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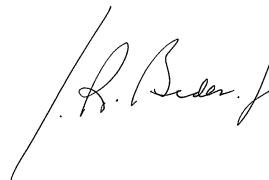
The President

Unexpected Urgent Refugee and Migration Needs

Memorandum for the Secretary of State

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 2(c)(1) of the Migration and Refugee Assistance Act of 1962 (22 U.S.C. 2601(c)(1)) (MRAA), I hereby determine, pursuant to section 2(c)(1) of the MRAA, that it is important to the national interest to furnish assistance under the MRAA in an amount not to exceed \$976.1 million from the United States Emergency Refugee and Migration Assistance Fund for the purpose of meeting unexpected urgent refugee and migration needs to support Operation Allies Welcome and related efforts by the Department of State, including additional relocations of individuals at risk as a result of the situation in Afghanistan and related expenses. Such assistance may be provided on a bilateral or multilateral basis as appropriate, including through contributions to international organizations and through funding to other nongovernmental organizations, governments, and United States departments and agencies.

You are authorized and directed to submit this determination to the Congress, along with the accompanying Justification, and to publish this determination in the *Federal Register*.



THE WHITE HOUSE,
Washington, October 22, 2021

Presidential Documents

Memorandum of October 29, 2021

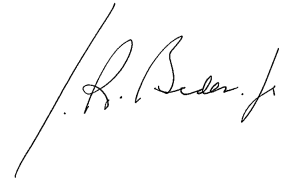
Delegation of Functions and Authorities Under Section 1299F(i) of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021

Memorandum for the Secretary of State

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 301 of title 3, United States Code, I hereby delegate to the Secretary of State all functions and authorities vested in the President by section 1299F(i) of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021 (Public Law 116–283).

Any reference herein to the Act related to the subject of this memorandum shall be deemed to include references to any hereafter-enacted provisions of law that are the same or substantially the same as such provisions.

You are authorized and directed to publish this memorandum in the *Federal Register*.



THE WHITE HOUSE,
Washington, October 29, 2021

Rules and Regulations

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

Rural Business—Cooperative Service

7 CFR Part 4284

[Docket No. RBS-21-BUSINESS-0033]

RIN 0570-AB06

Rural Innovation Stronger Economy Grant Program

AGENCY: Rural Business—Cooperative Service, USDA.

ACTION: Final rule, confirmation

SUMMARY: The Rural Business-Cooperative Service, a Rural Development agency of the United States Department of Agriculture (USDA), hereinafter referred to as “RBCS” or “the Agency,” published in the **Federal Register** on June 15, 2021, a final rule with request for comments. The Agency received no substantive comments, so this document confirms the final rule as published.

DATES: November 4, 2021.

FOR FURTHER INFORMATION CONTACT: David Chestnut, Program Management Division, U.S. Department of Agriculture, 1400 Independence Avenue SW, Washington, DC 20250-3201; telephone: (202) 692-5233; email: david.chestnut@usda.gov.

SUPPLEMENTARY INFORMATION: RBCS published a final rule with request for comments in the **Federal Register** on June 15, 2021, at 86 FR 31585. The final rule implemented a newly authorized program enacted under the authority of Section 6424 of the Agriculture Improvement Act of 2018 (Pub. L. 115-334) (Farm Bill).

Within the preamble to the final rule, the Agency addressed each of the 11 substantive public comments received from the request for comments published on July 22, 2020, in the **Federal Register** (85 FR 44273) as well as two public listening sessions held on July 28 and July 30, 2020, and one listening session held on July 21, 2020,

to receive comments from Agency staff. The final rule allowed the Agency: (a) To address comments received from the request for comments and the listening sessions and (b) to implement the final regulation.

The Agency did not receive any substantive or negative comments during the public comment period on the final rule and therefore confirms the rule without change.

Karama Neal,

Administrator, Rural Business—Cooperative Service.

[FR Doc. 2021-23986 Filed 11-3-21; 8:45 am]

BILLING CODE 3410-XP-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2021-0884; Project Identifier AD-2021-00998-A; Amendment 39-21785; AD 2021-22-12]

RIN 2120-AA64

Airworthiness Directives; Honda Aircraft Company LLC Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Honda Aircraft Company LLC (Honda) Model HA-420 airplanes. This AD was prompted by a report that the flap pushrod assemblies are susceptible to corrosion. This AD requires removing and cleaning the inner diameter of the flap control pushrods and repetitively applying corrosion inhibiting compound (CIC) to this area. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective November 19, 2021.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of November 19, 2021.

The FAA must receive comments on this AD by December 20, 2021.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- **Federal eRulemaking Portal:** Go to <https://www.regulations.gov>. Follow the instructions for submitting comments.

- **Fax:** (202) 493-2251.

- **Mail:** 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 to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this final rule, contact Honda Aircraft Company LLC, 6430 Ballinger Road, Greensboro, NC 27410; phone: (336) 662-0246; website: <https://www.hondajet.com>. You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, MO 64106. For information on the availability of this material at the FAA, call (816) 329-4148. It is also available at <https://www.regulations.gov> by searching for and locating Docket No. FAA-2021-0884.

Examining the AD Docket

You may examine the AD docket at <https://www.regulations.gov> by searching for and locating Docket No. FAA-2021-0884; 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, any comments received, and other information. The street address for the Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Samuel Kovitch, Aviation Safety Engineer, Atlanta ACO Branch, FAA, 1701 Columbia Avenue, College Park, GA 30337; phone: (404) 474-5570; email: samuel.kovitch@faa.gov.

SUPPLEMENTARY INFORMATION:

Background

The FAA was informed by Honda that the inner diameter of the flap control pushrod assemblies for certain Honda Model HA-420 airplanes are susceptible to corrosion, reducing the capability of the flap control pushrod to withstand normal operating conditions and resulting in its eventual failure. The corrosion was initially discovered during scheduled maintenance when a visual inspection of the flap control pushrod assemblies revealed signs of corrosion at the drain holes of the

welded tube center section of inboard and outboard assemblies. Later borescope inspections of the same airplane inside the welded tube section revealed pitting and discoloration of interior walls. On a later scheduled inspection of another airplane, similar corrosion was noted.

While the specific root cause of the corrosion is still under investigation, the flap control pushrods on the affected airplanes are susceptible to corrosion because the material of the pushrod is a low-alloy steel that had incomplete coverage of primer and CIC in the inner diameter. This incomplete coverage is potentially due to welding process spillover material creating voids that the primer could not reach and is exacerbated by general incomplete application. Drainage holes in the flap pushrod allow the external environment direct access to the inner diameter of the tube, exposing the improperly treated surface to the elements. As a result, corrosion may begin to develop immediately after the airplane enters service.

As a large majority of the fleet have been in service for longer than 12 months, during which time corrosion has progressed, the FAA finds the need for immediate action to preclude failure of the flap control pushrod. The compliance time of this AD prioritizes the affected fleet by risk and simultaneously requires all airplanes to be serviced as soon as possible.

Failure of a flap control pushrod, if not prevented, could result in uncontrolled and un-announced flap asymmetry, which could result in loss of control of the airplane. The FAA is issuing this AD to address the unsafe condition on these products.

FAA's Determination

The FAA is issuing this AD because the agency has determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Honda Aircraft Company Service Bulletin No. SB-420-27-008, dated August 31, 2021. This service information specifies procedures for removing and cleaning the inner diameter of the flap control pushrods and repetitively applying CIC to this area. 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 **ADDRESSES**.

AD Requirements

This AD requires accomplishing the actions specified in the service information already described.

Interim Action

The FAA considers this AD to be an interim action. Honda is currently considering implementing design changes to preclude the need for repetitively applying CIC and more permanently address the unsafe condition identified in this AD. Once these design changes are developed, approved, and available, the FAA may consider additional rulemaking.

Justification for Immediate Adoption and Determination of the Effective Date

Section 553(b)(3)(B) of the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*) authorizes agencies to dispense with notice and comment procedures for rules when the agency, for "good cause," finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under this section, an agency, upon finding good cause, may issue a final rule without providing notice and seeking comment prior to issuance. Further, section 553(d) of the APA authorizes agencies to make rules effective in less than thirty days, upon a finding of good cause.

An unsafe condition exists that requires the immediate adoption of this AD without providing an opportunity for public comments prior to adoption. The FAA has found that the risk to the flying public justifies foregoing notice and comment prior to adoption of this rule because the corrosion reduces the fatigue life and potentially initiates cracks in the pushrod. Crack propagation in a steel part could lead to immediate failure, resulting in un-announced, uncontrolled, and unrecoverable flap asymmetry. Because there is no primer or CIC on the affected part to prevent the corrosion from developing and worsening, the corrosion may appear immediately in service. As a large majority of the fleet has been in service for 12 to 24 months, during which time the corrosion has progressed, it is necessary to mitigate this unsafe condition by requiring the corroded pushrods to be serviced immediately. Also essential to correct the unsafe condition in the interim while a long term solution is developed is a requirement to reapply the CIC every 90 days to prevent the corrosion from developing further. Accordingly, notice and opportunity for prior public comment are impracticable and contrary

to the public interest pursuant to 5 U.S.C. 553(b)(3)(B).

In addition, the FAA finds that good cause exists pursuant to 5 U.S.C. 553(d) for making this amendment effective in less than 30 days, for the same reasons the FAA found good cause to forego notice and comment.

Comments Invited

The FAA invites you to send any written data, views, or arguments about this final rule. Send your comments to an address listed under **ADDRESSES**. Include "Docket No. FAA-2021-0884 and Project Identifier AD-2021-00998-A" at the beginning of your comments. The most helpful comments reference a specific portion of the final rule, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this final rule because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to <https://www.regulations.gov>, including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this final rule.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this AD contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this AD, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as "PROPIN." The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this AD. Submissions containing CBI should be sent to Samuel Kovitch, Aviation Safety Engineer, Atlanta ACO Branch, FAA, 1701 Columbia Avenue, College Park, GA 30337. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Regulatory Flexibility Act

The requirements of the Regulatory Flexibility Act (RFA) do not apply when

an agency finds good cause pursuant to 5 U.S.C. 553 to adopt a rule without prior notice and comment. Because FAA has determined that it has good cause to

adopt this rule without prior notice and comment, RFA analysis is not required.

Costs of Compliance

The FAA estimates that this AD affects 44 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
Remove, clean, and apply CIC to the flap control pushrods.	22 work-hours × \$85 per hour = \$1,870	\$70	\$1,940	\$85,360
Reapply CIC every 90 days (cost for each time).	1 work-hour × \$85 per hour = \$85	70	155	6,820

The FAA has included all known costs in its cost estimate. According to the manufacturer, however, some of the costs of this AD may be covered under warranty, thereby reducing the cost impact on affected operators.

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, and

(2) Will not affect intrastate aviation in Alaska.

List of Subjects in 14 CFR Part 39

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

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:

2021–22–12 Honda Aircraft Company LLC:
Amendment 39–21785; Docket No. FAA–2021–0884; Project Identifier AD–2021–00998–A.

(a) Effective Date

This airworthiness directive (AD) is effective November 19, 2021.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Honda Aircraft Company LLC Model HA–420 airplanes, serial numbers 42000153 through 42000158 and 42000160 through 42000206, certificated in any category.

(d) Subject

Joint Aircraft System Component (JASC) Code 2752, Trailing Edge Flap Actuator.

(e) Unsafe Condition

This AD was prompted by a report that the flap pushrod assemblies are susceptible to corrosion. The FAA is issuing this AD to prevent failure of the flap control pushrod. The unsafe condition, if not addressed, could result in uncontrolled and un-announced flap asymmetry with consequent loss of control of the airplane.

(f) Compliance

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

(g) Required Actions

(1) Within 90 days after the effective date of this AD or 18 months after issuance of the first standard certificate of airworthiness, whichever occurs later: Remove, clean, apply corrosion inhibiting compound (CIC) to, and reinstall the left and right inboard and outboard flap pushrod assemblies by following steps 3.0(3) through 3.0(6) of the Accomplishment Instructions in Honda Aircraft Company Service Bulletin No. SB–420–27–008, dated August 31, 2021.

(2) Within 90 days or 300 hours time-in-service (TIS), whichever occurs first after accomplishing the actions required by paragraph (g)(1) of this AD, and thereafter at intervals not to exceed 90 days or 300 hours TIS, whichever occurs first: Reapply CIC by following step 3.0(5)(a) through (c) of the Accomplishment Instructions in Honda Aircraft Company Service Bulletin No. SB–420–27–008, dated August 31, 2021.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Atlanta 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 (j) of this AD.

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

(3) For service information that contains steps that are labeled as Required for Compliance (RC), the following provisions apply.

(i) The steps labeled as RC, including substeps under an RC step and any figures identified in an RC step, must be done to comply with the AD. An AMOC is required for any deviations to RC steps, including substeps and identified figures.

(ii) Steps not labeled as RC may be deviated from using accepted methods in

accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the RC steps, including substeps and identified figures, can still be done as specified, and the airplane can be put back in an airworthy condition.

(j) Related Information

For more information about this AD, contact Samuel Kovitch, Aviation Safety Engineer, Atlanta ACO Branch, FAA, 1701 Columbia Avenue, College Park, GA 30337; phone: (404) 474-5570; email: samuel.kovitch@faa.gov.

(k) 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) Honda Aircraft Company Service Bulletin No. SB-420-27-008, dated August 31, 2021.

(ii) [Reserved]

(3) For Honda Aircraft Company LLC service information identified in this AD, contact Honda Aircraft Company LLC, 6430 Ballinger Road, Greensboro, NC 27410; phone: (336) 662-0246; website: <https://www.hondajet.com>.

(4) You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, MO 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: fr.inspection@nara.gov, or go to: <https://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued on October 15, 2021.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021-24097 Filed 11-3-21; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA-2021-0633; Airspace Docket No. 21-ANM-22]

RIN 2120-AA66

Modification and Establishment of Class E Airspace; Frank Wiley Field Airport, MT

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes Class E airspace, designated as an extension to a Class D or Class E surface area, at Frank Wiley Field Airport, Miles City, MT. This action also removes the Class E airspace extending upward from 1,200 feet above the surface. Additionally, the action implements an administrative update to the Class E2 and E5 text headers. This action ensures the safety and management of instrument flight rule (IFR) operations at the airport.

DATES: Effective 0901 UTC, January 27, 2022. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

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

FOR FURTHER INFORMATION CONTACT:

Matthew Van Der Wal, Federal Aviation Administration, Western Service Center, Operations Support Group, 2200 S 216th Street, Des Moines, WA 98198; telephone (206) 231-3695.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

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

History

The FAA published a notice of proposed rulemaking in the **Federal Register** (86 FR 44670; August 13, 2021) for Docket No. FAA-2021-0633 to establish and modify Class E airspace at Frank Wiley Field Airport, Miles City, MT. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Class E2, Class E4, and Class E5 airspace designations are published in paragraphs 6002, 6004, and 6005, respectively, of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in FAA Order JO 7400.11.

Availability and Summary of Documents for Incorporation by Reference

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

The Rule

This amendment to 14 CFR part 71 establishes Class E airspace, designated as an extension to a Class D or Class E surface area, at Frank Wiley Field Airport, Miles City, MT. The FAA proposes to amend the VOR RWY 4 approach and the amendment will relocate the point where aircraft descend below 1,000 feet above the surface from "3.35 miles" to "10.8 miles southwest of the airport." The additional Class E airspace will ensure the containment of IFR aircraft flying the approach.

This action also removes the Class E airspace extending upward from 1,200 feet above the surface. This airspace area is wholly contained within the Glasgow en route airspace and duplication is not necessary.

Additionally, the action implements an administrative update to the Class E2 and E5 text headers. The city name should not appear in the second line of the text header, and the term "Airport" should be added. This line of text should be changed from "Miles City, Frank Wiley Field, MT" to "Frank Wiley Field Airport, MT".

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

Regulatory Notices and Analyses

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

Environmental Review

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

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

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

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

- 1. The authority citation for 14 CFR part 71 continues to read as follows:

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

§ 71.1 [Amended]

- 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11F, Airspace Designations and Reporting

Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 6002 Class E Airspace Areas Designated as a Surface Area.

* * * * *

ANM MT E2 Miles City, MT [Amended]

Frank Wiley Field Airport, MT
(Lat. 46°25′41″ N, long. 105°53′10″ W)

That airspace extending upward from the surface within a 5-mile radius of the airport.

Paragraph 6004 Class E Airspace Areas Designated as an Extension to a Class D or Class E Surface Area.

* * * * *

ANM MT E4 Miles City, MT [New]

Frank Wiley Field Airport, MT
(Lat. 46°25′41″ N, long. 105°53′10″ W)

That airspace extending upward from the surface within 2.4 miles each side of the 225° bearing from the airport extending from the Class E2’s 5-mile radius of the airport to 10.8 miles southwest of the airport.

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

* * * * *

ANM MT E5 Miles City, MT [Amended]

Frank Wiley Field Airport, MT
(Lat. 46°25′41″ N, long. 105°53′10″ W)

That airspace extending upward from 700 feet above the surface within an 8-mile radius of the airport.

Issued in Des Moines, Washington, on October 28, 2021.

B.G. Chew,

Acting Group Manager, Operations Support Group, Western Service Center.

[FR Doc. 2021–23969 Filed 11–3–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–0637; Airspace Docket No. 21–ANM–31]

RIN 2120–AA66

Establishment of Class E Airspace; Portland-Troutdale Airport, OR

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes Class E airspace, designated as an extension to a Class D or Class E surface area, at Portland-Troutdale Airport, Portland, OR. This action also implements numerous administrative updates to the Class D and Class E2 text headers, and airspace descriptions. This action

ensures the safety and management of instrument flight rule (IFR) operations at the airport.

DATES: Effective 0901 UTC, January 27, 2022. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

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

FOR FURTHER INFORMATION CONTACT:

Matthew Van Der Wal, Federal Aviation Administration, Western Service Center, Operations Support Group, 2200 S 216th Street, Des Moines, WA 98198; telephone (206) 231–3695.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

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

History

The FAA published a notice of proposed rulemaking in the **Federal Register** (86 FR 44668; August 13, 2021) for Docket No. FAA–2021–0637 to establish Class E airspace at Portland-Troutdale Airport, Portland, OR. Interested parties were invited to participate in this rulemaking effort by

submitting written comments on the proposal to the FAA. No comments were received.

After the publication of the NPRM, the FAA discovered a typo in the longitudinal coordinates listed for Portland International Airport. The final rule corrects the coordinates from “lat. 45°35’19” N, long. 112°35’49” W” to “lat. 45°35’19” N, long. 122°35’49” W”.

Class D, Class E2, and Class E4 airspace designations are published in paragraphs 5000, 6002, and 6004, respectively, of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in FAA Order JO 7400.11.

Availability and Summary of Documents for Incorporation by Reference

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

The Rule

This amendment to 14 CFR part 71 establishes Class E airspace at Portland-Troutdale Airport, Portland, OR. The additional airspace is designed to properly contain IFR aircraft descending below 1,000 feet above the surface on the RNAV (GPS)-A approach.

This action also implements numerous administrative updates to the Class D and Class E2 text headers and airspace descriptions. The first line of the text headers is updated from “ANM OR D Portland-Troutdale, OR” to “ANM OR D Portland, OR”, Portland is the official city for the airport. The second line of the text headers is updated from “Portland-Troutdale Airport, Troutdale, OR” to “Portland-Troutdale Airport, OR”, this line should only list the airport name and state. A fourth and fifth line of text should be added to the headers. The lines should read “Portland International Airport, OR” and “(lat. 45°35’19” N, long. 122°35’49” W)”, respectively. The additional lines are necessary because the airspace descriptions contain exclusionary language for Portland International Airport’s Class C airspace area. The term Airport/Facility Directory” in the last sentence of the Class D airspace description is outdated and should be

corrected to “Chart Supplement.” The Class E2 airspace area is not in use continuously, to accurately describe the airspace, the following sentences should be added to the description. “This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.”

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

Regulatory Notices and Analyses

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

Environmental Review

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

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

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

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

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 5000 Class D Airspace.

* * * * *

ANM OR D Portland, OR [Amended]

Portland-Troutdale Airport, OR

(Lat. 45°32’58” N, long. 122°24’05” W)

Portland International Airport, OR

(Lat. 45°35’19” N, long. 122°35’49” W)

That airspace extending upward from the surface to and including 2,500 feet MSL within a 4-mile radius of the Portland-Troutdale Airport, excluding the portion within Portland International Airport’s Class C airspace area. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.

Paragraph 6002 Class E Airspace Areas Designated as a Surface Area.

* * * * *

ANM OR E2 Portland, OR [Amended]

Portland-Troutdale Airport, OR

(Lat. 45°32’58” N, long. 122°24’05” W)

Portland International Airport, OR

(Lat. 45°35’19” N, long. 122°35’49” W)

That airspace extending upward from the surface to and including 2,500 feet MSL within a 4-mile radius of the Portland-Troutdale Airport, excluding the portion within the Portland International Airport’s Class C airspace area. This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.

Paragraph 6004 Class E Airspace Areas Designated as an Extension to a Class D or Class E Surface Area.

* * * * *

ANM OR E4 Portland, OR [New]

Portland-Troutdale Airport, OR

(Lat. 45°32’58” N, long. 122°24’05” W)

That airspace extending upward from the surface within 2.3 miles each side of the 212° bearing from the airport extending from a 4-mile radius of the airport to 10.4 miles to the southwest of the airport.

Issued in Des Moines, Washington, on October 28, 2021.

B.G. Chew,

Acting Group Manager, Operations Support Group, Western Service Center.

[FR Doc. 2021-23980 Filed 11-3-21; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Part 744

[Docket No. 211019-0210]

RIN 0694-A164

Addition of Certain Entities to the Entity List

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Final rule.

SUMMARY: This final rule amends the Export Administration Regulations (EAR) by adding four entities to the Entity List. These four entities have been determined by the U.S. Government to be acting contrary to the foreign policy and national security interests of the United States and will be listed on the Entity List under the destinations of Israel, Russia, and Singapore.

DATES: This rule is effective November 4, 2021.

FOR FURTHER INFORMATION CONTACT: Chair, End-User Review Committee, Office of the Assistant Secretary for Export Administration, Bureau of Industry and Security, Department of Commerce, Phone: (202) 482-5991, Email: ERC@bis.doc.gov.

SUPPLEMENTARY INFORMATION:

Background

Entity List

The Entity List (supplement no. 4 to part 744 of the EAR) identifies entities for which there is reasonable cause to believe, based on specific and articulable facts, that the entities have been involved, are involved, or pose a significant risk of being or becoming involved in activities contrary to the national security or foreign policy interests of the United States. The EAR (15 CFR parts 730-774) impose additional license requirements on, and limit the availability of most license exceptions for, exports, reexports, and transfers (in-country) to listed entities. The license review policy for each listed entity is identified in the "License Review Policy" column on the Entity List, and the impact on the availability

of license exceptions is described in the relevant **Federal Register** document adding entities to the Entity List. Bureau of Industry and Security (BIS) places entities on the Entity List pursuant to part 744 (Control Policy: End-User and End-Use Based) and part 746 (Embargoes and Other Special Controls) of the EAR.

The End-User Review Committee (ERC), composed of representatives of the Departments of Commerce (Chair), State, Defense, Energy and, where appropriate, the Treasury, makes all decisions regarding additions to, removals from, or other modifications to the Entity List. The ERC makes all decisions to add an entry to the Entity List by majority vote and makes all decisions to remove or modify an entry by unanimous vote.

ERC Entity List Decisions

Additions to the Entity List

This rule implements the decision of the ERC to add four entities to the Entity List. The four entities are added based on § 744.11 (License requirements that apply to entities acting contrary to the national security or foreign policy interests of the United States) of the EAR. The four entities are located in Israel, Russia, and Singapore.

The ERC determined that NSO Group and Candiru be added to the Entity List based on § 744.11(b) of the EAR: Entities for which there is reasonable cause to believe, based on specific and articulated facts, that the entity has been involved, is involved, or poses a significant risk of being or becoming involved in activities that are contrary to the national security or foreign policy interests of the United States and those acting on behalf of such entities. Specifically, investigative information has shown that the Israeli companies NSO Group and Candiru developed and supplied spyware to foreign governments that used this tool to maliciously target government officials, journalists, businesspeople, activists, academics, and embassy workers.

