICA)	7085
* * * * *		

Timothy J. Shea,

Acting Administrator.

[FR Doc. 2020–14901 Filed 7–9–20; 10:00 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE**Drug Enforcement Administration****21 CFR Part 1308**

[Docket No. DEA-479]

Schedules of Controlled Substances: Extension of Temporary Placement of NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA in Schedule I of the Controlled Substances Act**AGENCY:** Drug Enforcement Administration, Department of Justice.**ACTION:** Temporary rule; temporary scheduling order; extension.

SUMMARY: The Acting Administrator of the Drug Enforcement Administration is issuing this temporary scheduling order to extend the temporary schedule I status of naphthalen-1-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (trivial names: NM2201; CBL2201), *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-1*H*-indazole-3-carboxamide (trivial name: 5F-AB-PINACA), 1-(4-cyanobutyl)-*N*-(2-phenylpropan-2-yl)-1*H*-indazole-3-carboxamide (trivial names: 4-CN-CUMYL-BUTINACA; 4-cyano-CUMYL-BUTINACA; 4-CN-CUMYL-BINACA; CUMYL-4CN-BINACA, SGT-78), methyl 2-(1-(cyclohexylmethyl)-1*H*-indole-3-carboxamido)-3-methylbutanoate (trivial names: MMB-CHMICA, AMB-CHMICA), and 1-(5-fluoropentyl)-*N*-(2-phenylpropan-2-yl)-1*H*-pyrrolo[2,3-*b*]pyridine-3-carboxamide (trivial name: 5F-CUMYL-P7AICA), including their optical, positional, and geometric isomers, salts, and salts of isomers. The schedule I status of NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA currently is in effect until July 10, 2020. This temporary order will extend the temporary scheduling of NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA for one year or until the permanent scheduling action for these substances is completed, whichever occurs first.

DATES: This temporary scheduling order, which extends the order (83 FR 31877, July 10, 2018), is effective July 10, 2020, and expires on July 10, 2021. If DEA publishes a final rule making this scheduling action permanent, this order will expire on the effective date of that rule, if the effective date is earlier than July 10, 2021.

FOR FURTHER INFORMATION CONTACT: Scott Brinks, Diversion Control

Division, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (571) 362-8209.

SUPPLEMENTARY INFORMATION:**Background and Legal Authority**

On July 10, 2018, the former Acting Administrator of the Drug Enforcement Administration (DEA) published a temporary scheduling order in the **Federal Register** (83 FR 31877) placing naphthalen-1-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (trivial names: NM2201; CBL2201), *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-1*H*-indazole-3-carboxamide (trivial name: 5F-AB-PINACA), 1-(4-cyanobutyl)-*N*-(2-phenylpropan-2-yl)-1*H*-indazole-3-carboxamide (trivial names: 4-CN-CUMYL-BUTINACA; 4-cyano-CUMYL-BUTINACA; 4-CN-CUMYL BINACA; CUMYL-4CN-BINACA, SGT-78), methyl 2-(1-(cyclohexylmethyl)-1*H*-indole-3-carboxamido)-3-methylbutanoate (trivial names: MMB-CHMICA, AMB-CHMICA), and 1-(5-fluoropentyl)-*N*-(2-phenylpropan-2-yl)-1*H*-pyrrolo[2,3-*b*]pyridine-3-carboxamide (trivial name: 5F-CUMYL-P7AICA) in schedule I of the Controlled Substances Act (CSA) pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). That order was effective on the date of publication, and was based on findings by the former Acting Administrator of DEA (Acting Administrator) that the temporary scheduling of these substances was necessary to avoid an imminent hazard to the public safety pursuant to subsection (h)(1). Subsection (h)(2) requires that the temporary control of these substances expire two years from the effective date of the scheduling order, *i.e.*, on July 10, 2020. However, this same subsection also provides that during the pendency of proceedings under 21 U.S.C. 811(a)(1) with respect to the substance, the temporary scheduling¹ of that substance may be extended for up to one year. Proceedings for the scheduling of a substance under 21 U.S.C. 811(a) may be initiated by the Attorney General (delegated to the Administrator of DEA pursuant to 28 CFR 0.100) on his own motion, at the request of the Secretary of Health and Human Services (HHS),²

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

² The Secretary of HHS has delegated to the Assistant Secretary for Health of HHS the authority

or on the petition of any interested party.