The ERC determined that Positive Technologies, located in Russia, and Computer Security Initiative Consultancy PTE. LTD., located in Singapore, be added to the Entity List based on their engagement in activities counter to U.S. national security. Specifically, these entities traffic in cyber exploits used to gain access to information systems, threatening the privacy and security of individuals and organizations worldwide.

Pursuant to § 744.11(b) of the EAR, the ERC determined that the conduct of the above-described four entities raises

sufficient concerns that prior review, via the imposition of a license requirement for exports, reexports, or transfers (in-country) of all items subject to the EAR involving these four entities and the possible issuance of license denials or the possible imposition of license conditions on shipments to these entities, will enhance BIS's ability to prevent violations of the EAR or otherwise protect U.S. national security or foreign policy interests. In addition, the ERC also determined that no license exceptions should be available for exports, reexports, or transfers (in-country) to the persons being added to the Entity List in this rule. The ERC imposed a license review policy of a presumption of denial for these four entities. The acronym "a.k.a.," which is an abbreviation of 'also known as,' is used in entries on the Entity List to identify aliases, thereby assisting exporters, reexporters, and transferors in identifying entities on the Entity List.

For the reasons described above, this final rule adds the following four entities to the Entity List and includes, where appropriate, aliases:

Israel

- Candiru; and
- NSO Group

Russia

- Positive Technologies

Singapore

- Computer Security Initiative Consultancy PTE. LTD.

Savings Clause

Shipments of items removed from eligibility for a License Exception or export, reexport, or transfer (in-country) without a license (NLR) as a result of this regulatory action that were en route aboard a carrier to a port of export, reexport, or transfer (in-country), on November 4, 2021, pursuant to actual orders for export, reexport, or transfer (in-country) to or within a foreign destination, may proceed to that destination under the previous eligibility for a License Exception or export, reexport, or transfer (in-country) without a license (NLR).

Export Control Reform Act of 2018

On August 13, 2018, the President signed into law the John S. McCain National Defense Authorization Act for Fiscal Year 2019, which included the Export Control Reform Act of 2018 (ECRA) (50 U.S.C. 4801-4852). ECRA provides the legal basis for BIS's principal authorities and serves as the authority under which BIS issues this rule.

Rulemaking Requirements

1. Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been determined to be not significant for purposes of Executive Order 12866.

2. Notwithstanding any other provision of law, no person is required to respond to or be subject to a penalty for failure to comply with a collection of information, subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. This regulation involves collections previously approved by OMB under control number 0694–0088, Simplified Network Application Processing System, which includes, among other things, license applications and commodity classification, and carries a burden

estimate of 29.6 minutes for a manual or electronic submission for a total burden estimate of 31,835 hours. Total burden hours associated with the PRA and OMB control number 0694–0088 are not expected to increase as a result of this rule.

3. This rule does not contain policies with federalism implications as that term is defined in Executive Order 13132.

4. Pursuant to section 1762 of ECRA, this action is exempt from the Administrative Procedure Act (5 U.S.C. 553) requirements for notice of proposed rulemaking, opportunity for public participation, and delay in effective date.

5. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule by 5 U.S.C. 553, or by any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.*, are not applicable. Accordingly, no regulatory flexibility analysis is required and none has been prepared.

List of Subjects in 15 CFR Part 744

Exports, Reporting and recordkeeping requirements, Terrorism.

Accordingly, part 744 of the Export Administration Regulations (15 CFR parts 730–774) is amended as follows:

PART 744—[AMENDED]

■ 1. The authority citation for 15 CFR part 744 is revised to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.*; 50 U.S.C. 1701 *et seq.*; 22 U.S.C. 3201 *et seq.*; 42 U.S.C. 2139a; 22 U.S.C. 7201 *et seq.*; 22 U.S.C. 7210; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13099, 63 FR 45167, 3 CFR, 1998 Comp., p. 208; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13224, 66 FR 49079, 3 CFR, 2001 Comp., p. 786; Notice of September 15, 2021, 86 FR 52069 (September 17, 2021); Notice of November 12, 2020, 85 FR 72897 (November 13, 2020).

■ 2. Supplement No. 4 to part 744 is amended:

- a. Under ISRAEL, by adding in alphabetical order entries for “Candiru” and “NSO Group”;
- b. Under RUSSIA, by adding in alphabetical order an entry for “Positive Technologies”; and
- c. Under SINGAPORE, by adding in alphabetical order an entry for “Computer Security Initiative Consultancy PTE. LTD.”.

The additions read as follows:

Supplement No. 4 to Part 744—Entity List

* * * * *

Country	Entity	License requirement	License review policy	Federal Register citation
*	*	*	*	*
ISRAEL	*	*	*	*
	Candiru, a.k.a., the following seven aliases: —Candiru Ltd.; —DF Associates Ltd.; —Grindavik Solutions Ltd.; —Taveta Ltd.; —Saito Tech Ltd.; —Greenwick Solutions; and —Tabatha Ltd. 21 Haarbua, Tel Aviv-Yafo, Israel 6473921.	All items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	86 FR [INSERT FR PAGE NUMBER] November 4, 2021.
	NSO Group, 22 Galgalei Haplada, Herzliya, Tel Aviv-Yafo, Israel 4672222.	All items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	86 FR [INSERT FR PAGE NUMBER] November 4, 2021.
*	*	*	*	*
RUSSIA	*	*	*	*
	Positive Technologies, 8 Preobrazhenskaya Square, Moscow, Russia 107061.	All items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	86 FR [INSERT FR PAGE NUMBER] November 4, 2021.
*	*	*	*	*

Country	Entity	License requirement	License review policy	Federal Register citation
*	*	*	*	*
SINGAPORE	Computer Security Initiative Consultancy PTE. LTD., a.k.a., the following alias: —COSEINC. 102F Pasir Panjang Rd., #08–02, Citilink Warehouse Complex, Singapore 118530.	All items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	86 FR [INSERT FR PAGE NUMBER] November 4, 2021.
*	*	*	*	*
*	*	*	*	*

* * * * *

Matthew S. Borman,
Deputy Assistant Secretary for Export Administration.

[FR Doc. 2021–24123 Filed 11–3–21; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–631]

Schedules of Controlled Substances: Placement of Isotonitazene in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final amendment; final order.

SUMMARY: With the issuance of this final order, the Administrator of the Drug Enforcement Administration is permanently placing *N,N*-diethyl-2-(2-(4-isopropoxybenzyl)-5-nitro-1*H*-benzimidazol-1-yl)ethan-1-amine (commonly known as

isotonitazene), including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation, in schedule I of the Controlled Substances Act. This scheduling action discharges the United States' obligations under the Single Convention on Narcotic Drugs (1961). This action continues to impose the 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 or conduct instructional activities with, or possess), or propose to handle isotonitazene.

DATES: Effective December 6, 2021.

FOR FURTHER INFORMATION CONTACT:

Terrence L. Boos, Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362–3249.

SUPPLEMENTARY INFORMATION:

Legal Authority

The United States is a party to the 1961 United Nations Single Convention on Narcotic Drugs (Single Convention), March 30, 1961, 18 U.S.T. 1407, 570 U.N.T.S. 151, as amended by the 1972 Protocol. Article 3, paragraph 7 of the Single Convention requires that if the Commission on Narcotic Drugs (Commission) adds a substance to one of the schedules of such Convention, and the United States receives notification of such scheduling decision from the Secretary-General of the United Nations (Secretary-General), the United States, as a signatory Member State, is obligated to control the substance under its national drug control legislation. Under 21 U.S.C. 811(d)(1), if control of a substance is required “by United States obligations under international treaties, conventions, or protocols in effect on October 27, 1970,” the Attorney General must issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, without regard to the findings required by 21 U.S.C. 811(a) or 812(b), and without regard to the procedures prescribed by 21 U.S.C. 811(a) and (b). The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the Drug Enforcement Administration (Administrator of DEA or Administrator). 28 CFR 0.100.

Background

On August 20, 2020, DEA issued a temporary scheduling order, placing isotonitazene (*N,N*-diethyl-2-(2-(4-isopropoxybenzyl)-5-nitro-1*H*-benzimidazol-1-yl)ethan-1-amine), in

schedule I of the Controlled Substances Act (CSA). 85 FR 51342. That order was based on findings by the Acting Administrator of DEA (Acting Administrator) that the temporary scheduling of this substance was necessary to avoid an imminent hazard to the public safety; the order was codified at 21 CFR 1308.11(h)(48).

In November 2020, the Director-General of the World Health Organization recommended to the Secretary-General that isotonitazene be placed in Schedule I of the Single Convention, as this substance has an opioid mechanism of action and similarity to drugs that are controlled in Schedule I of the Single Convention (*i.e.*, isotonitazene is similar to drugs such as morphine and fentanyl), and has dependence and abuse potential. On June 10, 2021, the Secretary-General advised the Secretary of State of the United States, by letter, that during its 64th session in April 2021, the Commission voted to place isotonitazene in Schedule I of the Single Convention (CND Apr/64/1).

Isotonitazene

As discussed in the background section, isotonitazene is temporarily controlled in schedule I of the CSA upon the Acting Administrator's finding it poses imminent hazard to the public safety. Isotonitazene has a pharmacological profile similar to etonitazene (schedule I), fentanyl (schedule II), and other schedule I and II synthetic opioids that act as mu-opioid receptor agonists. Because of the pharmacological similarities of isotonitazene to etonitazene (a potent mu-opioid agonist), the use of isotonitazene presents a high risk of abuse and has negatively affected users and communities. The abuse of isotonitazene has been associated with

at least 48^{1,2} fatalities in the United States between August 2019 and July 2020. The positive identification of this substance in post-mortem cases is a serious concern to the public safety.

Isotonitazene in the illicit drug market has been reported in Canada, Estonia, Germany, Latvia, Sweden, and the United States since April 2019.³ Law enforcement reports demonstrate that isotonitazene is being illicitly distributed and abused. The illicit use and distribution of this substance are similar to that of heroin (schedule I) and prescription opioid analgesics. According to the National Forensic Laboratory Information System (NFLIS-Drug) database, which collects drug identification results from drug cases submitted to and analyzed by Federal, State and local forensic laboratories, there have been 181 reports for isotonitazene between January 2019 and December 2020⁴ (query date: May 28, 2021).

DEA is not aware of any claims or any medical or scientific literature suggesting that isotonitazene has a currently accepted medical use in treatment in the United States. In addition, the Department of Health and Human Services advised DEA, by letter dated March 31, 2020, that there were no investigational new drug applications or approved new drug applications for isotonitazene in the United States. Because isotonitazene is not formulated or available for clinical use as an approved medicinal product, all current use of this substance by individuals is based on their own initiative, rather than on the basis of medical advice from a practitioner licensed by law to administer such a drug.

Therefore, consistent with 21 U.S.C. 811(d)(1), DEA concludes that isotonitazene has no currently accepted medical use in treatment in the United States⁵ and is most appropriately

placed in schedule I of the CSA, the same schedule in which it currently resides. Because control is required under the Single Convention, DEA will not be initiating regular rulemaking proceedings to schedule isotonitazene pursuant to 21 U.S.C. 811(a).

Conclusion

In order to meet the United States' obligations under the Single Convention and because isotonitazene has no currently accepted medical use in treatment in the United States, the Administrator has determined that isotonitazene, including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation, should remain in schedule I of the CSA.

Requirements for Handling

Isotonitazene has been controlled as a schedule I controlled substance since August 20, 2020. Upon the effective date of the final order contained in this document, isotonitazene will be permanently subject to the CSA's schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture of, distribution of, importation of, exportation of, engagement in research or conduct of instructional activities with, and possession of, schedule I controlled substances, including the following:

1. *Registration.* Any person who handles (manufactures, distributes, imports, exports, engages in research or conducts instructional activities with, or possesses), or who desires to handle, isotonitazene must 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. Retail sales of schedule I controlled substances to the general public are not allowed under the CSA. Possession of any quantity of these substances in a manner not authorized by the CSA is unlawful and those in

possession of any quantity of these substances may be subject to prosecution pursuant to the CSA.

2. *Disposal of stocks.* Isotonitazene must be disposed of in accordance with 21 CFR part 1317, in addition to all other applicable federal, state, local, and tribal laws.

3. *Security.* Isotonitazene is subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 821 and 823, and in accordance with 21 CFR 1301.71–1301.76. Non-practitioners handling isotonitazene must also comply with the employee screening requirements of 21 CFR 1301.90–1301.93.

4. *Labeling and packaging.* All labels, labeling, and packaging for commercial containers of isotonitazene must be in compliance with 21 U.S.C. 825 and 958(e), and be in accordance with 21 CFR part 1302.

5. *Quota.* Only registered manufacturers are permitted to manufacture isotonitazene in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303.

6. *Inventory.* Every DEA registrant who possesses any quantity of isotonitazene has been required to keep an inventory of all stocks of this substance on hand as of August 20, 2020, pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

7. *Records and Reports.* DEA registrants must maintain records and submit reports with respect to isotonitazene pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR parts 1304, 1312, and 1317, and § 1307.11. Manufacturers and distributors must submit reports regarding isotonitazene to the Automation of Reports and Consolidated Order System pursuant to 21 U.S.C. 827 and in accordance with 21 CFR parts 1304 and 1312.

8. *Order Forms.* All DEA registrants who distribute isotonitazene must continue to comply with order form requirements pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305.

9. *Importation and Exportation.* All importation and exportation of isotonitazene must continue to be in compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR parts 1304, 1312, and 1317.

10. *Liability.* Any activity involving isotonitazene not authorized by, or in violation of the CSA, is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

¹ Shover CL, Falasinnu TO, Freedman RB, Humphreys K. Emerging Characteristics of Isotonitazene-Involved Overdose Deaths: A Case-Control Study. *J Addict Med.* 2020 Nov 23;10.1097/ADM.0000000000000775.

² Krotulski AJ, Papsun DM, Kacinko SL, Logan BK. Isotonitazene Quantitation and Metabolite Discovery in Authentic Forensic Casework. *J Anal Toxicol.* 2020 Jul 31;44(6):521–530.

³ European Monitoring Centre for Drugs and Drug Addiction and Europol. (2020). EMCDDA initial report on the new psychoactive substance N,N-diethyl-2-[[4-(1-methylethoxy)phenyl]methyl]-5-nitro-1H-benzimidazole-1-ethanamine (isotonitazene). In accordance with Article 5b of Regulation (EC) No 1920/2006 (as amended), Publications Office of the European Union, Luxembourg.

⁴ Reports to NFLIS-Drug are still pending for 2020.

⁵ Although, as discussed above, there is no evidence suggesting that isotonitazene has a

currently accepted medical use in treatment in the United States, it bears noting that a drug cannot be found to have such medical use unless DEA concludes that it satisfies a five-part test. Specifically, with respect to a drug that has not been approved by the Food and Drug Administration, to have a currently accepted medical use in treatment in the United States, all of the following must be demonstrated: i. The drug's chemistry must be known and reproducible; ii. there must be adequate safety studies; iii. there must be adequate and well-controlled studies proving efficacy; iv. the drug must be accepted by qualified experts; and v. the scientific evidence must be widely available. 57 FR 10499 (1992), *pet. for rev. denied, Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131, 1135 (D.C. Cir. 1994).

Regulatory Analyses

Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review)

This action is not a significant regulatory action as defined by Executive Order (E.O.) 12866 (Regulatory Planning and Review), section 3(f), and the principles reaffirmed in E.O. 13563 (Improving Regulation and Regulatory Review); and, accordingly, this action has not been reviewed by the Office of Management and Budget (OMB).

Executive Order 12988, Civil Justice Reform

This action 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 action does not have federalism implications warranting the application of E.O. 13132. This action does not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications warranting the application of E.O. 13175. The action 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.

Administrative Procedure Act

The CSA provides for an expedited scheduling action where control is required by the United States' obligations under international treaties, conventions, or protocols. 21 U.S.C. 811(d)(1). If control is required pursuant to such international treaty, convention, or protocol, the Attorney General, as delegated to the Administrator, must issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, without regard to the findings or procedures otherwise required for scheduling actions. *Id.*

In accordance with 21 U.S.C. 811(d)(1), scheduling actions for drugs

that are required to be controlled by the United States' obligations under international treaties, conventions, or protocols in effect on October 27, 1970, shall be issued by order (as compared to scheduling by rule pursuant to 21 U.S.C. 811(a)). Therefore, DEA believes that the notice and comment requirements of section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553, do not apply to this scheduling action. In the alternative, even if this action does constitute "rule making" under 5 U.S.C. 551(5), this action is exempt from the notice and comment requirements of 5 U.S.C. 553 pursuant to 5 U.S.C. 553(a)(1) as an action involving a foreign affairs function of the United States because it is being done pursuant to 21 U.S.C. 811(d)(1), which requires that the United States comply with its obligations under the specified international agreements.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) applies to rules that are subject to notice and comment under section 553(b) of the APA or any other law. As explained above, the CSA exempts this final order from notice and comment. Consequently, the RFA does not apply to this action.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521. 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.

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 mandate that may result "in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 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.

Congressional Review Act

This order is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. However, DEA is submitting the required reports to the Government Accountability Office, the House, and the Senate under the CRA.

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 amends 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

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

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

■ 2. In § 1308.11:

■ a. Redesignate paragraphs (b)(46) through (90) as paragraphs (b)(47) through (91);

■ b. Add new paragraph (b)(46); and

■ c. Remove and reserve paragraph (h)(48).

The addition reads as follows:

§ 1308.11 Schedule I.

* * * * *

(b) * * *

(46) Isotonitazene (*N,N*-diethyl-2-(2-(4-isopropoxybenzyl)-5-nitro-1*H*-benzimidazol-1-yl)ethan-1-amine) 9614

* * * * *

Anne Milgram,

Administrator.

[FR Doc. 2021–23848 Filed 11–3–21; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2021–0582]

RIN 1625–AA08

Special Local Regulation; Atlantic Ocean, Key West, FL

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary special local regulation for power boat races. This action is necessary to ensure safety of life on navigable waters on the waters of the Key West Main Ship Channel, Key West Turning Basin, and Key West Harbor Entrance in Key West, FL. This regulation prohibits persons and vessels from entering, transiting through, anchoring in, or remaining within the regulated area without permission from the Captain of the Port Key West or a designated representative.

DATES: This rule is effective from 9:30 a.m. on November 10, 2021, until 4:30 p.m. on November 14, 2021. This rule will only be subject to enforcement from the hours of 9:30 a.m. to 4:30 p.m., on November 10, 12, and 14, 2021.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG–2021–0582 in the “SEARCH” box and click “SEARCH.” Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Lieutenant Junior Grade Vera Max, Sector Key West Waterways Management Division, Coast Guard; telephone (305) 292–8768, email SKWWaterways@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background Information and Regulatory History

On May 7, 2021, Race World Offshore notified the Coast Guard that it would be conducting high-speed boat races from 9:30 a.m. until 4:30 p.m. each day on November 10, 12, and 14, 2021. Approximately 50 participants and 200 spectator craft are expected to attend the event, which will take place in the Atlantic Ocean, off the tip of Key West, Florida, on the waters of the Key West Main Ship Channel, Key West Turning Basin, and Key West Harbor Entrance in Key West, FL. In response, on October 5, 2021, the Coast Guard published a notice of proposed rulemaking (NPRM) titled, “Special Local Regulation; Atlantic Ocean, Key West, FL” (86 FR 54879). There we stated why we issued the NPRM, and invited comments on our proposed regulatory action related to this power boat race event.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable because the event is taking place on November 10, 12, and 14, 2021, and immediate action is needed to respond to the potential safety hazards associated with this event.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70041. The Captain of the Port Key West (COTP) has determined that the potential hazards associated with the high-speed boat race would be a safety concern for the participants, participant vessels, and the general public. The purpose of this rule is to protect event participants, spectators, and vessels on the navigable waters of the Key West Main Ship Channel, Key West Turning Basin, and Key West Harbor Entrance before, during, and after the scheduled event.

IV. Discussion of Comments, Changes, and the Rule

As noted above, we received six comments on our NPRM published October 5, 2021. Four comments were in support of the rule, citing the need for safety around this large event. One comment was in support of the rule, but pointed out the possible effects on small entities and their options for working with the Coast Guard to mitigate those effects, as discussed in section V.B of this rule. We received one comment that raised concerns about the West Indian Manatee, calling for measures to be in place to account for injuries to manatees and other species that could be harmed by the high-speed boat races. The Coast Guard has conducted outreach with several state and federal agencies, including the Florida Keys National Marine Sanctuary and U.S. Department of Fish and Wildlife, through the Environmental Analysis discussed in Section V.F. The sponsor has provided a safety plan, including measures for protection of manatees. There are no changes in the regulatory text of this rule from the proposed rule in the NPRM.

This rule establishes a temporary special local regulation that will be subject to enforcement from 9:30 a.m. until 4:30 p.m. on November 10, 12, and 14, 2021. The temporary special local regulation consists of two regulated areas: (1) Race and safety buffer area, and (2) spectator area. These areas prohibit persons and vessels from entering, transiting through, anchoring in, or remaining within the race area or buffer zone and prohibit vessels from transiting at speeds that cause wake within the spectator area, unless authorized by the COTP Key West or a designated representative. The temporary special local regulation covers all navigable waters in the Atlantic Ocean, off the tip of Key West, Florida, on the waters of the Key West Main Ship Channel, Key West Turning Basin, and Key West Harbor Entrance.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

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

This regulatory action determination is based on the location, duration, and time-of-day of the regulated area. Although persons and vessels may not enter, transit through, anchor in, or remain within the area without authorization from the COTP or a designated representative, they will be able to safely transit around the area. Moreover, the Coast Guard will issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the area, and the rule will allow vessels to seek permission to enter the area between race heats.

B. Impact on Small Entities

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

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

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in

understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this 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 rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023-01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321-4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. Additionally, the event sponsor has provided a marine protection plan that includes aerial and on-water monitoring and provisions for halting the race should any manatees or turtles be observed in or near the race area. This rule involves a temporary special local regulation lasting 7 hours on 3 days that will prohibit entry into the race area or buffer zone, and prohibit vessels from transiting at speeds that cause wake within the spectator area. It is categorically excluded from further review under paragraph L61 of Appendix A, Table 1 of DHS Instruction Manual 023-01-001-01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket where indicated under **ADDRESSES**.

G. Protest Activities

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

List of Subjects in 33 CFR Part 100

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

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

■ 1. The authority citation for part 100 continues to read as follows:

Authority: 46 U.S.C. 70041; 33 CFR 1.05-1.

■ 2. Add temporary § 100.T799-0582 to read as follows:

§ 100.T799-0582 Special Local Regulation; Power Boat Races, Key West, FL.

(a) *Locations.* The following regulated areas are established as special local regulations. All coordinates are North American Datum 1983.

(1) *Race and safety buffer area.* Waters of the Atlantic Ocean of Key West, FL that are encompassed within the following points: Starting at Point 1 in position 24°32.506' N, 81°49.984' W; thence southwest to Point 2 in position 24°32.455' N, 81°49.040' W; thence northwest to Point 3 in position 24°32.559' N, 81°49.584' W; thence northwest to Point 4 in position 24°32.608' N, 81°49.628' W; thence northwest to Point 5 in position 24°33.095' N, 81°49.265' W; thence northeast to Point 6 in position 24°33.518' N, 81°48.902' W; thence northeast to Point 7 in position 24°33.908' N, 81°48.448' W; thence east to Point 8 in position 24°33.898' N, 81°48.364' W; thence southeast back to origin.

(2) *Spectator area.* All waters of the Atlantic Ocean in Key West, FL that are encompassed within the following points: starting at Point 1 in position 24°33.123' N, 81°49.290' W; thence northeast to Point 2 in position 24°33.545' N, 81°48.923' W; thence east to Point 3 in position 24°33.518' N, 81°48.902' W thence southwest to point 4 in position 24°33.095' N, 81°49.265' W thence west back to origin.

(b) *Definition.* As used in this section, the term “designated representative” means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port Key West in the enforcement of the safety zone.

(c) *Regulations.* (1) All non-participant persons and vessels, except those persons and vessels participating in the high-speed boat races, are prohibited from entering, transiting through, anchoring in, or remaining within the regulated areas described in paragraph (a) of this section unless authorized by the Captain of the Port Key West or their designated representative.

(2) All persons are prohibited from entering the water or swimming in the spectator area described in paragraph (a)(2) of this section.

(3) All vessels are prohibited from transiting at speeds that cause wake within the spectator area described in paragraph (a)(2) of this section.

(4) To seek permission to enter, contact the Captain of the Port Key West or a designated representative by telephone at (305) 433-0954, or via VHF radio on channel 16. If authorization is granted by the Captain of the Port Key West or a designated representative, all persons and vessels receiving such authorization must comply with the instructions of the Captain of the Port Key West or a designated representative.

(5) The Coast Guard will provide notice of the regulated area by Broadcast Notice to Mariners and on-scene designated representatives.

(d) *Enforcement period.* This section will be enforced from 9:30 a.m. until 4:30 p.m. on November 10, 12, and 14, 2021.

Dated: October 28, 2021.

A. Chamie,

Captain, U.S. Coast Guard, Captain of the Port Key West.

[FR Doc. 2021-23865 Filed 11-3-21; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2021-0801]

RIN 1625-AA00

Safety Zone; Munitions Transfer; Alameda, CA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone in the navigable waters of the Oakland Estuary in the Brooklyn Basin South Channel near Coast Guard Island in Alameda, CA in support of a munitions transfer on November 14, 2021, and November 21, 2021. This safety zone is necessary to protect personnel, vessels, and the marine environment from the dangers associated with live munitions. Unauthorized persons or vessels are prohibited from entering into, transiting through, or remaining in the safety zone without permission of the Captain of the Port or a designated representative.

DATES: This rule is effective from 8 a.m. on November 14, 2021, until 2 p.m. on November 21, 2021.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG-2021-0801 in the search box and click “Search.” Next, in the Document Type column, select “Supporting & Related Material.”

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Lieutenant Junior Grade William Harris, U.S. Coast Guard Sector San Francisco; telephone (415) 399-7443, email SFWaterways@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impractical and contrary to the public interest. The Coast Guard did not receive final details for this event until October 18, 2021. There was insufficient time to undergo the full rulemaking process, including providing a reasonable comment period and considering those comments because the Coast Guard must establish this temporary safety zone by November 14, 2021.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be contrary to public interest because immediate action is necessary to protect personnel, vessel, and the marine environment from the potential safety hazards associated with the munitions transfer near Alameda, CA beginning November 14, 2021.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The Captain of the Port San Francisco (COTP) has determined that potential hazards associated with the munitions transfer on November 14, 2021 and November 21, 2021 will be a safety concern for anyone within a 250-foot radius of the pier. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone around the munitions transfer site during the munitions transfer.

IV. Discussion of the Rule

This rule establishes a temporary safety zone from 8 a.m. until 2 p.m. on November 14, 2021 and from 8 a.m. until 2 p.m. on November 21, 2021. The temporary safety zone will cover all navigable waters, from surface to bottom, within 250 feet of the munitions transfer pier located on the southwest side of Coast Guard Island in the Brooklyn Basin South Channel of the Oakland Estuary. The temporary safety zone will be terminated at 2 p.m. on both November 14, 2021 and November 21, 2021 or once announced via broadcast notice to mariners.

This regulation is necessary to keep persons and vessels away from the immediate vicinity of the munitions transfer location to ensure the safety of people, vessels, and the marine environment. Except for persons or vessels authorized by the COTP or the COTP’s designated representative, no person or vessel may enter or remain in the restricted area. A “designated representative” means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel or a Federal, State, or local officer designated by or assisting the COTP in the enforcement of the safety zone.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a “significant regulatory action,” under

Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the limited duration and narrowly tailored geographic area of the safety zone. This safety zone impacts a 250-foot wide portion of the Brooklyn Basin South Channel of the Oakland Estuary along the southwest side of Coast Guard Island in Alameda, CA for six hours. Vessels desiring to transit through or around the temporary safety zone may do so upon express permission from the COTP or the COTP's designated representative.

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 rule will not have a significant economic impact on a substantial number of small entities.

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

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

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

about this rule or any policy or action of the Coast Guard.

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

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

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone lasting only six hours that will prohibit entry within 250 feet of vessels and machinery being used by personnel

to conduct munitions transfer. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

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

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

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

- 2. Add § 165.T11–082 to read as follows:

§ 165.T11–082 Safety Zone; Munitions Transfer, Oakland Estuary, Alameda, CA.

(a) *Location.* This temporary safety zone is established in the navigable waters of the Brooklyn Basin South Channel of the Oakland Estuary near the pier alongside the southwest side of Coast Guard Island in Alameda, CA as depicted in National Oceanic and Atmospheric Administration (NOAA) Chart 18662. From 8 a.m. until 2 p.m. daily on November 14, 2021, and November 21, 2021, the temporary safety zone will apply to all navigable waters of the Oakland Estuary in the Brooklyn Basin South Channel, from surface to bottom, within 250 feet of the pier along the southwest side of Coast Guard Island, during which time the pier will be used as the munitions transfer location.

(b) *Definitions.* As used in this section, “designated representative” means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer

on a Coast Guard vessel, or a Federal, State, or local officer designated by or assisting the Captain of the Port San Francisco (COTP) in the enforcement of the safety zone.

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

(2) The safety zone is closed to all vessel traffic, except as may be permitted by the COTP or the COTP's designated representative.

(3) Vessel operators desiring to enter or operate within the safety zone must contact the COTP or the COTP's designated representative to obtain permission to do so. Vessel operators given permission to enter or operate in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative. Persons and vessels may request permission to enter the safety zone on VHF-21A or through the 24-hour Command Center at telephone (415) 399-3547.

(d) *Enforcement period.* This section will be enforced from 8 a.m. until 2 p.m. on November 14, 2021, and from 8 a.m. until 2 p.m. on November 21, 2021, or until announced via broadcast notice to mariners.

(e) *Information broadcasts.* The COTP or the COTP's designated representative will notify the maritime community of periods during which this zone will be enforced in accordance with 33 CFR 165.7.

Dated: October 27, 2021.

Taylor Q. Lam,

Captain, U.S. Coast Guard, Captain of the Port, San Francisco.

[FR Doc. 2021-23895 Filed 11-3-21; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2021-0767]

RIN 1625-AA00

Safety Zone; 2021 Barge Based Fireworks, Hudson River, Manhattan, NY

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for certain navigable waters within a 600

foot radius of the fireworks launch site which is located on the Hudson River, Manhattan, NY, in the vicinity of the Hudson River Park and Pier 76. This safety zone is needed to protect personnel, vessels, and the marine environment from the potential hazards during a fireworks display on November 18, 2021. Entry of vessels or persons into, transiting through, mooring, or anchoring within this zone are prohibited unless authorized by the Captain of the Port New York.

DATES: This rule is effective from 9:30 p.m. through 11:30 p.m. on November 18, 2021.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG-2021-0767 in the search box and click "Search." Next, in the Document Type column, select "Supporting & Related Material."

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email MST1 S. Stevenson, Waterways Management Division, U.S. Coast Guard; telephone 719-354-4000, email D01-SMB-SecNY-Waterways@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because doing so would be impracticable and contrary to the public interest. The final details for this event were not known to the Coast Guard until there was insufficient time to publish an NPRM. Thus, delaying the effective date of this rule to wait for a comment period to run would be impracticable because it would inhibit the Coast Guard's ability to

protect the public and vessels from the hazards associated with a barge based fireworks display. The expeditious implementation of this rule is in the public interest because it will help ensure the safety of those involved in displaying the fireworks, the spectators, and users of the waterway during the fireworks event.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable and contrary to the public interest because the safety zone must be established for the fireworks display on November 18, 2021, to mitigate the potential safety hazards associated with a fireworks display in this location.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The Captain of the New York (COTP) has determined that potential hazards associated with this fireworks display, on November 18, 2021, will pose a significant risk to public safety and property. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the fallout zone immediately before, during, and after the fireworks display.

IV. Discussion of the Rule

This rule establishes a temporary safety zone on all navigable waters within a 600 foot radius of a barge located at approximate position 40°45'39.4" N, 74°00'35.8" W on the Hudson River, Manhattan, NY, in the vicinity of the Hudson River Park and Pier 76. No vessel or person will be permitted to enter the safety zone between 9:30 p.m. through 11:30 p.m. on November 18, 2021. The duration of the zone is intended to protect personnel, vessels, and the marine environment in these navigable waters during the fireworks display. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a Designated Representative.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

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

This regulatory action determination is based on the duration and time-of-day of the safety zone. This safety zone will restrict vessel traffic from entering or transiting within a 600 foot radius of the fireworks launch site which is located on the Hudson River, Manhattan, NY, in the vicinity of the Hudson River Park and Pier 76. The approximate position is 40°45′39.4″ N, 74°00′35.8″ W. Moreover, the Coast Guard will issue Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone, and the rule allows vessels to seek permission to enter the zone. Vessel traffic will be able to safely transit around the safety zone which would impact a small designated area of the Hudson River. Vessel traffic will only be restricted in the limited access area for two hours on November 18, 2021. Advance public notifications will also be made to local mariners through appropriate means, which may include Local Notice to Mariners and Broadcast Notice to Mariners.

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 rule will not have a significant economic impact on a substantial number of small entities.

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

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule

would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

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

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 (adjusted for inflation) or

more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone lasting only 2 hour that will prohibit entry within a 600 foot radius of the fireworks launch site. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination will be available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

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

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 46 U.S.C. 70034, 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.2.

■ 2. Add § 165.T01–0767 to read as follows:

§ 165.T01–0767 Safety Zone; 2021 Barge Based Fireworks, Hudson River, Manhattan, NY.

(a) *Location.* The safety zone will cover all navigable waters within a 600 foot radius of the fireworks launch site located on the Hudson River, Manhattan, NY, approximate position 40°45'39.4" N, 4°00'35.8" W, in the vicinity of the Hudson River Park and Pier 76.

(b) *Definitions.* As used in this section, *Designated representative* means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer or other officer operating a Coast Guard vessel and a Federal, State and local officer designated by or assisting the Captain of the Port New York (COTP) in the enforcement of this section.

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

(2) To seek permission to enter, contact the COTP or the COTP's Designated Representative via VHF–FM Marine Channel 16 or by contacting the Coast Guard Sector New York command center at (718) 354–4356 or on VHF 16 to obtain permission.

(d) *Enforcement period.* This rule will be enforced from 9:30 p.m. through 11:30 p.m. on November 18, 2021.

(e) *Information broadcasts.* The COTP or a designated representative will inform the public through Broadcast Notice to Mariners of any changes in the planned schedule.

Dated: October 25, 2021.

M. Sennick,

Captain, U.S. Coast Guard, Captain of the Port New York.

[FR Doc. 2021–23786 Filed 11–3–21; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF VETERANS AFFAIRS
38 CFR Part 1

RIN 2900–AR39

Release of Information From Department of Veterans Affairs' Records

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: This document amends the Department of Veterans Affairs' (VA) regulations governing the submission and processing of requests for

information under the Freedom of Information Act (FOIA).

DATES: This rule is effective December 6, 2021.

FOR FURTHER INFORMATION CONTACT: Catherine Nachmann, Attorney, Office of General Counsel (024), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420, (202) 461–7742 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: On April 1, 2019, VA published a final rule in the **Federal Register** [84 FR 12122]. The final rule amended VA's regulations pertaining to release of information under 5 U.S.C. 552 and implementation of the FOIA, codified at 38 CFR 1.550 through 1.562, and implemented amendments in the FOIA Improvement Act of 2016, Public Law 114–185, and those governing release of information from claimant records protected under the Privacy Act of 1974, namely 38 CFR 1.577(c) and (e) and 1.580. VA also amended the regulations to clarify sections as needed and streamline VA processes regarding release of information.

VA is now revising its regulation at 38 CFR 1.552, General Provisions, to change VA FOIA Service's website address. A Notice of Proposed Rulemaking is not required because no substantive changes are being proposed.

Paperwork Reduction Act

This document contains no provisions constituting a collection of information under the Paperwork Reduction Act (44 U.S.C. 3501–3521).

Regulatory Flexibility Act

The Secretary of Veterans Affairs hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. The provisions of this rulemaking only involve internal agency processes and no entities outside of VA. This final rule does not concern fees. Therefore, pursuant to 5 U.S.C. 605(b), the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604 do not apply.

Administrative Procedure Act

The Secretary of Veterans Affairs finds that there is good cause under the provisions of 5 U.S.C. 553(b)(B) to publish this rule without prior opportunity for public comment. Publication as a final rule will allow individuals who want to access VA FOIA Service's website to do so without delay or the additional effort required to access another website address after

redirection. Delay in updating the address would be contrary to the public interest because currently, individuals who seek information about VA's FOIA program are directed to a non-functioning website. To facilitate public access to such information, VA is issuing this rule as a final rule without a comment period.

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. The Office of Information and Regulatory Affairs has determined that this rule is not a significant regulatory action under Executive Order 12866. The Regulatory Impact Analysis associated with this rulemaking can be found as a supporting document at www.regulations.gov.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in an 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 year. This final rule would have no such effect on state, local, and tribal governments, or on the private sector.

Catalog of Federal Domestic Assistance

There is no Catalog of Federal Domestic Assistance number for the program affected by this final rule.

Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as not a major rule, as defined by 5 U.S.C. 804(2).

List of Subjects in 38 CFR Part 1

Administrative Practice and Procedure, Archives and Records, Cemeteries, Claims, Courts, Crime, Flags, Freedom of information, Government Contracts, Government Employees, Government Property,

Infants and Children, Inventions and Patents, Parking, Penalties, Privacy, Reporting and Recordkeeping Requirements, Seals and Insignia, Security Measures, and Wages.

Signing Authority

Denis McDonough, Secretary of Veterans Affairs, approved this document on October 26, 2021, and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs.

Consuela Benjamin,

Regulations Development Coordinator, Office of Regulation Policy & Management, Office of General Counsel, Department of Veterans Affairs.

For the reasons stated in the preamble, VA amends 38 CFR part 1 as follows:

PART 1—GENERAL PROVISIONS

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

Authority: 38 U.S.C. 501(a).

■ 2. In § 1.552, revise paragraph (a) to read as follows.

§ 1.552 General provisions.

* * * * *

(a) *Additional information.*

Information regarding VA's FOIA and Privacy Act process generally, including how to file FOIA requests, and information made available by VA under the FOIA, is available at the following internet address: <https://www.va.gov/foia>.

* * * * *

[FR Doc. 2021-23911 Filed 11-3-21; 8:45 am]

BILLING CODE 8320-01-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R09-OAR-2021-0524; FRL-8808-02-R9]

Air Plan Approval; California; Eastern Kern 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 Eastern Kern Air Pollution Control District (EKAPCD) portion of the California State Implementation Plan (SIP). This revision concerns EKAPCD's demonstration regarding reasonably available control technology (RACT) requirements and negative declarations for the 2008 8-hour ozone National Ambient Air Quality Standards (NAAQS or "standards") in the portion of the Kern County nonattainment area under the jurisdiction of EKAPCD.

DATES: This rule will be effective on December 6, 2021.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA-R09-OAR-2021-0524. 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. If you need assistance in a language other than English or if you are a person with disabilities who needs a reasonable accommodation at no cost to you, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT:

Nicole Law, EPA Region IX, 75 Hawthorne St., San Francisco, CA 94105. By phone: (415) 947-4126 or by email at Law.Nicole@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. Statutory and Executive Order Reviews

I. Proposed Action

On August 25, 2021 (86 FR 47435), the EPA proposed to approve the California Air Resources Board's (CARB) August 9, 2017 submittal of the Eastern Kern Air Pollution Control District Reasonable Available Control Technology (RACT) State Implementation Plan (SIP) for the 2008 Ozone National Ambient Air Quality Standards (NAAQS) ("2017 RACT SIP").

Local agency	Document	Adopted	Submitted
EKAPCD	Eastern Kern Air Pollution Control District Reasonable Available Control Technology (RACT) State Implementation Plan (SIP) for the 2008 Ozone National Ambient Air Quality Standards (NAAQS) ("2017 RACT SIP").	05/11/2017	08/09/2017

We proposed to approve this submittal because we determined that it complies with the relevant Clean Air Act ("Act") requirements. Our proposed action contains more information on the submittal 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

This action is one of three EPA actions on the EKAPCD 2017 RACT SIP submittal. The other two actions are as follows:

(1) On January 14, 2021 (86 FR 3816), the EPA approved EKAPCD's negative declaration for the Control Techniques Guidelines (CTG) category associated with the Oil and Natural Gas Industry (EPA-453/B-16-001). We assessed internet sites for California's Department of Conservation Geologic Energy Management Division's (CalGEM) Well Finder, CARB's pollution mapping tool, and the California Energy

Commission's California Natural Gas Pipelines and determined there were no oil and gas operations within EKAPCD's jurisdiction covered by the Oil and Natural Gas CTG.¹

(2) The amended rules for major source oxides of nitrogen (NO_x) were submitted separately on May 23, 2018, and August 22, 2018. These rules and the RACT certification

¹ Technical Support Document for EPA's Clean Air Act Rulemaking for the California State Implementation Plan Eastern Kern County Air Pollution Control District Negative Declaration for Control Techniques Guidelines for the Oil and Natural Gas Industry, dated August 2020 and prepared by Sina Schwenk-Mueller.

for major source NO_x will be addressed in a separate action.

This action addresses the remainder of the 2017 RACT SIP submission. Additional details about the submission and the EPA's separate actions thereon are available in the proposed action (86 FR 47435) and the technical support document (TSD).

No comments were submitted on the proposed action. Therefore, as authorized in section 110(k)(3) of the Act, the EPA is approving the 2017 RACT SIP into the California 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, 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);
- 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 January 3, 2022. 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, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: October 20, 2021.

Deborah Jordan,
Acting Regional Administrator, Region IX.

For the reasons stated in the preamble, the Environmental Protection Agency amends part 52, 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 F—California

■ 2. Section 52.220 is amended by adding paragraph (c)(503)(ii)(A)(2) to read as follows:

§ 52.220 Identification of plan-in part.

* * * * *
(c) * * *
(503) * * *
(ii) * * *
(A) * * *

(2) Reasonable Available Control Technology (RACT) State Implementation Plan (SIP) for the 2008 Ozone National Ambient Air Quality Standards (NAAQS) except the portion addressing the Negative Declaration for the Oil and Natural Gas CTG, as adopted on May 11, 2017.

* * * * *

■ 3. Section 52.222 is amended by revising paragraph (a)(16)(i) to read as follows:

§ 52.222 Negative declarations.

(a) * * *
(16) * * *

(i) The following negative declarations for the 2008 ozone standard were adopted by the District on May 11, 2017 and submitted to the EPA on August 9, 2017:

TABLE 16 TO PARAGRAPH (a)(16)(i)

EPA document No.	Title
EPA-450/2-77-008	Control of Volatile Organic Emissions from Existing Stationary Sources—Volume II: Surface Coating of Cans.

TABLE 16 TO PARAGRAPH (a)(16)(i)—Continued

EPA document No.	Title
EPA-450/2-77-008	Control of Volatile Organic Emissions from Existing Stationary Sources—Volume II: Surface Coating of Coils.
EPA-450/2-77-008	Control of Volatile Organic Emissions from Existing Stationary Sources—Volume II: Surface Coating of Paper.
EPA-450/2-77-008	Control of Volatile Organic Emissions from Existing Stationary Sources—Volume II: Surface Coating of Fabrics.
EPA-450/2-77-008	Control of Volatile Organic Emissions from Existing Stationary Sources—Volume II: Surface Coating of Automobiles, and Light-Duty Trucks.
EPA-450/2-77-025	Control of Refinery Vacuum Producing Systems, Wastewater Separators, and Process Unit Turnarounds.
EPA-450/2-77-026	Control of Hydrocarbons from Tank Truck Gasoline Loading Terminals.
EPA-450/2-77-032	Control of Volatile Organic Emissions from Existing Stationary Sources—Volume III: Surface Coating of Metal Furniture.
EPA-450/2-77-033	Control of Volatile Organic Emissions from Existing Stationary Sources—Volume IV: Surface Coating of Insulation of Magnet Wire.
EPA-450/2-77-034	Control of Volatile Organic Emissions from Existing Stationary Sources—Volume V: Surface Coating of Large Appliances.
EPA-450/2-77-035	Control of Volatile Organic Emissions from Bulk Gasoline Plants.
EPA-450/2-77-036	Control of Volatile Organic Emissions from Storage of Petroleum Liquids in Fixed-Roof Tanks.
EPA-450/2-77-037	Control of Volatile Organic Emissions from Use of Cutback Asphalt.
EPA-450/2-78-029	Control of Volatile Organic Emissions from Manufacture of Synthesized Pharmaceutical Products.
EPA-450/2-78-030	Control of Volatile Organic Emissions from Manufacture of Pneumatic Rubber Tires.
EPA-450/2-78-032	Control of Volatile Organic Emissions from Existing Stationary Sources—Volume VII: Factory Surface Coating of Flat Wood Paneling.
EPA-450/2-78-033	Control of Volatile Organic Emissions from Existing Stationary Sources—Volume VIII: Graphic Arts-Rotogravure and Flexography.
EPA-450/2-78-036	Control of Volatile Organic Compound Leaks from Petroleum Refinery Equipment.
EPA-450/2-78-047	Control of Volatile Organic Emissions from Petroleum Liquid Storage in External Floating Roof Tanks.
EPA-450/3-82-009	Control of Volatile Organic Compound Emissions from Large Petroleum Dry Cleaners.
EPA-450/3-83-006	Control of Volatile Organic Compound Leaks from Synthetic Organic Chemical Polymer and Resin Manufacturing Equipment.
EPA-450/3-83-007	Control of Volatile Organic Compound Equipment Leaks from Natural Gas/Gasoline Processing Plants.
EPA-450/3-83-008	Control of Volatile Organic Compound Emissions from Manufacture of High-Density Polyethylene, Polypropylene, and Polystyrene Resins.
EPA-450/3-84-015	Control of Volatile Organic Compound Emissions from Air Oxidation Processes in Synthetic Organic Chemical Manufacturing Industry.
EPA-450/4-91-031	Control of Volatile Organic Compound Emissions from Reactor Processes and Distillation Operations in Synthetic Organic Chemical Manufacturing Industry.
EPA-453/R-06-001	Control Techniques Guidelines for Industrial Cleaning Solvents.
EPA-453/R-06-002	Control Technology Guidelines for Offset Lithographic Printing and Letterpress Printing.
EPA-453/R-06-003	Control Techniques Guidelines for Flexible Package Printing.
EPA-453/R-06-004	Control Technique Guidelines for Flat Wood Paneling Coatings.
EPA-453/R-07-003	Control Techniques Guidelines for Paper Coatings.
EPA-453/R-07-003	Control Techniques Guidelines for Film Coatings.
EPA-453/R-07-003	Control Techniques Guidelines for Foil Coatings.
EPA-453/R-07-004	Control Techniques Guidelines for Large Appliance Coatings.
EPA-453/R-07-005	Control Techniques Guidelines for Metal Furniture Coatings.
EPA-453/R-08-004	Control Techniques Guidelines for Fiberglass Boat Manufacturing Materials.
EPA-453/R-08-005	Control Techniques Guidelines for Miscellaneous Industrial Adhesives.
EPA-453/R-08-006	Control Techniques Guidelines for Automobile and Light-duty Truck Assembly Coatings.
EPA-453/R-94-032	Alternative Control Technology Document—Surface Coating Operations at Shipbuilding and Ship Repair Facilities and Control Techniques Guidelines for Shipbuilding and Ship Repair Operations (Surface Coating), <i>see the Federal Register of 8/27/96.</i>
EPA-453/B-16-001	Control Techniques Guidelines for the Oil and Natural Gas Industry.

* * * * *

[FR Doc. 2021-23376 Filed 11-3-21; 8:45 am]

BILLING CODE 6560-50-P

**ENVIRONMENTAL PROTECTION
AGENCY****40 CFR Part 52****[EPA-R01-OAR-2021-0381; FRL-8782-02-R1]****Air Plan Approval; Maine; Chapter 100
Definitions and Chapter 113 Growth
Offset Regulations****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 Maine. This revision amends the definition of “Ozone Transport Region” in the State’s Chapter 100 Definitions Regulation and revises language in the State’s Chapter 113 Growth Offset Regulation regarding applicability of Nonattainment New Source Review in areas that, at a future date, may not be within the Ozone Transport Region. The intended effect of this action is to approve the submittal

into the Maine SIP. This action is being taken under the Clean Air Act (CAA).

DATES: This rule is effective on December 6, 2021.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA-R01-OAR-2021-0381. 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.*, 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 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: John Creilson, Air Quality Branch, U.S. Environmental Protection Agency, EPA Region 1, 5 Post Office Square—Suite 100, (Mail code 05-2), Boston, MA 02109, tel. (617) 918-1688, email creilson.john@epa.gov.