The Acting Administrator, on his own motion, has initiated proceedings under 21 U.S.C. 811(a)(1) to permanently schedule NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA. DEA is simultaneously publishing a notice of proposed rulemaking for the placement of NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA in schedule I elsewhere in this issue of the **Federal Register**. If that proposed rule is finalized, scheduling of these substances will be made permanent by publication of a final rule in the **Federal Register**.

Pursuant to 21 U.S.C. 811(h)(2), the Acting Administrator orders that the temporary scheduling of NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA, including their optical, positional, and geometric isomers, salts, and salts of isomers, be extended for one year, or until the permanent scheduling proceeding is completed, whichever occurs first.

Regulatory Matters

The CSA provides for an expedited temporary scheduling action where the Attorney General, as delegated to the Administrator of DEA, may, by order, place a substance in schedule I if such action is necessary to avoid an imminent hazard to the public safety. 21 U.S.C. 811(h). That same subsection also provides that the temporary scheduling of a substance shall expire at the end of two years from the date of the issuance of such temporary scheduling order, except that the Attorney General may, during the pendency of proceedings under 21 U.S.C. 811(a)(1) to permanently schedule the substance, extend the temporary scheduling for up to one year.

To the extent that 21 U.S.C. 811(h) directs that temporary scheduling actions be issued by order and sets forth the procedures by which such orders are to be issued and extended, DEA believes that the notice and comment requirements of section 553 of the Administrative Procedure Act, 5 U.S.C. 553, do not apply to this extension of the temporary scheduling action. The specific language chosen by Congress indicates an intention for DEA to proceed through the issuance of an order instead of proceeding by rulemaking. Given that Congress specifically requires the Attorney

to make domestic drug scheduling recommendations.

General to follow rulemaking procedures for other kinds of scheduling actions, see 21 U.S.C. 811(a), it is noteworthy that, in subsection 811(h), Congress authorized the issuance of temporary scheduling actions by order rather than by rule. In the alternative, even if this action were subject to 5 U.S.C. 553, the Acting Administrator finds that there is good cause to forgo the notice and comment period and the delayed effective date requirements of such section, as any further delays in the process for extending the temporary scheduling order would be impracticable and contrary to the public interest in view of the manifest urgency to avoid an imminent hazard to the public safety that these substances would present if scheduling expired, for the reasons expressed in the temporary scheduling order (83 FR 31877, July 10, 2018). Further, DEA believes that this order extending the temporary scheduling action is not a “rule” as defined by 5 U.S.C. 601(2), and, accordingly, is not subject to the requirements of the Regulatory Flexibility Act. The requirements for the preparation of an initial regulatory flexibility analysis in 5 U.S.C. 603(a) are not applicable where, as here, DEA is not required by 5 U.S.C. 553 or any other law to publish a general notice of proposed rulemaking.

Additionally, this action is not a significant regulatory action as defined

by Executive Order 12866 (Regulatory Planning and Review) section 3(f), the principles reaffirmed in Executive Order 13563 (Improving Regulation and Regulatory Review), and, accordingly, this action has not been reviewed by the Office of Management and Budget (OMB). This order is not an Executive Order 13771 regulatory action.

This action will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132 (Federalism), it is determined that this action does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment. As noted above, this action is an order, not a rule. Accordingly, the Congressional Review Act (CRA) is inapplicable, as it applies only to rules. 5 U.S.C. 801, 804(3). It is in the public interest to maintain the temporary placement of NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA in schedule I because they pose a public health risk, for the reasons expressed in the temporary scheduling order (83 FR 31877, July 10, 2018). The temporary scheduling action was taken pursuant to 21 U.S.C. 811(h), which is specifically designed to enable DEA to act in an

expeditious manner to avoid an imminent hazard to the public safety. Under 21 U.S.C. 811(h), temporary scheduling orders are not subject to notice and comment rulemaking procedures. DEA understands that the CSA frames temporary scheduling actions as orders rather than rules to ensure that the process moves swiftly, and this extension of the temporary scheduling order continues to serve that purpose. For the same reasons that underlie 21 U.S.C. 811(h), that is, the need to place these substances in schedule I because they pose an imminent hazard to public safety, it would be contrary to the public interest to delay implementation of this extension of the temporary scheduling order. Therefore, in accordance with 5 U.S.C. 808(2), this order extending the temporary scheduling order shall take effect immediately upon its publication. DEA has submitted a copy of this order to both Houses of Congress and to the Comptroller General, although such filing is not required under the Congressional Review Act, 5 U.S.C. 801–808 because, as noted above, this action is an order, not a rule.

Timothy J. Shea,

Acting Administrator.

[FR Doc. 2020–14902 Filed 7–9–20; 10:00 am]

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