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

Table of Contents

- I. Background and Purpose
- II. Response to Comments
- III. Final Action
- IV. Incorporation by Reference
- V. Statutory and Executive Order Reviews

I. Background and Purpose

On July 29, 2021 (86 FR 40793), EPA published a notice of proposed rulemaking (NPRM) for the State of Maine, proposing to approve two SIP revision submitted by the State on February 10 and 24, 2021. The SIP revision proposed to: (1) Amend the definition of “Ozone Transport Region” in their existing Code of Maine Rules (C.M.R.) Chapter 100 Definitions Regulation; and (2) revise language in Sections 1 and 2 of the existing C.M.R. Chapter 113 Growth Offset Regulation regarding applicability of Nonattainment New Source Review

(NNSR) in areas that, at a future date, may not be within the Ozone Transport Region (OTR). The proposed SIP revisions in the NPRM are consistent with the State's pending petition to remove certain portions of the State from the OTR. However, Maine's rule language was structured such that no such changes in the application of NNSR would occur until removal of portions of the State from the OTR was approved by the EPA Administrator. In addition, the NPRM addressed codification issues between the existing SIP and the amended portions of Maine's current regulations submitted as proposed SIP revisions.

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

II. Response to Comments

EPA received one public comment during the comment period. The one comment received supported EPA's proposed action. This comment is included in the docket of this action.

III. Final Action

EPA is approving Maine's February 10 and 24, 2021, SIP revision requests pertaining to its Chapter 113 Growth Offset and Chapter 100 Definitions Regulations, respectively.

IV. Incorporation by Reference

In this rule, EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is finalizing the incorporation by reference of C.M.R. Chapters 100 and 113 described in the amendments to 40 CFR part 52 set forth below. EPA has made, and will continue to make, these documents generally available through <https://www.regulations.gov> and at the EPA Region 1 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information). Therefore, these materials have been approved by EPA for inclusion in the State Implementation Plan, have been incorporated by reference by EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of EPA's approval, and will be incorporated by reference in the next update to the SIP compilation.¹

V. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the

provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided 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);
- 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).

¹ 62 FR 27968 (May 22, 1997).

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 January 3, 2022.

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, Nitrogen dioxide, Nitrogen oxides, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: October 26, 2021.

Deborah Szaro,

Acting Regional Administrator, EPA Region 1.

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

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart U—Maine

■ 2. In § 52.1020(c), amend the table by revising the entries for “Chapter 100” and “Chapter 113” to read as follows:

§ 52.1020 Identification of plan.

* * * * *

(c) * * *

EPA-APPROVED MAINE REGULATIONS

Maine state citation	Title/subject	State effective date	EPA approval date ¹	Explanations
* * * * *	* * * * *	* * * * *	* * * * *	* * * * *
Chapter 100	Definitions	February 9, 2021	November 4, 2021, [Insert Federal Register citation].	Amend the definition of Ozone Transport Region.
* * * * *	* * * * *	* * * * *	* * * * *	* * * * *
Chapter 113	Growth Offset Regulation	January 14, 2019	November 4, 2021, [Insert Federal Register citation].	Revisions to Sections 1 and 2 of the previously approved rule.
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¹ 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.

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[FR Doc. 2021-23798 Filed 11-3-21; 8:45 am]
BILLING CODE 6560-50-P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 2 and 27

[WT Docket No. 19-348; FCC 21-32; FR ID 55583]

Facilitating Shared Use in the 3100–3550 MHz Band

AGENCY: Federal Communications Commission.

ACTION: Final rule; announcement of compliance date.

SUMMARY: In this document, the Commission announces that the Office of Management and Budget has approved the information collection

requirements associated with the rules adopted in the Federal Communications Commission’s *3.45 GHz Second Report and Order*, FCC 21-32, requiring 3.45 GHz Service licensees, as well as incumbent, non-Federal, secondary radiolocation operators, to comply with certain technical rules, coordination practices, and information-sharing requirements designed to ensure the efficient deployment of flexible-use wireless services in the 3.45 GHz band without causing harmful interference to other operations. This document is consistent with the *3.45 GHz Second Report and Order*, FCC 21-32, which states that the Commission will publish a document in the **Federal Register** announcing a compliance date for the new rule sections.

DATES: Compliance with 47 CFR 2.106, 27.14, 27.1603, 27.1605, and 27.1607, published at 86 FR 17920 on April 7, 2021, is required on November 4, 2021.

FOR FURTHER INFORMATION CONTACT:

Joyce Jones, Mobility Division, Wireless Telecommunications Bureau, at (202) 418-1327 or Joyce.Jones@fcc.gov.

SUPPLEMENTARY INFORMATION: This document announces that the Office of Management and Budget (OMB) approved the information collection requirements in 47 CFR 2.106, 27.14, 27.1603, 27.1605, and 27.1607. This rule was adopted in the *3.45 GHz Second Report and Order*, FCC 21-32, published at 86 FR 17920 on April 7, 2021. The Commission publishes this document as an announcement of the compliance date for this new rule. All other rules contained in the *3.45 GHz Second Report and Order* became effective on June 7, 2021, see 86 FR 17920 (April 7, 2021). If you have any comments on the burden estimates listed below, or how the Commission can improve the collections and reduce any burdens caused thereby, please

contact Cathy Williams, Federal Communications Commission, 45 L Street NE, Washington, DC 20554, regarding OMB Control Number 3060–1294. Please include the OMB Control Number in your correspondence. The Commission will also accept your comments via email at PRA@fcc.gov.

To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an email to fcc504@fcc.gov or call the Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (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 final OMB approval on October 19, 2021, for the information collection requirements contained in 47 CFR 2.106, 27.14(w), 27.1603, 27.1605, and 27.1607 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 for the information collection requirements in 47 CFR 2.106, 27.14, 27.1603, 27.1605, and 27.1607 is 3060–1294.

The foregoing 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: 3060–1294.

OMB Approval Date: October 19, 2021.

OMB Expiration Date: October 31, 2024.

Title: FCC Authorization for Radio Service License—3.45 GHz Band Service.

Form Number: N/A.

Respondents: Business or other for-profit entities, state, local, or tribal government, and not for profit institutions.

Number of Respondents and Responses: 56 respondents; 8,201 responses.

Estimated Time per Response: 5–20 hours.

Frequency of Response: Third party disclosure requirement; on occasion reporting requirement and periodic reporting requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory

authority for these collections are contained in 47 U.S.C. 151, 152, 154, 154(i), 155(c), 157, 201, 202, 208, 214, 301, 302a, 303, 307, 308, 309, 310, 311, 314, 316, 319, 324, 331, 332, 333, 336, 534, 535, and 554 of the Communications Act of 1934.

Total Annual Burden: 9,200 hours.

Total Annual Cost: \$10,353,000.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: In general, there is no need for confidentiality with this collection of information. Insofar as confidential information is submitted to the Department of Defense as part of the coordination by 3.45 GHz Service licensees with Federal incumbents, the Department of Defense will ensure that information remains confidential.

Needs and Uses: On March 17, 2021, the Federal Communications Commission (“Commission” or “FCC”) adopted a Second Report and Order, FCC 21–32, GN Docket No. WT–19–348 (Second Report and Order) that establishes rules for flexible-use wireless access to the 100 megahertz in the 3450–3550 MHz (3.45 GHz) band, creating the new 3.45 GHz Service. The rules will create additional capacity for wireless broadband allowing full-power operations across the band in the entire contiguous United States, while also ensuring full protection of incumbent Federal operations remaining in particular locations. As part of this process, the Commission also adopted rules related to the relocation of incumbent non-Federal radiolocation operations, the selection of a third-party reimbursement clearinghouse, and reimbursement of expenses related to such relocation.

Sections 2.016 and 27.1603 require a 3.45 GHz Service licensee whose license area overlaps with a Cooperative Planning Area or Periodic Use Area, as defined in those sections, to coordinate deployments pursuant to those licenses in those areas with relevant Federal agencies. This coordination may take the form of a mutually acceptable operator-to-operator coordination agreement between the licensee and the relevant Federal agency. In the absence of such an agreement, this coordination will include a formal request for access through a Department of Defense online portal, which will include the submission of information related to the technical characteristics of the base stations and associated mobile units to be used in the covered area. It does not require a revision to the FCC Form 601.

Section 27.1605 provides for the selection of a reimbursement clearinghouse and requires non-Federal,

secondary radiolocation operations which are relocating from the 3.45 GHz band to alternate spectrum to clear the band for new flexible-use wireless operations to submit certain information to the clearinghouse in order to ensure their relocation costs are fairly reimbursed. It does not require a revision to the FCC Form 601.

Section 27.1607 requires 3.45 GHz Service licensees to share certain information about their network operations in that band with operators in the adjacent Citizens Broadband Radio Service in order to enable the latter to synchronize their operations to reduce the risk of harmful interference. In response to a request by a Citizens Broadband Radio Service operator, a 3.45 GHz Service licensee must provide information to enable Time Division Duplex synchronization. The exact nature of the information to be provided will be determined by a negotiation between the two entities, conducted on a good faith basis. The 3.45 GHz Service licensee must keep the information current as its network operations change. This does not require a revision to the FCC Form 601.

Section 27.14(w) requires 3.45 GHz Service licensees to provide information on the extent to which they provide service in their license areas. Licensees are required to file two such reports: The first four (4) years after its initial license grant and the second eight (8) years after such grant, unless they failed to meet the first set of performance requirements, in which case the second report is due seven (7) years after the initial grant. These reports are filed alongside the Form 601 and require no revisions to it.

Federal Communications Commission.

Katura Jackson,

Federal Register Liaison Officer.

[FR Doc. 2021–23847 Filed 11–3–21; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 20

[WT Docket No. 20–3; FCC 21–28; FR ID–55565]

Standards for Hearing Aid-Compatible Handsets

AGENCY: Federal Communications Commission.

ACTION: Final rule; announcement of effective date.

SUMMARY: The Federal Communications Commission (Commission) announces that the Office of Management and

Budget (OMB) has approved, for a period of three years, the information collection requirements associated with the amendment of the Commission's rules governing standards for hearing aid-compatible handsets. This document is consistent with the Report and Order, which stated that the Commission would publish a document in the **Federal Register** announcing OMB approval and the effective date of the information collection requirements.

DATES: The rule amendments contained in 47 CFR 20.19(f), (h)(1), and (i), published at 86 FR 23614, May 4, 2021, are effective on November 4, 2021.

FOR FURTHER INFORMATION CONTACT: For additional information contact Cathy Williams, at (202) 418–2918 or via email: Cathy.Williams@fcc.gov.

SUPPLEMENTARY INFORMATION: This document announces that, on October 19, 2021, OMB approved the information collection requirements contained in the Commission's Report and Order, FCC 21–28, published at 86 FR 23614, May 4, 2021. The OMB Control Number is 3060–0999. The Commission publishes this document as an announcement of the effective date of the information collection requirements.

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 October 19, 2021, for the information collection requirements contained in the revisions to § 20.19(f), (h)(1), and (i).

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 Numbers is 3060–0999.

The foregoing 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 No.: 3060–0999.

OMB Approval Date: October 19, 2021.

OMB Expiration Date: October 31, 2024.

Title: Hearing Aid Compatibility Status Report and Section 20.19, Hearing Aid-Compatible Mobile Handsets (Hearing Aid Compatibility Act).

Form Numbers: FCC Form 655 and FCC Form 855.

Respondents: Business or other for-profit entities.

Number of Respondents and Responses: 934 respondents; 934 responses.

Estimated Time per Response: 13.9710921 hours per response (average).

Frequency of Response: On occasion and annual reporting requirements, recordkeeping requirements, and third-party disclosure requirements.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. 151, 154(i), 157, 160, 201, 202, 214, 301, 303, 308, 309(j), 310, and 610 of the Communications Act of 1934, as amended.

Total Annual Burden: 13,049 hours.

Total Annual Cost: No cost.

Needs and Uses: The changes to the information collection concern the Commission's wireless hearing aid compatibility rules as they relate to the obligations of wireless handset manufacturers and wireless service providers to: (1) Label and disclose certain information related to handset packaging; (2) post certain information on their publicly accessible websites; and (3) file annual status reports and certification. No changes were made to the information collection as related to standards development and the approved number of estimated respondents and responses.

The revisions to the information collection were necessitated by a Report and Order in WT Docket No. 20–3, FCC 21–28, adopted on February 16, 2021, published at 86 FR 23614, May 4, 2021. In the Report and Order, the Commission adopted a new technical standard for determining hearing aid compatibility between hearing aids and wireless handsets and made other corresponding and implementation changes. In addition, the Commission revised the information that handset manufacturers and service providers must include on hearing aid-compatible wireless handset package labels and in the related package inserts or user manuals. The Commission revised the labeling rule to streamline the rule and remove outdated requirements. The new rule requires that the package label provide the volume control capabilities of a hearing aid-compatible handset that meets volume control requirements, and it maintains the requirement that a hearing aid-compatible handset's package label state that the handset is hearing aid-compatible. The new rule still requires hearing aid-compatible handsets to list the handset's hearing aid-compatible rating but moves the location in which it is required to be listed from the package label to the

package insert or user manual. The other requirements for package inserts and user manuals have not changed, but the requirements have been reorganized to make them easier to follow. The Commission's labeling revisions continue to allow consumers to access the information that they need to understand the hearing aid compatibility of handsets they are considering for purchase. At the same time, the labeling revisions give handset manufacturers and service providers flexibility in designing package labels and conveying supplemental information.

The Report and Order also revised website posting requirements for handset manufacturers and service providers. The revised rule requires handset manufacturers and service providers to post to their publicly accessible websites the technical standard used to determine hearing aid compatibility in addition to the information that handset manufacturers and service providers are presently required to post. Further, the website posting requirement has been revised to eliminate the requirement that service providers post to their publicly accessible websites the different levels of functionality of the hearing aid-compatible handsets that they offer to the public. This change offsets any burden added by the requirement that service providers post the technical standard used to determine hearing aid compatibility.

Finally, the Report and Order addressed the status reporting and certification requirements for handset manufacturers and service providers. The Report and Order revised the dates that service providers must file their FCC Form 855 certifications and handset manufacturers must file their FCC Form 655 status reports. The forms were due January 15 and July 15 each year, respectfully, and now are due by January 31 and July 31. These changes were made to accommodate Federal holidays at the start of January and July and to make sure the forms contain information for the full preceding 12-month periods. The Commission uses these forms as the principal way to ensure compliance with its wireless hearing aid compatibility requirements. The Commission also revised the forms to reflect the Commission's current hearing aid compatibility *de minimis* provisions and to reflect the Commission's new mailing address.

The changes that the Commission made to the wireless hearing aid compatibility information collection benefit handset manufacturers and service providers by reducing regulatory

burden while continuing to ensure that the Commission can fulfill its statutory obligation to monitor compliance with

its hearing aid compatibility rules and make more complete and accessible information available to consumers.

Federal Communications Commission.
Katura Jackson,
Federal Register Liaison Officer.
[FR Doc. 2021–23845 Filed 11–3–21; 8:45 am]
BILLING CODE 6712–01–P

Proposed Rules

Federal Register

Vol. 86, No. 211

Thursday, November 4, 2021

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

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

9 CFR Part 201

[Doc. No. AMS–FTPP–21–0052]

RIN 0580–AB26

Poultry Grower Ranking Systems; Withdrawal of Proposed Rule

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule; withdrawal.

SUMMARY: The United States Department of Agriculture's (USDA) Agricultural Marketing Service (AMS) is withdrawing a proposed rule published in the **Federal Register** on December 20, 2016. The proposed rule would have identified criteria that the Secretary of Agriculture (Secretary) could consider when determining whether a live poultry dealer's use of a system for ranking poultry growers for settlement purposes is unfair, unjustly discriminatory, or deceptive or gives an undue or unreasonable preference, advantage, prejudice, or disadvantage. Proposed amendments would also have clarified that, absent demonstration of a legitimate business justification, failing to use a poultry grower ranking system in a fair manner after applying the identified criteria is unfair, unjustly discriminatory, or deceptive and a violation of the Packers and Stockyards Act, regardless of whether it harms or is likely to harm competition. The Secretary has determined to withdraw the 2016 proposed rule and develop revised proposals pertaining to poultry grower ranking systems.

DATES: The proposed rule published at 81 FR 92723 on December 20, 2016, is withdrawn as of November 4, 2021.

FOR FURTHER INFORMATION CONTACT: S. Brett Offutt, Chief Legal Officer/Policy Advisor, Packers and Stockyards Division, USDA AMS Fair Trade Practices Program, 1400 Independence Ave. SW, Washington, DC 20250;

Phone: (202) 690–4355; or email: s.brett.offutt@usda.gov.

SUPPLEMENTARY INFORMATION: A proposed rule published at 81 FR 92723 on December 20, 2016, would have identified criteria the Secretary could consider when determining whether a live poultry dealer's use of a poultry grower ranking system for ranking poultry growers for settlement purposes is unfair, unjustly discriminatory, or deceptive or gives an undue or unreasonable preference, advantage, prejudice, or disadvantage. Further, the 2016 proposed rule would have amended regulations under the Packers and Stockyards Act (regulations) to clarify that, absent demonstration of a legitimate business justification, failure to use a poultry grower ranking system in a fair manner after applying the identified criteria is unfair, unjustly discriminatory, or deceptive and a violation of section 202(a) of the Packers and Stockyards Act, 1921, as amended and supplemented (Act), regardless of whether it harms or is likely to harm competition.

The December 2016 proposed rule published by USDA's former Grain Inspection, Packers and Stockyards Administration (GIPSA) was a modification to an earlier GIPSA proposed rule (75 FR 35338; June 22, 2010) that included requirements regarding a live poultry dealer's use of a poultry grower ranking system when determining payment for grower services. The 2010 proposed rule would have required live poultry dealers paying growers on a tournament system to pay growers raising the same type and kind of poultry the same base pay and would have required that growers be settled in groups with other growers with like house types. Upon review of public comments received both in writing and through public meetings held during the comment period in 2010, GIPSA elected not to finalize the 2010 proposed rule, and instead modified the earlier proposal, published the modification in the December 2016 proposed rule, and requested further public comment.

The comment period for the December 2016 proposed rule was originally scheduled to close on February 21, 2017. GIPSA extended the comment period until March 24, 2017 (82 FR 9533; February 7, 2017), consistent with the memorandum of

January 20, 2017, to heads of executive departments and agencies from the Assistant to the President and Chief of Staff entitled "Regulatory Freeze Pending Review." In total, GIPSA received 239 comment submissions on the December 2016 proposed rule. A number of submissions included lists of signatories or multiple copies of identical form letters signed by different individuals.

In November 2017, responsibility for GIPSA activities was transferred to AMS, which now administers the Packers and Stockyards Act and regulations, and which has assumed responsibility for this rulemaking.

Comments submitted on the December 2016 proposed rule, as well as comments submitted in response to a related Packers and Stockyards proposed rule (85 FR 1771; January 13, 2020) and input from the industry, reflected both support for and opposition to the December 2016 proposals.

Comments on the December 2016 rule were submitted by individual poultry growers and processors, associations representing poultry growers and processors, other livestock producers and producer associations, individual consumers and consumer advocacy groups, and other interested entities. Many grower and consumer commenters supported proposals, saying the criteria in proposed § 201.214 offered tools with which poultry growers and family farms could protect themselves from severe economic losses under potentially unfair contract terms. Commenters further suggested adoption of the proposed rule and its grower protections would strengthen rural economies and the U.S. poultry industry's position in the global marketplace. Some commenters said that provisions of the proposed rule would help level the playing field between poultry growers and processors by giving growers greater contracting power. Other commenters said the proposed criteria for evaluating contract terms would ensure farmers can continue to operate with basic protections under the law. A comment from an animal welfare organization supported the proposed rule because they believe its provisions would protect growers who speak out about inhumane practices from retaliation.

Some commenters expected the rule to make changes they would have considered more favorable to growers, such as the abolition of grower ranking systems. According to one commenter, “a tournament system is itself an undue preference in any case where the farmer’s pay is penalized based on input factors that affect farmer performance beyond their control.” Other commenters supported the proposed rule, but asked USDA to provide a codified list of behaviors that in and of themselves would be violations of the Act, including clear examples of actions that may be unfair, discriminatory, or deceptive; a non-exhaustive list of Section 202(a) violations; or provisions clarifying that failing to comply with 9 CFR 201.100 is inherently unfair, unjustly discriminatory, or a deceptive practice. Several commenters also recommended requiring live poultry dealers to disclose critical information regarding acquiring, handling, processing, and quality of poultry to all producers in the tournament if such information is disclosed to one. Commenters suggested this type of information would allow growers to make better-informed decisions about entering into production contracts.

Many commenters, while supportive of the proposed rule generally, opposed inclusion of the criterion (proposed § 201.214(d)) that would have allowed the Secretary of Agriculture to consider whether a live poultry dealer has demonstrated a legitimate business justification for use of a poultry grower ranking system that might otherwise be unfair, unjustly discriminatory, or deceptive; give an undue or unreasonable preference or advantage to any poultry grower; or subject any poultry grower to an undue or unreasonable prejudice or advantage. Commenters asserted that this criterion could offer live poultry dealers a “loophole” through which they could justify actions that otherwise might be considered violations of the Act. These commenters recommended this criterion be eliminated from the proposed rule. Several commenters further speculated that the vagueness of the term “legitimate business justification” could lead to increased litigation and expense as courts attempt to interpret its meaning, and further that every judge or jury could interpret the term differently.

One commenter wrote that the use of the “legitimate business justification” is a recognized “monopoly defense” that is unfounded and misplaced in the proposed rule. According to the commenter, Sections 202(a) and (b) of the Act were designed by Congress to address wrongful and unlawful acts

“not of the anti-trust variety.” The commenter asserted the defense should not be included in the proposed rule because the term “monopoly” does not appear in Sections 202(a) and (b) of the Act, whereas Sections 202(c) through (e) clearly address anti-trust related unlawful practices. The commenter cited examples of “unfair practices” under the Act where proof of competitive injury is not required, such as failure to pay livestock sellers “before the close of the next business day” following livestock purchases (see Sec. 409), or late payments to a poultry grower (see Sec. 410). The commenter argued that the Secretary has no authority to effectively amend the Act by proposing to inject the monopoly defense into the regulations. According to the commenter, such inclusion exceeds the legal authority granted the Secretary under the Act, violates the separation of powers as established by the United States Constitution, defies Congressional intent, and practically guarantees litigation against the Secretary for violation of the Administrative Procedures Act. Further, the commenter claimed that use of the “legitimate business justification” defense would embolden poultry integrators to “wrench away what few rights growers have left.”

A number of poultry grower commenters opposed the December 2016 proposed rule entirely, some saying the rule is simply unnecessary. Others asked that USDA not force changes on the poultry grower ranking system they claimed has worked well for decades. Commenters contended changing the system could eliminate growers’ incentive to maximize efficiency and adopt innovative production practices, and that such changes would unfairly reward mediocre performers who do not invest effort and capital into continuously improving production.

A number of commenters stated that proposed criteria were too vague, citing for example the terms “fair manner” in proposed § 201.210(b)(10), “pattern or practice” in the introductory paragraph of proposed § 201.214, and “sufficient business information” and “informed business decisions” in proposed § 201.214(a). Commenters asked USDA instead to identify specific behaviors that would be considered violations of the Act to eliminate confusion for contracting parties.

Comments from several poultry processors and associations representing poultry and other meat and food processing industries opposed the proposed rule for various economic and legal reasons. A number of commenters

said the rule “ran afoul” of Executive Order 13771¹ regarding regulatory reform in that that GIPSA’s impact analysis predicted administering and litigating the rule would be costly, although GIPSA did not quantify benefits of the rule. Some commenters speculated that actual costs of litigating the rule could be much higher than GIPSA’s estimates because the inclusion of vague regulatory terminology would increase uncertainty for contracting parties and invite further litigation. Commenters asserted the proposed rule was unsound because it was premised on the “fatally flawed” interim final rule titled “Scope of Sections 202(a) and (b) of the Packers and Stockyards Act” (81 FR 92566, December 20, 2016) that was published by GIPSA on the same date as the proposed Poultry Grower Ranking Systems rule. Commenters claimed the “Scope” rule erroneously asserted that claimants do not need to demonstrate injury to competition to establish a violation of Sections 202(a) and (b) of the Act.

A number of commenters said the proposed rule was arbitrary and capricious in that GIPSA failed to provide investigative data or evidence of any actual problems with the current grower ranking systems or of any need for regulatory intervention, basing its proposed actions rather on anecdotal complaints.

A few commenters objected to GIPSA’s use of an example in the rule’s preamble that processors might supply non-comparable inputs to growers. Commenters pointed out that in the rule’s economic impact analysis GIPSA stated it had no evidence processors have done this. Other commenters warned that USDA should not base the proposed criteria on the assumption that processors intentionally provide non-comparable inputs to growers. Those commenters explained it is in the best interest of processors that all their poultry growers receive high quality inputs (animals, feed, veterinary medicines) to ensure a reliable flow of high-quality poultry to plants. For that reason, according to these commenters, processors are unlikely to intentionally target and sabotage their growers, as suggested by other commenters.

Several commenters suggested that GIPSA incorrectly assumed in its impact analysis that growers carry most of the risk related to poultry production. According to commenters, processors

¹ Executive Order 13771—*Reducing Regulation and Controlling Regulatory Costs* (January 30, 2017)—has since been rescinded by Executive Order 13992—*Revocation of Certain Executive Orders Concerning Federal Regulation* (January 20, 2021).

carry a greater proportion of the risk because they supply most of the production inputs. Further, these commenters asserted that vertically integrated processors are in a better position than growers to assume most of the risk because those processors can operate on a more efficient scale than growers.

According to the comment from an association of chicken production and processing companies, GIPSA's regulatory impact analysis projected decreased certainty for regulated entities and increased risk of litigation due to the proposed rule. This commenter suggested the regulation should instead increase certainty for regulated entities and decrease risk of wasteful litigation.

Some commenters maintained that the provisions of the proposed rule would establish an "unprecedented level of government intervention" that would have negative ramifications for the industry and consumers. Others insisted that the rule contradicted the Packers and Stockyards Act's provisions and intent,² exceeded the Congressional mandate of the 2008 Farm Bill,³ and/or conflicted with court precedence with respect to competitive harm.

A comment from a federation of turkey producers opposed the proposed rule. The commenter asserted that the proposed rule failed to recognize important distinctions between broiler chicken and turkey production in matters such as breeder diversity, production cycle length, gender segregation, and farm and facility size. The commenter said proposed requirements intended to address broiler production issues would not always be applicable to turkey production models and could prove to be injurious to the turkey industry. The commenter recommended that USDA rescind the proposed rule and pay significant attention to the effects on turkey production in future rulemaking attempts.

Several commenters, although purportedly responding to the proposed rule, submitted comments that were outside the scope of this particular rulemaking. For example, commenters

offered suggestions about alternative contract production and pay methods the industry could adopt or discussed issues related to cattle production and marketing. Several commenters criticized GIPSA for disregarding public input about systematic abuses suffered by contract poultry growers. According to commenters, such abuses were described by participants in a May 2010 USDA/Department of Justice-sponsored workshop held to better understand industry concerns. Other commenters addressed provisions of the two other rules GIPSA published on December 20, 2016, including the previously mentioned "Scope of Sections 202(a) and (b) of the Packers and Stockyards Act," and the proposed rule titled "Unfair Practices and Undue Preferences in Violation of the Packers and Stockyards Act" (81 FR 92703).

AMS values the input of all commenters. AMS finds that many of the comments on the proposed rule—both supportive and opposed—identified reasonable concerns regarding the proposed regulation's structure and language. These concerns included uncertainties about USDA's method for applying criteria and vague criteria language. AMS recognizes that differences in broiler and turkey production systems need fair consideration. Moreover, the proposed rule may not have adequately addressed information imbalances between contracting parties. In light of these comments, AMS prefers to reexamine regulatory requirements, specific potential violations, general criteria, and recordkeeping aspects, as well as the structure, of a rule regarding poultry production contracts.

Because of the breadth of this reexamination, AMS concludes that this proposed rulemaking is unable to address many of the commenters' concerns without material changes. AMS intends to consider further the issues raised by the commenters, as well as study any developments since publication of the proposed rule. Following those activities, we plan to issue and solicit comments on a new regulatory proposal pertaining to poultry grower ranking systems. Therefore, we are withdrawing the December 2016 proposed rule.

Authority: 7 U.S.C. 181–229c.

Erin Morris,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2021–23945 Filed 11–3–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–0924; Airspace Docket No. 21–ANM–48]

RIN 2120–AA66

Proposed Establishment of Class E airspace; Monticello Airport, UT

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to establish Class E airspace at Monticello Airport, Monticello, UT. The establishment of airspace supports the airport's transition from visual flight rules to instrument flight rule (IFR) operations. This action would ensure the safety and management of IFR operations at the airport.

DATES: Comments must be received on or before December 20, 2021.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590; telephone: 1–800–647–5527, or (202) 366–9826. You must identify FAA Docket No. FAA–2021–0924; Airspace Docket No. 21–ANM–48, at the beginning of your comments. You may also submit comments through the internet at <https://www.regulations.gov>.

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

FOR FURTHER INFORMATION CONTACT:

Matthew Van Der Wal, Federal Aviation Administration, Western Service Center, Operations Support Group, 2200 S 216th Street, Des Moines, WA 98198; telephone (206) 231–3695.

SUPPLEMENTARY INFORMATION:

² Some commenters asserted that the Act protects individual growers from the effects of competitive harm, while other argued that a violation of Section 202(a) or (b) has not occurred unless there is harm to multiple individuals in the market. One commenter argued that the Act provides clear authority to USDA to clarify terms and interpret the Act's intent.

³ Provisions of Title XI of the Food, Conservation, and Energy Act of 2008 (2008 Farm Bill; Pub. L. 110–234) require the Secretary of Agriculture to establish criteria to consider when determining whether the Packers and Stockyards Act has been violated.

Authority for This Rulemaking

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

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Persons wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. FAA-2021-0924; Airspace Docket No. 21-ANM-48". The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at <https://www.regulations.gov>. Recently published rulemaking documents can also be accessed through the FAA's web page at <https://www.faa.gov>.

www.faa.gov/air_traffic/publications/airspace_amendments/.

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Northwest Mountain Regional Office of the Federal Aviation Administration, Air Traffic Organization, Western Service Center, Operations Support Group, 2200 S 216th Street, Des Moines, WA 98198.

Availability and Summary of Documents for Incorporation by Reference

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

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 by establishing Class E airspace extending upward from 700 feet above the surface at Monticello Airport, Monticello, UT. This airspace is designed to contain the new Area Navigation (RNAV) approaches into the airport and the instrument departures from the airport. The airspace supports the airport's transition from visual flight rules to IFR operations.

Class E5 airspace designations are published in paragraphs 6005 of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

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

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial, and unlikely to result in adverse or negative comments. It, therefore: (1) Is not a "significant regulatory action" under

Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, "Environmental Impacts: Policies and Procedures" prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

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

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

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

* * * * *

ANM UT E5 Monticello, UT [New]

Monticello Airport, UT
(Lat. 37°55'57" N, long. 109°20'28" W)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of the airport.

Issued in Des Moines, Washington, on October 28, 2021.

B.G. Chew,

Acting Group Manager, Operations Support Group, Western Service Center.

[FR Doc. 2021–23967 Filed 11–3–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–0925; Airspace Docket No. 21–ANM–49]

RIN 2120–AA66

Proposed Establishment of Class E Airspace; Joseph State Airport, OR

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to establish Class E airspace at Joseph State Airport, Joseph, OR. The establishment of airspace supports the airport's transition from visual flight rules to instrument flight rule (IFR) operations. This action would ensure the safety and management of IFR operations at the airport.

DATES: Comments must be received on or before December 20, 2021.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590; telephone: 1–800–647–5527, or (202) 366–9826. You must identify FAA Docket No. FAA–2021–0925; Airspace Docket No. 21–ANM–49, at the beginning of your comments. You may also submit comments through the internet at <https://www.regulations.gov>.

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

FOR FURTHER INFORMATION CONTACT:

Matthew Van Der Wal, Federal Aviation Administration, Western Service Center, Operations Support Group, 2200 S 216th Street, Des Moines, WA 98198; telephone (206) 231–3695.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

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

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Persons wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. FAA–2021–0925; Airspace Docket No. 21–ANM–49". The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at <https://www.regulations.gov>. Recently published rulemaking documents can also be accessed through the FAA's web page at https://www.faa.gov/air_traffic/publications/airspace_amendments/.

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Northwest Mountain Regional Office of the Federal Aviation Administration, Air Traffic Organization, Western Service Center, Operations Support Group, 2200 S 216th Street, Des Moines, WA 98198.

Availability and Summary of Documents for Incorporation by Reference

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

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 by establishing Class E airspace extending upward from 700 feet above the surface at Joseph State Airport, Joseph, OR. This airspace is designed to contain the new Area Navigation (RNAV) approach into the airport and the instrument departure from the airport. The airspace supports the airport's transition from visual flight rules to IFR operations.

Class E5 airspace designations are published in paragraphs 6005 of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

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

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established

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

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, "Environmental Impacts: Policies and Procedures" prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

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

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

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

* * * * *

ANM OR E5 Joseph, OR [New]

Joseph State Airport, OR

(Lat. 45°21'34" N, long. 117°15'14" W)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of the airport beginning at the 316°

bearing from the airport clockwise to the 170° bearing from the airport, then to the point of beginning 6.5 miles northwest of the airport.

Issued in Des Moines, Washington, on October 28, 2021.

B.G. Chew,

Acting Group Manager, Operations Support Group, Western Service Center.

[FR Doc. 2021–23952 Filed 11–3–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–0938; Airspace Docket No. 21–ASW–18]

RIN 2120–AA66

Proposed Establishment of Class E Airspace; Dewitt, AR

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to establish Class E airspace extending upward from 700 feet above the surface for Dewitt Municipal Airport/Whitcomb Field, Dewitt, AR, to accommodate area navigation (RNAV) global positioning system (GPS) standard instrument approach procedures (SIAPs) serving this airport. Controlled airspace is necessary for the safety and management of instrument flight rules (IFR) operations in the area.

DATES: Comments must be received on or before December 20, 2021.

ADDRESSES: Send comments on this proposal to: The U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001; Telephone: (800) 647–5527, or (202) 366–9826. You must identify the Docket No. FAA–2021–0938; Airspace Docket No. 21–ASW–18, at the beginning of your comments. You may also submit comments through the internet at <https://www.regulations.gov>.

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

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

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

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would establish Class E airspace for Dewitt Municipal Airport/Whitcomb Field, Dewitt, AR.

Comments Invited

Interested persons are invited to comment on this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (Docket No. FAA–2021–0938 and Airspace Docket No. 21–ASW–18) and be submitted in triplicate to DOT Docket Operations (see the **ADDRESSES** section for the address and phone number). You may also submit comments through the internet at <https://www.regulations.gov>.

Persons wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed stamped postcard on which the following statement is made: "Comments to FAA Docket No. FAA–2021–0938; Airspace Docket No. 21–ASW–18". The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this document may be changed in light of the comments received. All comments submitted will be available for examination in the public docket both before and after the comment closing date. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at <https://www.regulations.gov>. Recently published rulemaking documents can also be accessed through the FAA's web page at https://www.faa.gov/air_traffic/publications/airspace_amendments/.

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined between 8:00 a.m. and 4:30 p.m., Monday through Friday, except federal holidays, at the office of the Eastern Service Center, Federal Aviation Administration, Room 350, 1701 Columbia Avenue, College Park, GA 30337.

Availability and Summary of Documents for Incorporation by Reference

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

The Proposal

The FAA proposes an amendment to 14 CFR part 71 to establish Class E airspace extending upward from 700 feet above the surface within a 6.4-mile radius of Dewitt Municipal Airport/Whitcomb Field, Dewitt, AR. This proposed amendment provides the controlled airspace required to support RNAV (GPS) standard instrument approach procedures for IFR operations at this airport.

Class E airspace designations are published in Paragraph 6005 of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in the FAA Order JO 7400.11.

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

Regulatory Notices and Analyses

The FAA has determined that this proposed 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. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, "Environmental Impacts: Policies and Procedures" prior to any FAA final regulatory action.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

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

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

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

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

§ 71.1 [Amended]

- 2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation

Administration Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

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

* * * * *

ASW AR E5 Dewitt, AR [Established]

Dewitt Municipal Airport/Whitcomb Field, AR

(Lat. 34°15'44" W" N, long. 91°18'27" W)

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of Dewitt Municipal Airport/Whitcomb Field.

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

Andree C. Davis,

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

[FR Doc. 2021–23966 Filed 11–3–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–837]

Schedules of Controlled Substances: Removal of [18F]FP-CIT From Control

AGENCY: Drug Enforcement Administration, Department of Justice.
ACTION: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration proposes to remove [18F]FP-CIT (chemical names: [18F]N-ω-fluoropropyl-β-CIT; fluorine-18-N-3-fluoropropyl-2-beta-carbomethoxy-3-beta-(4-iodophenyl)tropane; [18F]fluoropropylcarbomethoxy nortropane) from the schedules of the Controlled Substances Act (CSA). This scheduling action is pursuant to the CSA which requires that such actions be made on the record after opportunity for a hearing through formal rulemaking. [18F]FP-CIT is currently a schedule II controlled substance because it can be derived from cocaine, a schedule II substance, via ecgonine, also a schedule II substance. This action would remove the regulatory controls and administrative, civil, and criminal sanctions applicable to controlled substances, including those specific to schedule II controlled substances, on persons who handle (manufacture, distribute, reverse distribute, dispense, conduct research, import, export, or

conduct chemical analysis) or propose to handle [¹⁸F]FP-CIT.

DATES: Interested persons may file written comments on this proposal in accordance with 21 CFR 1308.43(g). Electronic comments must be submitted, and written comments must be postmarked, on or before December 6, 2021. 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 participation pursuant to 21 CFR 1308.44 and in accordance with 21 CFR 1316.45, 1316.47, 1316.48, or 1316.49, as applicable. Requests for hearing, notices of appearance, and waivers of an opportunity for a hearing or to participate in a hearing must be received on or before December 6, 2021.

ADDRESSES: To ensure proper handling of comments, please reference “Docket No. DEA-837” on all correspondence, including any attachments.

- **Electronic comments:** DEA encourages that all comments be submitted through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or to 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 electronic submissions are not necessary and are discouraged. Should you wish to mail a paper comment *in lieu of* an electronic format, 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.

FOR FURTHER INFORMATION CONTACT: Terrence L. Boos, Drug & Chemical Evaluation Section, Diversion Control

Division, Drug Enforcement Administration; 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 and confidential business information identified, as directed above, will generally be made publicly available in redacted form. If a comment has so much confidential business information or personal identifying 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. DEA specifically solicits written comments regarding DEA’s economic analysis of the impact of these proposed changes. DEA requests that commenters provide detailed descriptions in their

comments of any expected economic impacts, especially to small entities. Commenters should provide empirical data to illustrate the nature and scope of such impact.

Request for Hearing, Notice of Appearance at or Waiver of Participation in 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, and 21 CFR part 1316 subpart D. In accordance with 21 CFR 1308.44 (a)–(c), requests for hearing, notices of appearance, and waivers of an opportunity for a hearing or to participate in a hearing may be submitted by interested persons. Such requests or notices must conform to the requirements of 21 CFR 1308.44(a) or (b), and 1316.47 or 1316.48, as applicable, and include a statement of the interest of the person 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 1316.49, including a written statement regarding the interested person’s position on the matters of fact and law involved in any hearing.

Please note that, pursuant to 21 U.S.C. 811(a)(2), the purpose of a hearing would be to determine whether [¹⁸F]FP-CIT should be removed from the list of controlled substances based on a finding that the drug does not meet the requirements for inclusion in any schedule. All requests for hearing and waivers of participation must be sent to DEA using the address information above, on or before the date specified 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

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, March 8, 1985. The Secretary of HHS has delegated to the Assistant Secretary for Health of HHS the authority to make

of any interested party. 21 U.S.C. 811(a). This action was initiated by a petition to remove [¹⁸F]FP-CIT from the list of scheduled controlled substances of the CSA, and is supported by, *inter alia*, a recommendation from the Assistant Secretary for Health of HHS and an evaluation of all relevant data by DEA. If finalized, this action would remove the regulatory controls and administrative, civil, and criminal sanctions applicable to controlled substances, including those specific to schedule II controlled substances, on persons who handle or propose to handle [¹⁸F]FP-CIT.

Background

[¹⁸F]FP-CIT (chemical names: [¹⁸F]N-ω-fluoropropyl-β-CIT; fluorine-18-N-3-fluoropropyl-2-beta-carbomethoxy-3-beta-(4-iodophenyl)tropane; [¹⁸F]fluoropropylcarbomethoxy nortropane) is described as a diagnostic substance that is used in assisting the evaluation of adult patients with suspected Parkinsonian syndromes. It is an entity used in the visualization of striatal dopamine transporters (DAT) using positron emission tomography (PET) imaging. [¹⁸F]FP-CIT is not yet approved by the United States Food and Drug Administration (FDA) and no New Drug Application (NDA) for [¹⁸F]FP-CIT or any [¹⁸F]FP-CIT-containing drug has been submitted to FDA.

[¹⁸F]FP-CIT is structurally similar to [¹²³I]ioflupane, known as DaTscan or [¹²³I]FP-CIT. Both [¹⁸F]FP-CIT and [¹²³I]ioflupane were developed as clinical diagnostic substances to visualize DAT and contain the same tracer amount of the precursor, ecgonine. The only difference between these two compounds is the radiotracer (¹²³I versus ¹⁸F). On January 14, 2011, FDA approved the NDA for [¹²³I]ioflupane-containing drug product, DaTscan, for use to visualize striatal DAT in the brains of adult patients with suspected Parkinsonian syndromes using single photon emission computed tomography (SPECT) imaging. DEA removed [¹²³I]ioflupane from schedule II of the CSA on September 11, 2015 (80 FR 54715).

The starting material for the synthesis of [¹⁸F]FP-CIT and [¹²³I]ioflupane is N-nor-β-CIT (2β-carbomethoxy-3β-(4-iodophenyl) nortropane), which is derived from cocaine, a schedule II substance, via ecgonine (a schedule II substance). Thus, by definition [¹⁸F]FP-CIT is a schedule II controlled substance under the CSA. On June 28, 2018, DEA received a petition from Advanced

Imaging Projects to initiate proceedings to amend 21 CFR 1308.12(b)(4) so as to decontrol [¹⁸F]FP-CIT (proposed tradename Fluoroseek) from schedule II of the CSA. On October 6, 2018 and November 6, 2018, DEA received supplemental information from the Petitioner; DEA accepted the petition on November 28, 2018.

Proposed Determination To Decontrol [¹⁸F]FP-CIT

Pursuant to 21 U.S.C. 811(b), on May 2, 2019, DEA, having gathered the necessary data on [¹⁸F]FP-CIT, forwarded that data and the petition to HHS with a request for scientific and medical evaluation and scheduling recommendation for [¹⁸F]FP-CIT. On April 16, 2021, DEA received from HHS a scientific and medical evaluation conducted by FDA entitled “Basis for the recommendation to remove [¹⁸F]FP-CIT from schedule II of the Controlled Substances Act” and a scheduling recommendation. The National Institute on Drug Abuse (NIDA) concurred with the scientific and medical evaluation conducted by FDA. Based on the totality of the available scientific data, [¹⁸F]FP-CIT does not conform with the findings for schedule II in 21 U.S.C. 812(b)(2) or in any other schedule as set forth in 21 U.S.C. 812(b). Based on FDA’s scientific and medical review of the eight factors and findings related to the substance’s abuse potential, legitimate medical use, and dependence liability, HHS recommended that [¹⁸F]FP-CIT be removed from all schedules of the CSA.

The CSA requires DEA, as delegated by the Attorney General,² to determine whether HHS’s scientific and medical evaluation, scheduling recommendation, and all other relevant data constitute substantial evidence that a substance should be scheduled. 21 U.S.C. 811(b). DEA reviewed the scientific and medical evaluation and scheduling recommendation provided by HHS, and all other relevant data, and completed its own eight-factor review document on [¹⁸F]FP-CIT 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 this proposal to remove [¹⁸F]FP-CIT from the schedules of the CSA. Both DEA and HHS analyses are available in their entirety under “Supporting and Related Material” of the public docket for this rule at <http://www.regulations.gov> under docket number DEA-837.

1. The Drug’s Actual or Relative Potential for Abuse

The first factor that must be considered is the actual or relative potential for abuse of [¹⁸F]FP-CIT. The term “abuse” is not defined in the CSA. However, the legislative history of the CSA suggests the following points in determining whether a particular drug or substance has a potential for abuse:³

a. Whether 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.

According to HHS’s scientific and medical evaluation, there are no data demonstrating that individuals are taking either [¹⁸F]FP-CIT or [¹²³I]ioflupane in amounts sufficient to create a hazard to their health or to the safety of other individuals or to the community. Additionally, as reported in the [¹²³I]ioflupane HHS review, no case reports or clinical trials were published in scientific or medical literature that describe any incidents of drug abuse, misuse, or diversion of [¹²³I]ioflupane.

HHS notes that in their assessment of the abuse potential of [¹²³I]ioflupane from studies conducted in animals, it was estimated that doses of the radiolabeled FP-CIT in the milligram range would be needed to elicit stimulant effects. Since the active pharmaceutical ingredient (API) is the same, the same calculations apply to [¹⁸F]FP-CIT. HHS further states that upon receiving prescriptions from physicians [¹⁸F]FP-CIT will be manufactured immediately prior to its shipment and its limited availability will make its abuse logistically not possible.

b. Whether there is significant diversion of the drug or drugs containing such a substance from legitimate drug channels.

There has been no demonstrated diversion of [¹²³I]ioflupane or [¹⁸F]FP-CIT. According to DEA’s forensic laboratory databases, the National Forensic Laboratory Information System (NFLIS),⁴ there are no cases of [¹²³I]ioflupane or [¹⁸F]FP-CIT (queried May 27, 2021). Further, according to data assessed for [¹²³I]ioflupane, it is highly unlikely that [¹⁸F]FP-CIT or [¹⁸F]FP-CIT-containing products will be diverted in the United States. In the

³ Comprehensive Drug Abuse Prevention and Control Act of 1970, H.R. Rep. No. 91-1444, 91st Cong., Sess. 1 (1970); 1970 U.S.C.C.A.N. 4566, 4603.

⁴ NFLIS is 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.

domestic drug scheduling recommendations. 58 FR 35460, July 1, 1993.

² 28 CFR 0.100(b).

United States, the Nuclear Regulatory Commission (NRC), the Occupational Safety and Health Administration, the Environmental Protection Agency, the Department of Transportation, and state legislation regulate the production, handling, transportation, and disposal of radiopharmaceuticals, all of which limit the trade to licensed radiopharmacies with a valid prescription.⁵ [¹⁸F]FP-CIT and any [¹⁸F]FP-CIT-containing products will be subject to oversight by such agencies.

HHS notes that with the manufacturing limits and current restrictions regarding distribution, handling and disposal will limit the potential for diversion of [¹⁸F]FP-CIT from legitimate drug channels.

c. Whether 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.

There has been no demonstrated diversion of [¹⁸F]FP-CIT nor published case reports or epidemiological data indicating that individuals are using [¹⁸F]FP-CIT-containing products on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such substances. Due to the radioactive properties, [¹⁸F]FP-CIT will not be administered by the patient or be available for self-administration by patients.

d. Whether the drug or drugs containing such a substance are new drugs so related in their action to a substance already listed as having a potential for abuse to make it likely that it 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 they have a substantial capability of creating hazards to the health of the user or to the safety of the community.

As noted above, [¹⁸F]FP-CIT is chemically and pharmacologically similar to [¹²³I]ioflupane. A formulation containing [¹⁸F]FP-CIT, similar to [¹²³I]ioflupane, that is intended for diagnostic purposes, would contain the API in amounts too low than what is feasible for eliciting a central nervous system (CNS) stimulant

pharmacological effect. It is estimated that milligram quantities would have to be administered to elicit a stimulant effect. Due to the manufacturing limitations and expected low concentrations of [¹⁸F]FP-CIT in an approved product, the volume of [¹⁸F]FP-CIT-containing product that would need to be administered to achieve a psychoactive effect for abuse is not logistically possible.

2. Scientific Evidence of the Drug's Pharmacological Effects, if Known

Preclinical Studies

According to HHS scientific review of [¹²³I]ioflupane, non-radiolabeled FP-CIT acts on the CNS by blocking monoamine transporters, including DAT and other monoamine transporters (e.g., serotonin) and is mechanistically similar to cocaine (a schedule II substance). FP-CIT's affinity for DAT is between 10- and 100-fold greater than cocaine's affinity for DAT and appears to be more potent than cocaine in some behavioral assessments. HHS states that this mechanism of action suggests, like [¹²³I]ioflupane, [¹⁸F]FP-CIT may potentially have abuse potential if the dose taken is high enough and if the deterrent effect of the extremely low concentration of the available radioligand is not considered.

Drug discrimination assays in animals can be used to predict if a test drug will have abuse potential in humans. According to HHS, in a drug discrimination study, administration of non-radiolabeled FP-CIT at doses >0.1 mg/kg (i.v.) resulted in cocaine-appropriate responses in rats trained to discriminate cocaine (10 mg/kg, i.p.) from saline. Thus, non-radiolabeled FP-CIT may produce cocaine-like subjective effects.

HHS's review also noted that the administration of non-radiolabeled FP-CIT resulted in an increase of locomotor activity in rodents relative to vehicle, but produced a lower maximum level and was less potent compared to cocaine (schedule II substance), however the locomotor effects induced by FP-CIT lasted longer than cocaine.

Human Studies

HHS notes that when [¹⁸F]FP-CIT was administered at doses used in diagnostic tests there was no clinical evidence of stimulant effects.

3. The State of Current Scientific Knowledge Regarding the Drug or Other Substance

The international non-proprietary name of [¹⁸F]FP-CIT is methyl (1R,2S,3S,5S)-8-[3-(fluoro-¹⁸F)propyl]-3-

(4-iodophenyl)-8-azabicyclo[3.2.1]octane-2-carboxylate. The molecular formula of [¹⁸F]FP-CIT is C₁₈H₂₃[¹⁸F]INO₂ and the molecular weight is 431.28 g/mol.

The petitioner states that their expected [¹⁸F]FP-CIT-containing product (Fluoroseek) exists only as a clear, colorless to slightly yellow liquid solution in ethanol and saline solution (sodium chloride 0.9% in water) and contains antioxidants such as gentisic acid and sodium ascorbate, with sodium carbonate as a pH modifier. The general chemical properties of [¹⁸F]FP-CIT are inferred from the chemical properties of the non-radioactive FP-CIT substance. FP-CIT is a white solid with a melting point of 83 °C to 87 °C and soluble in water (less than 0.1 mg/ml), sodium acetate buffer (pH 7.4; 16 mg/ml), and ethanol (27 mg/ml).

As noted by HHS, there are no currently marketed [¹⁸F]FP-CIT-containing products available. However, in a letter dated January 8, 2020, the Petitioner sent a response to DEA on a request for information regarding the composition of the product and the expected doses patients will receive. In this communication, the Petitioner states that the synthesized product “. . . contains 40 micrograms (μg) of [¹⁸F] Fluoroseek per 29 milliliters (mL). Each patient will receive 0.3–3.0 mL of the solution.” Thus, based on the concentration (40 μg/29 mL) of the product, as indicated by the Petitioner, and the amount of the [¹⁸F]FP-CIT solution that the Petitioner estimates patients will receive (0.3–3.0 mL), the doses a patient may receive will be in the range of 0.41 μg to 4.13 μg.

For [¹²³I]ioflupane, HHS mentions that the meaningful extraction of [¹²³I]ioflupane from the marketed drug product, DaTscan, would be impossible due to its limited production and availability and it is technically complex and would require advanced equipment not available to the general public.

Medical Use

According to HHS, as of April 2021, the petitioner has yet to submit an NDA for the [¹⁸F]FP-CIT-containing drug product (Fluoroseek). It is expected that, similar to [¹²³I]ioflupane, [¹⁸F]FP-CIT will be used as a diagnostic agent, potentially in conjunction with PET imaging, whereas [¹²³I]ioflupane is used in SPECT imaging.

4. Its History and Current Pattern of Abuse

There have been no reports of abuse of [¹⁸F]FP-CIT or [¹²³I]ioflupane at the doses used for diagnostic purposes.

⁵ For radioactive substances there are controls other than those imposed by the CSA and its implementing regulations, including regulations by the NRC under 10 CFR part 35 and/or by states, which limit the public's exposure to radioactivity in radiopharmaceuticals, thus limiting the potential for toxicity imposed on the public.

Similar to [¹²³I]ioflupane, [¹⁸F]FP-CIT was developed for diagnostic purposes and contains a small amount of the API. The amount of [¹⁸F]FP-CIT in each vial of [¹⁸F]FP-CIT would be limited and it is produced based on demand. Additional regulations and control mechanisms by the NRC and other federal agencies exist for the production, handling and use of [¹⁸F]FP-CIT due to its radioactivity.

5. The Scope, Duration, and Significance of Abuse

DEA has searched the scientific literature and the Federal, State, and local forensic laboratory databases such as NFLIS to assess the scope of [¹⁸F]FP-CIT abuse in the United States. There were no reports of [¹⁸F]FP-CIT seizures during the period of January 2010–April 2021.

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

The risk to public health is unknown for [¹⁸F]FP-CIT. However, as stated by HHS the radioactive nature of the substance, limited amounts of substance needed for imaging purposes, and the existence of stringent regulatory controls on the manufacturing and handling, [¹⁸F]FP-CIT poses little or no practical risk to public health. Because the API for [¹⁸F]FP-CIT is the same as [¹²³I]ioflupane, [¹⁸F]FP-CIT is expected to have the same product characteristics.

7. Its Psychic or Physiological Dependence Liability

HHS reports that no systemic evaluation has been conducted to determine whether [¹²³I]ioflupane or [¹⁸F]FP-CIT produces psychic or physiological dependence in animals or humans. It is expected that the use of the radiolabeled agents (*i.e.*, [¹²³I]ioflupane and [¹⁸F]FP-CIT) will not produce psychic or physiological dependence due to the low dose and short-term exposure.

8. Whether the Substance Is an Immediate Precursor of a Substance Already Controlled Under the CSA

Similar to [¹²³I]ioflupane, [¹⁸F]FP-CIT is not an immediate precursor of a substance already controlled under the CSA.

Conclusion

Based on consideration of the scientific and medical evaluation and accompanying recommendation of HHS, and based on DEA's consideration of its own eight-factor analysis, DEA finds that these facts and all relevant data demonstrate that [¹⁸F]FP-CIT does not

possess abuse or dependence potential. According to HHS, no NDA containing [¹⁸F]FP-CIT has been submitted. However, the finding that [¹⁸F]FP-CIT lacks abuse potential would, irrespective of other findings, permit decontrol of [¹⁸F]FP-CIT prior to or in the absence of an FDA action under 21 U.S.C. 355(c). Accordingly, DEA finds that [¹⁸F]FP-CIT does not meet the requirements for inclusion in any schedule, and should be removed from control under the CSA.

Regulatory Analyses

Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review)

In accordance with 21 U.S.C. 811(a), this scheduling action is subject to formal rulemaking procedures done “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 removing a drug or other substance from the list of controlled substances. Such actions are exempt from review by Office of Management and Budget pursuant to section 3(d)(1) of Executive Order (E.O.) 12866 and the principles reaffirmed in E.O. 13563.

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 Civil Justice Reform 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 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 relationship between the Federal 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. This proposed rule 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 Administrator, in accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612), 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. The purpose of this proposed rule is to remove [¹⁸F]FP-CIT from the list of schedules of the CSA. This action will remove regulatory controls and administrative, civil, and criminal sanctions applicable to controlled substances for handlers and proposed handlers of [¹⁸F]FP-CIT. Accordingly, it has the potential for some economic impact in the form of cost savings.

If finalized, the proposed rule will affect all persons who would handle, or propose to handle [¹⁸F]FP-CIT. [¹⁸F]FP-CIT is not currently available or marketed in any country. Due to the wide variety of unidentifiable and unquantifiable variables that potentially could influence the distribution and dispensing rates, if any, of [¹⁸F]FP-CIT, DEA is unable to determine the number of entities and small entities which might handle [¹⁸F]FP-CIT. In some instances where a controlled pharmaceutical drug is removed from the schedules of the CSA, DEA is able to quantify the estimated number of affected entities and small entities because the handling of the drug is expected to be limited to DEA registrants even after removal from the schedules. In such instances, DEA's knowledge of its registrant population forms the basis for estimating the number of affected entities and small entities. However, DEA does not have a basis to estimate whether [¹⁸F]FP-CIT is expected to be handled by persons who hold DEA registrations, by persons who are not currently registered with DEA to handle controlled substances, or both. Therefore, DEA is unable to estimate the number of entities and small entities who plan to handle [¹⁸F]FP-CIT.

Although DEA does not have a reliable basis to estimate the number of affected entities and quantify the economic impact of this proposed rule, a qualitative analysis indicates that this rule is likely to result in some cost savings. As noted above, DEA is specifically soliciting comments on the economic impact of this proposed rule. DEA will revise this section if warranted after consideration of any comments received. Any person planning to handle [¹⁸F]FP-CIT will realize cost savings in the form of saved DEA registration fees, and the elimination of physical security, recordkeeping, and reporting requirements.

Because of these factors, DEA projects that this proposed rule will not result in a significant economic impact 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 that this action would not result “in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 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 requirement under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521

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, 21 CFR part 1308 is proposed to be amended to read 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 § 1308.12, revise paragraphs (b)(4)(i) through (iii) to read as follows:

§ 1308.12 Schedule II.

- * * * * *
- (b) * * *
- (4)(i) Decocainized coca leaves or extraction of coca leaves, which extractions do not contain cocaine or ecgonine;
- (ii) [¹²³I]ioflupane; or
- (iii) [¹⁸F]FP-CIT.
- * * * * *

Anne Milgram,
Administrator.

[FR Doc. 2021–23852 Filed 11–3–21; 8:45 am]

BILLING CODE 4410–09–P

Notices

Federal Register

Vol. 86, No. 211

Thursday, November 4, 2021

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

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request; Correction

November 1, 2021.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding: Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by December 6, 2021 will be considered. Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it

displays a currently valid OMB control number.

National Agricultural Statistics Service

Title: Local Food Marketing Practices Survey.

OMB Control Number: 0535–0259.

Summary of Collection: The Department of Agriculture published a document in the **Federal Register** on October 29, 2021, Volume 86, page 59976 concerning a request for comments on the Information Collection “Local Food Marketing Practices Survey” OMB control number 0535–0259. This FRN was a duplicate for this collection that was published on October 15, 2021, Volume 86, page 57407. We are requesting that the duplicate FRN published on October 29, 2021, Volume 86, page 59976 be withdrawn from the **Federal Register**.

Levi S. Harrell,

Departmental Information Collection Clearance Officer.

[FR Doc. 2021–24086 Filed 11–3–21; 8:45 am]

BILLING CODE 3410–20–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–70–2021]

Foreign-Trade Zone (FTZ) 82—Mobile, Alabama; Notification of Proposed Production Activity; Aker Solutions, Inc. (Subsea Oil and Gas Systems); Mobile, Alabama

Aker Solutions, Inc. (Aker) submitted a notification of proposed production activity to the FTZ Board (the Board) for its facility in Mobile, Alabama within City FTZ 82. The notification conforming to the requirements of the Board's regulations (15 CFR 400.22) was received on October 28, 2021.

Pursuant to 15 CFR 400.14(b), FTZ production activity would be limited to the specific foreign-status material/component described in the submitted notification (summarized below) and subsequently authorized by the Board. The benefits that may stem from conducting production activity under FTZ procedures are explained in the background section of the Board's website—accessible via www.trade.gov/ftz. The proposed material/component would be added to the production authority that the Board previously

approved for the operation, as reflected on the Board's website.

The proposed foreign-status material/component is super duplex steel rods (duty rate is duty-free). The request indicates that the material/component is subject to duties under Section 232 of the Trade Expansion Act of 1962 (Section 232) and Section 301 of the Trade Act of 1974 (Section 301), depending on the country of origin. The applicable Section 232 and Section 301 decisions require subject merchandise to be admitted to FTZs in privileged foreign status (19 CFR 146.41).

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary and sent to: ftz@trade.gov. The closing period for their receipt is December 14, 2021.

A copy of the notification will be available for public inspection in the “Online FTZ Information System” section of the Board's website.

For further information, contact Juanita Chen at juanita.chen@trade.gov.

Dated: October 29, 2021.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2021–24043 Filed 11–3–21; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–69–2021]

Proposed Foreign-Trade Zone—Smith County, Texas; Under Alternative Site Framework

An application has been submitted to the Foreign-Trade Zones (FTZ) Board by the Tyler Economic Development Council to establish a foreign-trade zone in Smith County, Texas, under the alternative site framework (ASF) adopted by the FTZ Board (15 CFR 400.2(c)). The ASF is an option for grantees for the establishment or reorganization of zones and can permit significantly greater flexibility in the designation of new “subzones” or “usage-driven” FTZ sites for operators/users located within a grantee's “service area” in the context of the FTZ Board's standard 2,000-acre activation limit for a zone project. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as

amended (19 U.S.C. 81a–81u), and the regulations of the Board (15 CFR part 400). It was formally docketed on October 28, 2021. The applicant is authorized to make the proposal under Texas Business and Commerce Code, Title 15, Chapter 681, Foreign-Trade Zones.

The proposed zone would be the fourth zone for the Shreveport-Bossier City CBP port of entry. The existing zones are as follows: FTZ 145, Shreveport, Louisiana (Grantee: Caddo-Bossier Parishes Port Commission, Board Order 370, January 7, 1988); FTZ 234, Gregg County, Texas (Grantee: Gregg County, Texas, Board Order 1003, November 4, 1998); and, FTZ 258, Bowie County, Texas (Grantee: TexAmericas Center, Board Order 1287, October 9, 2003).

The applicant's proposed service area under the ASF would be a portion of Smith County, as described in the application. If approved, the applicant would be able to serve sites throughout the service area based on companies' needs for FTZ designation. The application indicates that the proposed service area is adjacent to the Shreveport-Bossier City Customs and Border Protection port of entry.

The application indicates a need for zone services within a portion of Smith County, Texas. Several firms have indicated an interest in using zone procedures for warehousing/distribution activities for a variety of products. Specific production approvals are not being sought at this time. Such requests would be made to the FTZ Board on a case-by-case basis.

In accordance with the FTZ Board's regulations, Camille Evans and Christopher Wedderburn of the FTZ Staff are designated examiners to evaluate and analyze the facts and information presented in the application and case record and to report findings and recommendations to the FTZ Board.

Public comment is invited from interested parties. Submissions shall be addressed to the FTZ Board's Executive Secretary and sent to: ftz@trade.gov. The closing period for their receipt is January 3, 2022. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to January 18, 2022.

A copy of the application will be available for public inspection in the "Online FTZ Information Section" section of the FTZ Board's website, which is accessible via www.trade.gov/ftz.

For further information, contact Camille Evans and Christopher Wedderburn at Camille.Evans@trade.gov

trade.gov and Chris.Wedderburn@trade.gov.

Dated: October 29, 2021.

Andrew McGilvray,
Executive Secretary.

[FR Doc. 2021–24044 Filed 11–3–21; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–533–877]

Stainless Steel Flanges From India: Preliminary Results of Antidumping Duty Administrative Review, Preliminary Successor-in-Interest Determination, and Partial Rescission; 2019–2020

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily finds that certain producers/exporters of stainless steel flanges (flanges) from India made sales of subject merchandise in the United States at prices below normal value (NV) during the period of review (POR), October 1, 2019, through September 30, 2020. We preliminarily find that BFN Forgings Private Limited (BFN Forgings) is the successor-in-interest to Bebitz Flanges Works Private Limited (Bebitz Flanges). Finally, we are rescinding this review with respect to 38 companies. We invite interested parties to comment on these preliminary results.

DATES: Applicable November 4, 2021.

FOR FURTHER INFORMATION CONTACT: Benito Ballesteros or Christopher Maciuba, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4725 or (202) 482–0413, respectively.

SUPPLEMENTARY INFORMATION:

Background

On December 8, 2020, Commerce initiated an administrative review of the antidumping duty order on flanges from India, in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act).¹ This administrative review covers 19 companies,² including the

¹ See *Initiation of Antidumping and Countervailing Duty Administrative Reviews*, 85 FR 78990 (December 8, 2020) (*Initiation Notice*).

² Although we initiated a review of the companies "Jay Jagdamba Limited" and "Jay Jagdamba Ltd.," we are treating these companies as the same entity for purposes of this segment of the proceeding. See

mandatory respondents Chandan Steel Limited (Chandan) and Kisaan Die Tech Private Limited (KDT).³ On June 24, 2021, we extended the deadline for the preliminary results until October 29, 2021.⁴ For details regarding the events that occurred subsequent to the initiation of this review, see the Preliminary Decision Memorandum.⁵ A list of topics included in the Preliminary Decision Memorandum is included as an appendix to this notice. The Preliminary Decision Memorandum is a public document and is made available to the public via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at <http://access.trade.gov>. In addition, a complete version of the Preliminary Decision Memorandum is available at <https://access.trade.gov/public/FRNoticesListLayout.aspx>.

Scope of the Order

The merchandise covered by the Order is stainless steel flanges from India.⁶ For a full description of the scope, see the Preliminary Decision Memorandum.

Preliminary Successor-in-Interest Determination

BFN Forgings reported that, during the POR, it changed its name from "Bebitz Flanges Works Private Limited" to "BFN Forgings Private Limited." Based on our analysis of the information on the record regarding any changes with respect to corporate structure, manufacturing facilities, customers, and suppliers, we preliminarily determine that BFN Forgings is the successor-in-interest to Bebitz Flanges, and, as a result, should be accorded the same treatment previously accorded to Bebitz Flanges. For further discussion, see the Preliminary Decision Memorandum at "Preliminary Successor-In-Interest Determination."

Initiation Notice. Additionally, we preliminarily find BFN Forgings to be the successor-in-interest to Bebitz Flanges. For further discussion, see the section "Preliminary Successor-in-Interest Determination" below.

³ We referred to this company in the *Initiation Notice* as "Kisaan Die Tech." The company's full name is Kisaan Die Tech Private Limited.

⁴ See Memorandum, "Stainless Steel Flanges from India: Extension of Deadline for Preliminary Results of Antidumping Duty Administrative Review, 2019–2020," dated June 24, 2021.

⁵ See Memorandum, "Decision Memorandum for the Preliminary Results of the Antidumping Duty Administrative Review of Stainless Steel Flanges from India: 2019–2020," dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

⁶ See *Stainless Steel Flanges from India: Antidumping Duty Order*, 83 FR 50639 (October 9, 2018) (*Order*).

Partial Rescission of Administrative Review

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if a party who requested the review withdraws the request within 90 days of the date of the date of publication of notice of initiation of the requested review. On March 8, 2021, the Coalition of American Flange Producers (the petitioner) timely withdrew its request for an administrative review for 38 companies. No other party requested a review of these companies. For a complete list of the companies for which we are rescinding this review, see Appendix II. Accordingly, we are rescinding this review with respect to these companies, pursuant to 19 CFR 351.213(d)(1).

Rate for Non-Selected Companies

The Act and Commerce's regulations do not address the 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 less-than-fair value (LTFV) 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}." We preliminarily calculated a 5.78 percent dumping margin for Chandan and a 1.18 percent dumping margin for KDT, the mandatory respondents in this review, and we have assigned to the non-selected companies a rate of 5.28 percent, which is the weighted-average of Chandan's and KDT's margins based on publicly ranged data.⁷ For additional

information, see the Preliminary Decision Memorandum at "Rates for Non-Selected Companies."

Methodology

Commerce is conducting this review in accordance with section 751(a)(1) and (2) of the Act. We calculated export price and constructed export price in accordance with section 772 of the Act. We calculated NV in accordance with section 773 of the Act. For a full description of the methodology underlying these preliminary results, see the Preliminary Decision Memorandum.

Preliminary Results of Review

We preliminarily determine the following weighted-average dumping margins exist for the period October 1, 2019, through September 30, 2020:

Exporter/producer	Weighted-average dumping margin (percent)
Chandan Steel Limited	5.78
Kisaan Die Tech Private Limited	1.18
Companies Not Individually Examined ⁸	5.28

Assessment Rates

Upon completion of the final results of this administrative review, Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries.

Pursuant to 19 CFR 351.212(b)(1), because the individually-examined respondents reported the entered value for their U.S. sales, we will calculate importer-specific *ad valorem* antidumping duty assessment rates based on the ratio of the total amount of antidumping duties calculated for the examined sales to the total entered value of those same sales. Where either the respondent's weighted-average dumping margin is zero or *de minimis* within the meaning of 19 CFR 351.106(c), or an importer-specific rate is zero or *de minimis*, we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.

In accordance with Commerce's "automatic assessment" practice, for entries of subject merchandise during the POR produced by each respondent for which the company did not know

that the merchandise was destined for the United States, we will instruct CBP to liquidate those entries at the all-others rate established in the original LTFV investigation (*i.e.*, 7.00 percent)⁹ if there is no rate for the intermediate company(ies) involved in the transaction.¹⁰

For the companies which were not selected for individual review, we intend to assign an assessment rate based on the review-specific average rate, calculated as noted in the "Preliminary Results of Review" section, above. The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by this review and for future deposits of estimated duties, where applicable.¹¹

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.*, within 90 days of publication).

Cash Deposit Requirements

The following cash deposit requirements will be effective 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 the companies under review will be equal to the weighted-average dumping margin established in the final results of this review, except if the rate is *de minimis* within the meaning of 19 CFR 351.106(c)(1) (*i.e.*, less than 0.50 percent), in which case the cash deposit rate will be zero; (2) for previously reviewed or investigated companies not in this review, 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 examined; (3) if the exporter is not a firm covered in this review, a prior review, or the original

⁷ See, e.g., *Xanthan Gum from the People's Republic of China: Preliminary Results of the Antidumping Duty Administrative Review, and Partial Rescission*; 2018–2019, 85 FR 75686, 74687 (November 23, 2020), unchanged in *Xanthan Gum from the People's Republic of China: Final Results of Antidumping Duty Administrative Review*; 2018–2019, 86 FR 16189 (March 26, 2021); *Albemarle Corp. v. United States*, 821 F. 3d 1345 (Fed. Cir. 2016); and *Emulsion Styrene-Butadiene Rubber from the Republic of Korea: Preliminary Results of the Administrative Review of the Antidumping Duty Order*; 2018–2019, 85 FR 39534 (July 1, 2020), unchanged in *Emulsion Styrene-Butadiene Rubber*

From the Republic of Korea: Final Results of the Administrative Review of the Antidumping Duty Order; 2018–2019, 85 FR 67512 (October 23, 2020); see also Memorandum, "Preliminary Results of the Antidumping Duty Administrative Review of Stainless Steel Flanges from India: Calculation of Margin for Respondents Not Selected for Individual Examination," dated October 29, 2021.

⁸ See Appendix III for a full list of companies not individually examined in this review.

⁹ See *Stainless Steel Flanges from India: Notice of Court Decision Not in Harmony with the Final Determination of Antidumping Investigation; Notice of Amended Final Determination*, 86 FR 50325 (September 8, 2021) (*Amended Final*).

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 section 751(a)(2)(C) of the Act.

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 merchandise; and (4) the cash deposit rate for all other producers or exporters will continue to be 7.00 percent,¹² the all-others rate established in the amended final determination of the LTFV investigation. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Disclosure and Public Comment

We intend to disclose the calculations performed to parties within five days after public announcement of the preliminary results.¹³ Pursuant to 19 CFR 351.309(c), interested parties may submit case briefs no later than 30 days after the date of publication of this notice. Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than seven days after the date for filing case briefs.¹⁴ Parties who submit case briefs or rebuttal briefs in this proceeding are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.¹⁵ Case and rebuttal briefs should be filed using ACCESS¹⁶ and must be served on interested parties.¹⁷ Executive summaries should be limited to five pages total, including footnotes. Note that Commerce has modified certain of its requirements for serving documents containing business proprietary information until further notice.¹⁸

Interested parties who wish to request a hearing must do so within 30 days of publication of these preliminary results by submitting a written request to the Assistant Secretary for Enforcement and Compliance using Enforcement and Compliance's ACCESS system.¹⁹ 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. Issues raised in the hearing will be limited to those raised in the respective case and rebuttal briefs.²⁰ Parties are reminded

that all briefs and hearing requests must be filed electronically using ACCESS and received successfully in their entirety by 5:00 p.m. Eastern Time on the due date.

Final Results of Review

Unless otherwise extended, Commerce intends to issue the final results of this administrative review, including the results of its analysis of the issues raised in any written briefs, not later than 120 days after the date of publication of this notice, pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(1).

Notification to Importers

This notice also serves as a 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 doubled antidumping duties.

Notification to Interested Parties

This administrative review and notice are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.213 and 351.221(b)(4).

Dated: October 29, 2021.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Preliminary Decision Memorandum

- I. Summary
- II. Background
- III. Scope of the Order
- IV. Preliminary Successor-In-Interest Determination
- V. Partial Rescission of Review
- VI. Rate for Non-Selected Companies
- VII. Discussion of the Methodology
- VIII. Recommendation

Appendix II

Companies for Which the Review Request Was Withdrawn and for Which Commerce Is Rescinding This Review

1. Arien Global
2. Armstrong International Pvt. Ltd.
3. Avini Metal Limited
4. Bee Gee Enterprises
5. Bsl Freight Solutions Pvt., Ltd.
6. CD Industries (Prop. Kisaan Engineering Works Pvt. Ltd.)
7. Cipriani Harrison Valves Pvt. Ltd.
8. CTL Logistics (India) Pvt. Ltd.

9. Echjay Forgings Pvt. Ltd.
10. Fivebros Forgings Pvt. Ltd.
11. Fluid Controls Pvt. Ltd.
12. Geodis Oversea Pvt., Ltd.
13. Globelink WW India Pvt., Ltd.
14. Good Luck Engineering Co.
15. Goodluck India Ltd.
16. Hilton Metal Forging Limited
17. Kunj Forgings Pvt. Ltd.
18. Montane Shipping Pvt., Ltd.
19. Noble Shipping Pvt. Ltd.
20. Paramount Forge
21. Pashupati Ispat Pvt. Ltd.
22. Pashupati Tradex Pvt., Ltd.
23. Peekay Steel Castings Pvt. Ltd.
24. Pradeep Metals Ltd.
25. R D Forge Pvt., Ltd.
26. Rolex Fittings India Pvt. Ltd.
27. Rollwell Forge Pvt. Ltd.
28. Safewater Lines (I) Pvt. Ltd.
29. Saini Flange Pvt. Ltd.
30. SAR Transport Systems
31. Shilpan Steelcast Pvt. Ltd.
32. Teamglobal Logistics Pvt. Ltd.
33. Technical Products Corporation
34. Technocraft Industries India Ltd.
35. Transworld Global Logistics Solutions (India) Pvt. Ltd.
36. VEEYES Engineering Pvt. Ltd.
37. Vishal Shipping Agencies Pvt. Ltd.
38. Yusen Logistics (India) Pvt. Ltd.

Appendix III

List of Companies Not Selected for Individual Examination

- Ae Engineers & Exporters
Balkrishna Steel Forge Pvt. Ltd.
BFN Forgings Private Limited (former name Bebitz Flanges Works Private Limited)²¹
Broadway Overseas Ltd.
Dongguan Good Luck Furniture Industrial Co., Ltd.
DSV Air and Sea Pvt. Ltd.
DSV Logistics
G.I. Auto Pvt. Ltd.
Jai Auto Pvt. Ltd.
Jay Jagdamba Forgings Private Limited
Jay Jagdamba Limited²²
Jay Jagdamba Profile Private Limited
Katariya Steel Distributors
Lotus CNC Components
Motor Aids
Shree Jay Jagdamba Flanges Private Limited
Transworld Enterprises
Transworld Group
Viraj Profiles Ltd.

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¹² See *Amended Final*, 86 FR at 50326.

¹³ See 19 CFR 351.224(b).

¹⁴ See 19 CFR 351.309(c)(1)(ii) and 351.309(d)(1); see also *Temporary Rule Modifying AD/CVD Service Requirements Due to COVID-19; Extension of Effective Period*, 85 FR 41363 (July 10, 2020) (*Temporary Rule*).

¹⁵ See 19 CFR 351.309(c)(2) and (d)(2).

¹⁶ See generally 19 CFR 351.303.

¹⁷ See 19 CFR 351.303(f).

¹⁸ See *Temporary Rule*.

¹⁹ See 19 CFR 351.310(c).

²⁰ See 19 CFR 351.310.

²¹ We preliminary find BFN Forgings Private Limited to be the successor-in-interest to Bebitz Flanges Works Private Limited.

²² We also initiated a review of this company under the name "Jay Jagdamba Ltd." We are treating these companies as the same entity for purposes of this segment of the proceeding.

DEPARTMENT OF COMMERCE

International Trade Administration

[C-533-878]

Stainless Steel Flanges From India: Preliminary Results of Countervailing Duty Administrative Review; 2019

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 stainless steel flanges from India during the period of review, January 1, 2019, through December 31, 2019. Interested parties are invited to comment on these preliminary results.

DATES: Applicable November 4, 2021.

FOR FURTHER INFORMATION CONTACT: Rachel Greenberg or Eliza Siordia, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482-1110 or (202) 482-3878, respectively.

SUPPLEMENTARY INFORMATION:**Background**

On December 8, 2020, Commerce published a notice of initiation of an administrative review of the countervailing duty order on stainless steel flanges from India.¹ On June 2, 2021, Commerce extended the time period for issuing these preliminary results by 118 days, in accordance with section 751(a)(3)(A) of the Tariff Act of 1930, as amended (the Act).² The revised deadline for these preliminary results is now October 29, 2021.

For a complete description of the events that followed the initiation of this review, *see* the Preliminary Decision Memorandum.³ A list of topics discussed in the Preliminary Decision Memorandum is included at the appendix 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>. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at <https://access.trade.gov/public/FRNoticesListLayout.aspx>.

Scope of the Order

The merchandise covered by the Order are stainless steel flanges from India. For a complete description of the scope of the Order, *see* the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this review in accordance with section 751(a)(1)(A) of the Act. For each of the subsidy programs found countervailable, we preliminarily determine that there is a subsidy, *i.e.*, a financial contribution that gives rise to a benefit to the recipient, and the subsidy is specific.⁴ For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum.

Companies Not Selected for Individual Review

The Act and Commerce's regulations do not directly address the subsidy rate to be applied to companies not selected for individual examination where Commerce limits its examination in an administrative review pursuant to section 777A(e)(2) of the Act. However, Commerce normally determines the rates for non-selected companies in reviews in a manner that is consistent with section 705(c)(5) of the Act, which provides instructions for calculating the all-others rate in an investigation. Section 777A(e)(2) of the Act provides that "the individual countervailable subsidy rates determined under subparagraph (A) shall be used to determine the all-others rate under section 705(c)(5) {of the Act}." Section 705(c)(5)(A) of the Act states that for companies not investigated, in general, we will determine an all-others rate by weight-averaging the countervailable subsidy rates established for each of the companies individually investigated, excluding zero and *de minimis* rates or any rates based solely on the facts available.

Accordingly, to determine the rate for companies not selected for individual examination, Commerce's practice is to

weight average the net subsidy rates for the selected mandatory companies, excluding rates that are zero, *de minimis*, or based entirely on facts available.⁵ We preliminarily determine that Chandan Steel Limited (Chandan) and Kisaan Die Tech Pvt Ltd. (Kisaan) received countervailing subsidies that are above *de minimis* and are not based entirely on facts available. Therefore, we preliminarily determine to apply the weighted-average of the net subsidy rates calculated for Chandan and Kisaan using publicly-ranged sales data submitted by those respondents to the non-selected companies.⁶ For a list of the 54 companies for which a review was requested, and which were not selected as mandatory respondents or found to be cross-owned with a mandatory respondent, *see* Appendix II to this notice.

Preliminary Results of Review

For the period January 1, 2019, through December 31, 2019, we preliminarily find that the following net subsidy rates exist:

Company	Subsidy rate (percent <i>ad valorem</i>)
Chandan Steel Limited	5.51
Kisaan Die Tech Pvt. Ltd.	5.28
Non-Selected Companies Under Review ⁷	5.49

Assessment Rate

Consistent with section 751(a)(2)(C) of the Act, upon issuance of the final results, Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, countervailing duties on all appropriate entries in accordance with the final results of this review. If the assessment rate calculated in the final results in zero or *de minimis*, we will instruct CBP to liquidate all appropriate entries without regard to countervailing duties. Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.*, within 90 days of publication).

⁵ *See, e.g., Certain Pasta from Italy: Final Results of the 13th (2008) Countervailing Duty Administrative Review*, 75 FR 37386, 37387 (June 29, 2010).

⁶ *See* Memorandum, "Calculation of Subsidy Rate for Non-Selected Companies Under Review," dated October 29, 2021.

⁷ *See* Appendix II for a list of companies not selected for individual examination.

¹ *See Initiation and Countervailing Duty Administrative Reviews*, 85 FR 78990 (December 8, 2020); *see also Stainless Steel Flanges from India: Countervailing Duty Order*, 83 FR 50336 (October 5, 2018) (Order).

² *See* Memorandum, "Stainless Steel Flanges from India: Extension of Deadline for Preliminary Results of Countervailing Duty Administrative Review, 2019," dated June 2, 2021.

³ *See* Memorandum, "Decision Memorandum for the Preliminary Results of Countervailing Duty Administrative Review: Stainless Steel Flanges from India; 2019," dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

⁴ *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.

Cash Deposit Requirements

Pursuant to section 751(a)(2)(C) of the Act, Commerce intends to instruct CBP to collect cash deposits of estimated countervailing duties in the amounts indicated above, except, where the rate calculated in the final results is *de minimis*, no cash deposit will be required on shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this review. For all non-reviewed firms, we will instruct CBP to continue to collect cash deposits of estimated countervailing duties at the most recent company-specific or all-others rate applicable to the company, as appropriate. These cash deposit instructions, when imposed, shall remain in effect until further notice.

Disclosure and Public Comment

We will disclose to parties to this proceeding the calculations performed in reaching the preliminary results within five days of the date of publication of these preliminary results.⁸ Pursuant to 19 CFR 351.309(c), interested parties may submit case briefs no later than 30 days after the date of publication of this notice. Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than seven days after the date for filing case briefs.⁹ Parties who submit case briefs or rebuttal briefs in this proceeding are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.¹⁰ Case and rebuttal briefs should be filed using ACCESS¹¹ and must be served on interested parties.¹² Executive summaries should be limited to five pages total, including footnotes. Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information, until further notice.¹³

Interested parties who wish to request a hearing must do so within 30 days of publication of these preliminary results by submitting a written request to the Assistant Secretary for Enforcement and Compliance using Enforcement and Compliance's ACCESS system.¹⁴

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. Issues raised in the hearing will be limited to those raised in the respective case and rebuttal briefs.¹⁵ If a request for a hearing is made, Commerce intends to hold the hearing at a time and date to be determined. Parties should confirm the date and time of the hearing two days before the scheduled date. Parties are reminded that all briefs and hearing requests must be filed electronically using ACCESS and received successfully in their entirety by 5:00 p.m. Eastern Time on the due date.

Final Results of Review

Unless the deadline is extended pursuant to section 751(a)(3)(A) of the Act, Commerce intends to issue the final results of this administrative review, including the results of our analysis of the issues raised by the parties in their comments, within 120 days after publication of these preliminary results.

Notification to Interested Parties

This administrative review and notice are in issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.213.

Dated: October 29, 2021.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Preliminary Decision Memorandum

- I. Summary
- II. Background
- III. Scope of the Order
- IV. Period of Review
- V. Rate for Non-Examined Companies
- VI. Subsidies Valuation Information
- VII. Benchmarks and Discount Rates
- VIII. Analysis of Programs
- IX. Recommendation

Appendix II

List of Non-Selected Companies

Arien Global
Arien Metals Private Limited
Armstrong International Pvt. Ltd.
Avini Metal Limited
Balkrishna Steel Forge Pvt. Ltd.
Bebitz Flanges Works Pvt. Ltd.
Bee Gee Enterprises
BFN Forgings Private Limited
Bsl Freight Solutions Pvt., Ltd.
CD Industries (Prop. Kisaan Engineering Works Pvt. Ltd.).
Cipriani Harrison Valves Pvt. Ltd.
CTL Logistics (India) Pvt. Ltd.

Dongguan Good Luck Furniture Industrial Co., Ltd.
DSV Air and Sea Pvt. Ltd.
DSV Logistics
Echjay Forgings Pvt. Ltd.
Fivebros Forgings Pvt. Ltd.
Fluid Controls Pvt. Ltd.
Geodis Oversea Pvt., Ltd.
Globelink WW India Pvt., Ltd.
Good Luck Engineering Co.
Goodluck India Ltd.
Hilton Metal Forging Limited
Jai Auto Pvt. Ltd.
Jay Jagdamba Limited
Jay Jagdamba Profile Private Limited
Jay Jagdamba Forgings Private Limited
Katariya Steel Distributors
Kunj Forgings Pvt. Ltd.
Montane Shipping Pvt., Ltd.
Noble Shipping Pvt. Ltd.
Paramount Forge
Pashupati Ispat Pvt. Ltd.
Pashupati Tradex Pvt., Ltd.
Peekay Steel Castings Pvt. Ltd.
Pradeep Metals Ltd.
R D Forge Pvt., Ltd.
Rolex Fittings India Pvt. Ltd.
Rollwell Forge Pvt. Ltd.
Safewater Lines (I) Pvt. Ltd.
Saini Flange Pvt. Ltd.
SAR Transport Systems
Shilpan Steelcast Pvt. Ltd.
Shree Jay Jagdamba Flanges Private Limited
Teamglobal Logistics Pvt. Ltd.
Technical Products
Technical Products Corporation
Technocraft Industries India Ltd.
Transworld Enterprises
Transworld Global Logistics Solutions (India) Pvt. Ltd.
Transworld Group
VEEYES Engineering Pvt. Ltd.
Viraj Profiles Ltd.
Vishal Shipping Agencies Pvt. Ltd.
Yusen Logistics (India) Pvt. Ltd.

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DEPARTMENT OF COMMERCE

International Trade Administration

U.S. Department of Commerce Trade Finance Advisory Council

AGENCY: International Trade Administration, U.S. Department of Commerce.

ACTION: Notice of an open meeting.

SUMMARY: The U.S. Department of Commerce Trade Finance Advisory Council (TFAC or the Council) will hold a virtual meeting on Thursday, December 2, 2021. The meeting is open to the public with registration instructions provided below.

DATES: Thursday, December 2, 2021, from approximately 1:00 p.m. to 3:00 p.m. Eastern Standard Time (EST). The deadline for members of the public to register, including requests to make comments during the meeting and for

⁸ See 19 CFR 351.224(b).

⁹ See 19 CFR 351.309(c)(1)(ii) and 351.309(d)(1); see also *Temporary Rule Modifying AD/CVD Service Requirements Due to COVID-19; Extension of Effective Period*, 85 FR 41363 (July 10, 2020) (*Temporary Rule*).

¹⁰ See 19 CFR 351.309(c)(2) and (d)(2).

¹¹ See generally 19 CFR 351.303.

¹² See 19 CFR 351.303(f).

¹³ See *Temporary Rule*.

¹⁴ See 19 CFR 351.310(c).

¹⁵ See 19 CFR 351.310.

auxiliary aids, or to submit written comments for dissemination prior to the meeting, is 5:00 p.m. EST on Monday, November 29, 2021. Registration, comments, and any auxiliary aid requests should be submitted via email to Patrick.Zimet@trade.gov.

ADDRESSES: The meeting will be held virtually via WebEx video conferencing.

FOR FURTHER INFORMATION CONTACT: Patrick Zimet, Designated Federal Officer, Office of Finance and Insurance Industries (OFII), International Trade Administration, U.S. Department of Commerce at (202) 306-9474; email: Patrick.Zimet@trade.gov.

SUPPLEMENTARY INFORMATION:

Background

The TFAC was originally chartered on August 11, 2016, pursuant to discretionary authority and in accordance with the Federal Advisory Committee Act, as amended, 5 U.S.C. App., and was most recently re-chartered on August 7, 2020. The TFAC serves as the principal advisory body to the Secretary of Commerce on policy matters relating to access to trade finance for U.S. exporters, including small- and medium-sized enterprises, and their foreign buyers. The TFAC is the sole mechanism by which the Department of Commerce (the Department) convenes private sector stakeholders to identify and develop consensus-based solutions to trade finance challenges. The Council is comprised of a diverse group of stakeholders from the trade finance industry and the U.S. exporting community, as well as experts from academia and public policy organizations.

On Thursday, December 2, 2021, the TFAC will hold the second meeting of its 2020–2022 charter term. During the meeting, members will discuss initial recommendations put forth by the TFAC's four subcommittees: Inclusive Growth, International Policy, Fintech, and Supply Chain Finance. The TFAC will deliberate over the proposed recommendations, provide feedback to the subcommittees, and establish next steps in order to finalize the recommendations by the end of the TFAC's third term.

Meeting minutes will be available within 90 days of the meeting upon request or on the TFAC's website at <https://www.trade.gov/about-us/trade-finance-advisory-council-tfac>.

Public Participation

The meeting will be open to the public and there will be limited time permitted for public comments.

Members of the public seeking to attend the meeting, make comments during the meeting, request auxiliary aids, or submit written comments for consideration prior to the meeting, are required to submit their requests electronically to Patrick.Zimet@trade.gov by 5:00 p.m. EST on Monday, November 29, 2021. Requests received after this deadline will be accepted but may not be possible to accommodate.

Members of the public may submit written comments concerning TFAC affairs at any time before or after a meeting. Comments may be submitted to Patrick Zimet, at the contact information indicated above. All comments and statements received, including attachments and other supporting materials, are part of the public record and subject to public disclosure.

Heather Helm,

Acting Executive Director for Services, Office of the Deputy Assistant Secretary for Services.
[FR Doc. 2021-24093 Filed 11-3-21; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[C-580-884]

Certain Hot-Rolled Steel Flat Products From the Republic of Korea: Preliminary Results of Countervailing Duty Administrative Review and Rescission in Part; 2019

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that certain producers/exporters of certain hot-rolled steel flat products (hot-rolled steel) from the Republic of Korea (Korea) received countervailable subsidies during the period of review (POR) January 1, 2019, through December 31, 2019. Additionally, we are rescinding this review with respect to 13 companies. We invite interested parties to comment on these preliminary results.

DATES: Applicable November 4, 2021.

FOR FURTHER INFORMATION CONTACT: Kelsie Hohenberger, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482-2517.

SUPPLEMENTARY INFORMATION:

Background

On December 8, 2020, Commerce published a notice of initiation of an administrative review of the countervailing duty (CVD) order on hot-rolled steel from Korea.¹ On January 12, 2021, Commerce selected Hyundai Steel as the mandatory respondent in this administrative review.² On June 16, 2021, Commerce extended the deadline for the preliminary results of this review.³ The revised deadline for these preliminary results is now October 29, 2021.

For a complete description of the events that followed the initiation of this review, see the Preliminary Decision Memorandum.⁴ A list of topics discussed in the Preliminary Decision Memorandum is included at Appendix I 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>. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at <https://access.trade.gov/public/FRNoticesListLayout.aspx>.

Scope of the Order

The product covered by the Order is hot-rolled steel from Korea. For a complete description of the scope of the Order, see the Preliminary Decision Memorandum.

Rescission of Administrative Review, in Part

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if the parties that requested a review withdraw the request within 90

¹ See *Initiation of Antidumping and Countervailing Duty Administrative Reviews*, 85 FR 78990 (December 8, 2020); see also *Certain Hot-Rolled Steel Flat Products from Brazil and the Republic of Korea: Amended Final Affirmative Countervailing Duty Determinations and Countervailing Duty Orders*, 81 FR 67960 (October 3, 2016) (Order).

² See Memorandum, "Administrative Review of the Countervailing Duty Order of Certain Hot-Rolled Steel Flat Products from the Republic of Korea: Respondent Selection," dated January 12, 2021.

³ See Memorandum, "Certain Hot-Rolled Steel Flat Products from the Republic of Korea: Extension of Deadline for Preliminary Results of Countervailing Duty Administrative Review," dated June 16, 2021.

⁴ See Memorandum, "Decision Memorandum for the Preliminary Results of the Countervailing Duty Administrative Review, 2019: Certain Hot-Rolled Steel Flat Products from the Republic of Korea," dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

days of the date of publication of the notice of initiation. Commerce received a timely-filed withdrawal request from the petitioners,⁵ pursuant to 19 CFR 351.213(d)(1). Because the withdrawal request was timely filed, and no other party requested a review of these companies, in accordance with 19 CFR 351.213(d)(1), Commerce is rescinding this review with respect to the following companies: DCE Inc.; Dong Chuel America Inc.; Dong Chuel Industrial Co., Ltd.; Dongbu Incheon Steel Co., Ltd.; Dongbu Steel Co., Ltd.; Dongkuk Industries Co., Ltd.; Dongkuk Steel Mill Co., Ltd.; Hyewon Sni Corporation (H.S.I.); JFE Shoji Trade Korea Ltd.; POSCO Coated & Color Steel Co., Ltd.; POSCO Daewoo Corporation; Soon Hong Trading Co., Ltd.; and Sung-A Steel Co., Ltd.

Methodology

Commerce is conducting this review in accordance with section 751(a)(1)(A) of the Tariff Act of 1930, as amended (the Act). For each of the subsidy programs found countervailable, we preliminarily determine that there is a subsidy, *i.e.*, a government-provided financial contribution that gives rise to a benefit to the recipient, and that the subsidy is specific.⁶ For a full description of the methodology underlying all of Commerce's conclusions, see the Preliminary Decision Memorandum.

Preliminary Rate for Non-Selected Company Under Review

There is one company in this review that was not selected as a mandatory respondent, *i.e.*, POSCO. The Act and Commerce's regulations do not directly address the rates to be applied to companies not selected for individual examination where Commerce limits its examination in an administrative review pursuant to section 777A(e)(2) of the Act. However, Commerce normally determines the rates for non-selected companies in reviews in a manner that is consistent with section 705(c)(5) of the Act, which provides instructions for calculating the all-others rate in an investigation.

Section 705(c)(5)(A)(i) of the Act instructs Commerce, as a general rule, to calculate an all-others rate equal to the weighted average of the countervailable subsidy rates established for exporters

and/or producers individually examined, excluding any rates that are zero, *de minimis*, or based entirely on facts available. Commerce is, accordingly, basing the subsidy rate for POSCO on the rate calculated for Hyundai Steel.

Preliminary Results of Administrative Review

We preliminarily determine the following net countervailable subsidy rates for the period January 1, 2019, through December 31, 2019:

Company	Subsidy rate (percent <i>ad valorem</i>)
Hyundai Steel Co., Ltd.	0.56
POSCO	0.56

Disclosure and Public Comment

We will disclose to the parties in this proceeding the calculations performed in reaching the preliminary results within five days of the date of publication of these preliminary results.⁷ Case briefs, or other written comments, may be submitted to the Assistant Secretary for Enforcement and Compliance at a date to be determined. Rebuttal comments (rebuttal briefs), limited to issues raised in case briefs, may be filed within seven days⁸ after the time limit for filing case briefs. Parties who submit arguments are requested to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.⁹ All briefs must be filed electronically using ACCESS. Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information under further notice.¹⁰

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS by 5 p.m. Eastern Time within 30 days after the date of publication of this notice.¹¹ Hearing requests should contain: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) a list of the issues to be discussed. Issues addressed at the hearing will be limited to those raised in the briefs. If a request for a hearing is made, Commerce intends to

hold the hearing at a time and date to be determined. Parties should confirm the date and time of the hearing two days before the scheduled date. Parties are reminded that all briefs and hearing requests must be filed electronically using ACCESS and received successfully in their entirety by 5:00 p.m. Eastern Time on the due date.

Assessment Rate

Pursuant to section 751(a)(2)(C) of the Act, upon issuance of the final results, Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, countervailing duties on all appropriate entries of subject merchandise in accordance with the final results of this review. If the assessment rate calculated in the final results in zero or *de minimis*, we will instruct CBP to liquidate all appropriate entries without regard to countervailing duties. Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.*, within 90 days of publication).

Cash Deposit Requirements

In accordance with section 751(a)(2)(C) of the Act, Commerce intends to instruct CBP to collect cash deposits of estimated countervailing duties in the amounts shown for the companies listed above, except, where the rate calculated in the final results is *de minimis*, no cash deposit will be required on shipments of the subject merchandise entered or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this review. For all non-reviewed firms, we will instruct CBP to continue to collect cash deposits of estimated countervailing duties at the most recent company-specific or all-others rate applicable to the company, as appropriate. These cash deposits, when imposed, shall remain in effect until further notice.

Final Results of Review

Commerce intends to issue the final results of this administrative review, including the results of our analysis of the issues raised by the parties in their comments, no later than 120 days after the date of publication of this notice, pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(1), unless this deadline is extended.

⁵ The petitioners are AK Steel Corporation, ArcelorMittal USA LLC, Nucor Corporation (Nucor), SSAB Enterprises, LLC, Steel Dynamics, Inc., and United States Steel Corporation.

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.

⁷ See 19 CFR 351.224(b).

⁸ See *Temporary Rule Modifying AD/CVD Service Requirements Due to COVID-19; Extension of Effective Period*, 85 FR 41363 (July 10, 2020) (*Temporary Rule*).

⁹ See 19 CFR 351.309(c)(2) and 351.309(d)(2).

¹⁰ See *Temporary Rule*.

¹¹ See 19 CFR 351.310(c).

Notice to Interested Parties

These preliminary results are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.213 and 19 CFR 351.221(b)(4).

Dated: October 29, 2021.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

- I. Summary
- II. Background
- III. Period of Review
- IV. Partial Rescission of Administrative Review
- V. Scope of the Order
- VI. Non-Selected Company Under Review
- VII. Subsidies Valuation Information
- VIII. Analysis of Programs
- IX. Recommendation

[FR Doc. 2021–24080 Filed 11–3–21; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–201–830]

Carbon and Certain Alloy Steel Wire Rod From Mexico: Preliminary Results of Antidumping Duty Administrative Review and Partial Rescission of Antidumping Duty Administrative Review; 2019–2020

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that sales of carbon and certain alloy steel wire rod (wire rod) from Mexico were made at less than normal value during the period of review (POR), October 1, 2019, through September 30, 2020. Further, Commerce is rescinding the administrative review, in part. We invite interested parties to comment on these preliminary results.

DATES: Applicable November 4, 2021.

FOR FURTHER INFORMATION CONTACT: Benjamin A. Smith, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2181.

SUPPLEMENTARY INFORMATION:

Background

On October 29, 2002, Commerce published the antidumping duty order on wire rod from Mexico in the **Federal Register**.¹ On October 1, 2020, we published in the **Federal Register** a notice of opportunity to request an administrative review of the *Order*.² On December 8, 2020, pursuant to section 751(a)(1) of the Act, Commerce initiated an administrative review of the *Order*.³ On June 14, 2021, Commerce extended the deadline for the preliminary results to October 29, 2021.⁴ For a complete description of the events that followed the initiation of this review, see the Preliminary Decision Memorandum.⁵

Scope of the Order

The merchandise subject to the *Order* is wire rod, in coils, of approximately round cross section, 5.00 mm or more, but less than 19.00 mm, in solid cross-sectional diameter. The subject merchandise is classifiable in the Harmonized Tariff Schedule of the United States (HTSUS) primarily under the subheadings: 7213.91.3000, 7213.91.3010, 7213.91.3011, 7213.91.3015, 7213.91.3020, 7213.91.3090, 7213.91.3091, 7213.91.3092, 7213.91.3093, 7213.91.4500, 7213.91.4510, 7213.91.4590, 7213.91.6000, 7213.91.6010, 7213.91.6090, 7213.99.0030, 7213.99.0031, 7213.99.0038, 7213.99.0090, 7227.20.0000, 7227.20.0010, 7227.20.0020, 7227.20.0030,

¹ See *Notice of Antidumping Duty Orders: Carbon and Certain Alloy Steel Wire Rod from Brazil, Indonesia, Mexico, Moldova, Trinidad and Tobago, and Ukraine*, 67 FR 65945 (October 29, 2002) (*Order*).

² See *Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review*, 85 FR 61926 (October 1, 2020).

³ See *Initiation of Antidumping and Countervailing Duty Administrative Reviews*, 85 FR 78990 (December 8, 2020) (*Initiation Notice*). The *Initiation Notice* listed ArcelorMittal Las Truchas, S.A. de C.V. (AMLT) as one of the producers/exporters under review. *Id.* at 78993. However, Commerce later clarified that the initiation of the review with respect to AMLT was in error, as AMLT is no longer in operation and its assets have been sold to ArcelorMittal Mexico S.A. de C.V., and thus AMLT was not subject to the instant review. See *Initiation of Antidumping and Countervailing Duty Administrative Reviews*, 86 FR 511, 512–13 n.5 (January 6, 2021).

⁴ See Memorandum, “Carbon and Certain Alloy Steel Wire Rod from Mexico: Extension of Deadline for Preliminary Results of Antidumping Duty Administrative Review,” dated June 14, 2021.

⁵ See Memorandum, “Decision Memorandum for the Preliminary Results, Preliminary Determination of No Shipments, and Partial Rescission of the 2018–2019 Administrative Review of the Antidumping Duty Order on Carbon and Certain Alloy Steel Wire Rod from Mexico,” dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

7227.20.0080, 7227.20.0090, 7227.20.0095, 7227.90.6010, 7227.90.6020, 7227.90.6030, 7227.90.6035, 7227.90.6050, 7227.90.6051, 7227.90.6053, 7227.90.6058, 7227.90.6059, 7227.90.6080, and 7227.90.6085. The HTSUS subheadings are provided for convenience and customs purposes only; the written product description remains dispositive.

A full description of the scope of the *Order* is contained in the Preliminary Decision Memorandum.

Partial Rescission of Administrative Review

Nucor Corporation withdrew its request for an administrative review of Grupo Villacero S.A. de C.V. (Villacero) and Talleres y Aceros S.A. de C.V. (Talleres y Aceros).⁶ As no other party requested a review of Talleres y Aceros, and Villacero, we are therefore partially rescinding this administrative review with respect to Talleres y Aceros and Villacero pursuant to 19 CFR 351.213(d)(1). The review will continue with respect to Deacero S.A.P.I. de C.V. and Ternium Mexico S.A. de C.V.

Methodology

Commerce is conducting this review in accordance with section 751(a)(1)(B) of the Tariff Act of 1930, as amended (the Act). Constructed export price was calculated in accordance with section 772 of the Act. Normal value was calculated in accordance with section 773 of the Act. For a full description of the methodology underlying our conclusions, see the Preliminary Decision Memorandum. 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 <https://access.trade.gov>. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at <https://access.trade.gov/public/FRNoticesListLayout.aspx>. A list of topics discussed in the Preliminary Decision Memorandum is attached as an appendix to this notice.

Preliminary Results of the Review

As a result of this review, we preliminarily determine the following weighted-average dumping margins exist for the POR:

⁶ See Nucor’s Letter, “Carbon and Alloy Steel Wire Rod from Mexico: Request for Withdrawal of Administrative Review Concerning AMLT,” dated March 8, 2021.

Manufacturer/producer/exporter	Weighted-average dumping margins (percent)
Deacero S.A.P.I. de C.V.	26.12
Ternium Mexico S.A. de C.V.	26.12

Assessment Rates

Upon issuance of the final results, Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries covered by this review. If the weighted-average dumping margin for Deacero S.A.P.I. de C.V. (Deacero) (*i.e.*, the sole individually examined respondent in this review) is not zero or *de minimis* (*i.e.*, less than 0.5 percent), we will calculate importer-specific *ad valorem* antidumping duty assessment rates based on the ratio of the total amount of dumping calculated for the importer's examined sales to the total entered value of those same sales in accordance with 19 CFR 351.212(b)(1).⁷ We will instruct CBP to assess antidumping duties on all appropriate entries covered by this review when the importer-specific assessment rate calculated in the final results of this review is above *de minimis* (*i.e.*, 0.5 percent). Where either the respondent's weighted-average dumping margin is zero or *de minimis*, or an importer-specific assessment rate is zero or *de minimis*, we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties. 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 where applicable.

For the company which was not selected for individual review (*i.e.*, Ternium Mexico S.A. de C.V.), we will assign an assessment rate based on the weighted-average dumping margin calculated for the sole individually examined respondent in this review, Deacero. 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.⁸

In accordance with Commerce's "automatic assessment" practice, for entries of subject merchandise during the POR produced by Deacero which

did not know that its merchandise was destined for the United States, we will instruct CBP to liquidate entries not reviewed at the all-others rate of 20.11 percent⁹ if there is no rate for the intermediate company(ies) involved in the transaction. Commerce intends to issue assessment instructions to CBP no earlier than 41 days after the date of publication of the final results of this review in the **Federal Register**, in accordance with 19 CFR 356.8(a).

For the companies for which this review is rescinded, Villacero and Talleres y Aceros, antidumping duties shall be assessed at rates equal to the cash deposit rate of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption. Commerce intends to issue assessment instructions to CBP no earlier than 41 days after the date of publication of this rescission notice in the **Federal Register**.

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the notice of final results of administrative review for all shipments of wire rod from Mexico entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results, as provided by section 751(a)(2) of the Act: (1) The cash deposit rate for the firms listed above will be equal to the dumping margins established in the final results of this review, except if the ultimate rates are *de minimis* within the meaning of 19 CFR 351.106(c)(1), in which case the cash deposit rates will be zero; (2) for merchandise exported by producers or exporters not covered in this administrative review but covered in a prior segment of the proceeding, the cash deposit rate will continue to be the company-specific rate published for the most recently completed segment of this proceeding in which the producer or exporter participated; (3) if the exporter is not a firm covered in this review, a prior review, or the original less-than-fair-value investigation but the producer is, then the cash deposit rate will be the rate established for the most recently completed segment of the proceeding for the producer of the merchandise; and (4) the cash deposit rate for all other producers or exporters will continue to be 20.11 percent, the all-others rate established in the antidumping duty investigation.¹⁰ These cash deposit requirements, when imposed, shall remain in effect until further notice.

Disclosure

We intend to disclose the calculations performed in these preliminary results to parties in this proceeding within five days of the date of publication of this notice.¹¹

Public Comment

Pursuant to 19 CFR 351.309(c)(1)(ii), interested parties may submit case briefs no later than 30 days after the date of publication of this notice. Rebuttal briefs, limited to issues raised in the case briefs, may be filed no later than seven days after the date for filing case briefs.¹² Parties who submit case briefs or rebuttal briefs in this proceeding are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.¹³ All briefs must be filed electronically using ACCESS. An electronically filed document must be received successfully in its entirety by the established deadline. Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information, until further notice.¹⁴

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, within 30 days after the date of publication of this notice. Requests should contain: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. If a request for a hearing is made, Commerce intends to hold the hearing at a time and date to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties 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

⁷ In the preliminary results, Commerce applied the assessment rate calculation method adopted in *Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings*; Final Modification, 77 FR 8101 (February 14, 2012).

⁸ See section 751(a)(2)(C) of the Act.

⁹ See *Order*, 67 FR at 65947.

¹⁰ See *Order*, 67 FR at 65947.

¹¹ See 19 CFR 351.224(b).

¹² See 19 CFR 351.309(d); see also *Temporary Rule Modifying AD/CVD Service Requirements Due to COVID-19; Extension of Effective Period*, 85 FR 41363 (July 10, 2020) (*Temporary Rule*).

¹³ See 19 CFR 351.309(c)(2) and (d)(2) and 19 CFR 351.303 (for general filing requirements).

¹⁴ See *Temporary Rule*.

occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

We are issuing and publishing these results in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.213(h)(1).

Dated: October 29, 2021.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

- I. Summary
- II. Background
- III. Scope of the Order
- IV. Partial Rescission of Administrative Review
- V. Margin for Companies Not Selected for Individual Examination
- VI. Discussion of the Methodology
- VII. Currency Conversion
- VIII. Recommendation

[FR Doc. 2021-24081 Filed 11-3-21; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

[Docket Number 211026-0219]

Study on People's Republic of China (PRC) Policies and Influence in the Development of International Standards for Emerging Technologies

AGENCY: National Institute of Standards and Technology (NIST), Commerce.

ACTION: Request for information.

SUMMARY: The National Institute of Standards and Technology (NIST) is soliciting public comment on People's Republic of China (PRC) policies and influence in the development of international standards for emerging technologies. Section 9414 of the National Defense Authorization Act (NDAA) of 2021 directs NIST to enter into an agreement with an appropriate entity to conduct a study and provide recommendations with respect to the effect of policies of the PRC and coordination among industrial entities within the PRC on international bodies engaged in developing and setting international standards for emerging technologies. NIST is seeking comments to provide information for the study and resulting recommendations. In addition to the specific topic areas found in the Request for Information section of this notice, commenters may provide

responses to any other relevant issues. Recommendations on the actions the United States could take to mitigate any undue influence of the PRC and bolster United States public and private sector participation in international standards-setting bodies are also sought. Comments received in response to this request will be used to inform the work of the entity.

DATES: Comments must be received by 5:00 p.m. Eastern time on December 6, 2021. Written comments in response to the RFI should be submitted according to the instructions in the **ADDRESSES** section below. Submissions received after that date may not be considered.

ADDRESSES: Comments may be submitted by any of the following methods:

- **Electronic submission:** Submit electronic public comments via the Federal e-Rulemaking Portal.
 1. Go to www.regulations.gov and enter NIST-2021-0006 in the search field,
 2. Click the "Comment Now!" icon, complete the required fields, and
 3. Enter or attach your comments.Comments containing references, studies, research, and other empirical data that are not widely published should include copies of the referenced materials. All submissions, including attachments and other supporting materials, will become part of the public record and subject to public disclosure. NIST reserves the right to publish relevant comments publicly, unedited and in their entirety. Personal information, such as account numbers or Social Security numbers, or names of other individuals, should not be included. Do not submit confidential business information, or otherwise sensitive or protected information. Comments that contain profanity, vulgarity, threats, or other inappropriate language or content will not be considered.

FOR FURTHER INFORMATION CONTACT:

David F. Alderman, Standards Services Division, National Institute of Standards and Technology via email: david.alderman@nist.gov, or phone; 240-446-8843. Please direct media inquiries to NIST's Office of Public Affairs at (301) 975-2762 or inquiries@nist.gov.

SUPPLEMENTARY INFORMATION: NIST's Standards Coordination Office (SCO), initiates and manages programs, tools and activities to enhance U.S. industry competitiveness and federal agencies' coordination on issues related to technical standards and conformity assessment.

SCO monitors and participates in standards development and conformity assessment activities globally, consults with other federal agencies on standards policy issues, offers workshops and educational seminars for domestic and international audiences, and provides standards-related research and information services. More information can be found at <https://www.nist.gov/standardsgov/about-standardsgov>.

All industries use standardized processes and specifications to ensure that products are built to work together seamlessly. If each country or company did not adhere to the same standards, technologies would not be able to easily work with products designed by other companies or to work in other markets. In effect, standards allow products to be designed and produced at scale and used worldwide, which facilitates global trade. For example, the Wi-Fi standard provides the requirements for wireless local area networks and has facilitated the broad-based adoption of Wi-Fi wireless technology, which is now ubiquitous and has become indispensable for home networking, public internet connectivity, supporting the Internet of Things, and more.

Standards can also be proprietary and for-profit. For example, an operating system in a phone is open-source in order to promote standardization among smartphone makers and app developers, but companies still must pay licensing fees to use it.

There is not a single process by which all standards are created. Generally speaking, standards are set by a combination of private companies who are industry leaders as well as by international industry associations. Standards are enforced either as a convention—a "best practice"—or as formal agreements, depending on the industry and product.

Standards are not just useful for solving practical issues of compatibility, but also because they accelerate innovation. When companies use open standards rather than proprietary ones, they do not need to devote resources to developing their own internal systems and can instead follow established practices. International standards allow regulators and governments to improve trade policies and develop better regulations. International standards developed in a process consistent with the World Trade Organization's Technical Barriers to Trade Agreement provide an ideal tool to support trade agreements, and to provide confidence that requirements for products and testing have global relevance and are accepted worldwide.

Requirements of the Statutory Provision

Section 9414 of the National Defense Authorization Act for Fiscal Year 2021 (“William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021”) (Pub. L. 116–283) requires NIST to enter into an agreement with an appropriate entity to study the effect of the policies of the People’s Republic of China and coordination among industrial entities within the People’s Republic of China on international bodies engaged in developing and setting international standards for emerging technologies.

“Made in China 2025” is a strategic plan that was initiated in 2015 to reduce China’s dependence on foreign technology and promote Chinese technological manufacturers in the global marketplace. The goal was to reach this objective by the year 2025, a decade from the year when the plan first took root. More information on the “Made in China 2025” policy can be found at http://english.www.gov.cn/policies/latest_releases/2015/05/19/content_281475110703534.htm.

The “China Standards 2035” project will most likely build upon Made in China 2025. The “China Standards 2035” plan will lay out a blueprint for China’s government and leading technology companies to set global standards for emerging technologies in areas such as artificial intelligence and advanced communications technology.

International standards need to be relevant and to effectively respond to regulatory and market needs, as well as scientific and technological developments in various countries. They should not distort the global market, have adverse effects on fair competition, or stifle innovation and technological development. In addition, they should not give preference to the characteristics or requirements of specific countries or regions when different needs or interests exist in other countries or regions. Whenever possible, international standards should be performance based rather than based on design or descriptive characteristics.

Request for Information

To ensure that the broad perspective of the standards community informs the development of and aligns with government’s future plans and approaches, this RFI invites stakeholders throughout the scientific research, advocacy, industry, and non-scientific communities, including the general public, to comment. The enumerated list of topics below covers the major areas about which NIST seeks comment and is not intended to limit

the topics that may be addressed.

Commenters may provide responses to other relevant issues, such as the extent to which the PRC partners with foreign governments or multinational corporations to promote technical standards that may advantage PRC companies, entities, or state objectives; the aims of the PRC in international standards setting organizations, including an analysis of Chinese-language sources; the standardization strategy of the PRC, as identified in the stated intentions of the “China Standards 2035” plan, including how and to what extent that strategy has been implemented and has influenced PRC industry and academic sectors, including in the development of indigenous standards with international implications. Commenters may also offer comments on whether international standards for select emerging technologies (e.g., electronics, artificial intelligence, the Internet of Things (IoT), blockchain and financial technologies, clean energy technologies, and quantum information technologies) are being designed to promote or favor interests of the PRC, as expressed in the “Made in China 2025” plan, to the exclusion or disadvantage of other participants or in a way that may not result in the best technological solution. Responses may include any topic believed to have implications for the study.

1. The participation of the People’s Republic of China in international standards setting organizations over the previous 10 years, including leadership roles in standards drafting technical committees, and the quality or value of that participation;

2. The effect of the standardization strategy of the People’s Republic of China, as identified in the “China Standards 2035” plan on international bodies engaged in developing and setting standards for select emerging technologies, such as advanced communication technologies, or cloud computing and cloud services;

3. Whether international standards for select emerging technologies are being designed to promote interests of the People’s Republic of China as expressed in the “Made in China 2025” plan to the exclusion of other participants;

4. How previous practices used by the People’s Republic of China while participating in international standards setting organizations may foretell how the People’s Republic of China is likely to engage in international standardization activities of critical technologies like artificial intelligence and quantum information science, and what may be the consequences;

5. Recommendations on how the United States can take steps to mitigate the influence of the People’s Republic of China and bolster United States public and private sector participation in international standards-setting bodies.

Alicia Chambers,

NIST Executive Secretariat.

[FR Doc. 2021–24090 Filed 11–3–21; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Final Management Plans for the Lake Superior and Mission-Aransas National Estuarine Research Reserves

AGENCY: Office for Coastal Management, National Ocean Service, National Oceanic and Atmospheric Administration, U.S. Department of Commerce.

ACTION: Notice of approval of the revised management plan for the Lake Superior and Mission-Aransas National Estuarine Research Reserves.

SUMMARY: Notice is hereby given that the Office for Coastal Management, National Ocean Service, National Oceanic and Atmospheric Administration, U.S. Department of Commerce approves the revised management plans for the Lake Superior National Estuarine Research Reserve in Wisconsin and the Mission-Aransas National Estuarine Research Reserve in Texas. In accordance with applicable Federal regulations, the University of Wisconsin-Madison Division of Extension revised the Lake Superior Reserve’s management plan, which replaces the plan previously approved in 2010, and the University of Texas at Austin revised the Mission-Aransas Reserve’s management plan, which replaces the plan previously approved in 2015.

ADDRESSES: The approved Lake Superior Reserve management plan can be downloaded or viewed at <https://lakesuperiorreserve.org/files/2020/03/lsnerr-management-plan.pdf>. The approved Mission-Aransas Reserve management plan can be downloaded or viewed at <https://sites.cns.utexas.edu/manerr/about/management-plan>. These documents are also available by sending a written request to the point of contact identified below (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: For the Lake Superior revised management plan—Bridget Faust-Accola of NOAA’s Office for Coastal Management, by email

at bridget.faust@noaa.gov, phone at (651) 983-0235, or mail at: 1735 Lake Drive West, Chanhassen, MN 55317-8582. For the Mission-Aransas revised management plan—Matt Chasse of NOAA's Office for Coastal Management, by email at matt.chasse@noaa.gov, phone at 410-570-1020.

SUPPLEMENTARY INFORMATION: Pursuant to 15 CFR 921.33(c), a state must revise the management plan for a research reserve at least every five years. Changes to a reserve's management plan may be made only after receiving written approval from NOAA. NOAA approves changes to management plans via notice in the **Federal Register**. On November 02, 2020, NOAA issued a notice in the **Federal Register** announcing a thirty-day public comment period for the proposed revision of the management plan for the Lake Superior National Estuarine Research Reserve (81 FR 69320). On July 1, 2021, NOAA issued a notice in the **Federal Register** announcing a thirty-day public comment period for the proposed revision of the management plan for the Mission-Aransas National Estuarine Research Reserve (86 FR 35072). Responses to written and oral comments received, and an explanation of how comments were incorporated into the final versions of the revised management plans, are available in appendix B of the Lake Superior plan and appendix 8 of the Mission-Aransas plan.

The revised management plans outline each reserve's: Strategic goals and objectives; administrative structure; programs for conducting research and monitoring, education, and training; resource protection, restoration, and manipulation plans; public access and visitor use plans; consideration for future land acquisition; and facility development to support reserve operations.

The Lake Superior revised management plan focuses on changes to facilities through acquiring permanent housing for visiting students and researchers; growing the sectors by structurally supporting additional staff; advancing geographic information systems (GIS) and data management priorities; and developing a formal advisory board and strategic relationships with the private sector in the region. Since September 2010, the reserve has acquired permanent facilities for the reserve's operations; hired core sector leads and support staff; opened a public interpretive center and classroom; and expanded formal partnerships in research and education across the region. The revised

management plan will serve as the guiding document for the 16,697-acre research reserve for the next five years.

The Mission-Aransas revised management plan builds upon past successes and accomplishments and is designed to address specific priority coastal management issues. The priority issues for research and monitoring include marine debris, industrial growth impacts, eDNA, freshwater inflow, biological monitoring, and sea level rise and coastal subsidence. For education and training, priorities to be addressed include connecting children and nature; outdoor education programming, climate change and its effects on coastal environments; coastal ecology and habitat diversity; marine debris and its impacts on the coastal environment; and stewardship of estuarine and coastal resources.

Since its inception, this reserve has engaged in strategic partnerships with its land managing partners and others based on mutual interests. These partnerships are expected to be maintained or expanded through the revised management plan including reserve administration of the Amos Rehabilitation Keep (ARK), providing animal rehabilitation services for species endemic to the estuary. The reserve is also planning to maintain and improve reserve facilities including Fennessey Ranch, the Bay Education Center, the ARK, and the Patton Marine Science Education Center.

Neither the Lake Superior or Mission-Aransas revised management plans change the total acreage of either reserve.

NOAA reviewed the environmental impacts of the Lake Superior and Mission-Aransas revised management plans and determined that these actions are categorically-excluded from further analysis under the National Environmental Policy Act, consistent with NOAA Administrative Order 216-6.]

Authority: 16 U.S.C. 1451 *et seq.*; 15 CFR 921.33.

Keelin S. Kuipers,

Deputy Director, Office for Coastal Management, National Ocean Service, National Oceanic and Atmospheric Administration.

[FR Doc. 2021-24062 Filed 11-3-21; 8:45 am]

BILLING CODE 3510-NK-P

DEPARTMENT OF DEFENSE

Department of the Army

[Docket ID USA-2021-HQ-0023]

Proposed Collection; Comment Request

AGENCY: Department of the Army, Department of Defense (DoD).

ACTION: Information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995*, the Program Executive Officer, Enterprise Information Systems (PEO EIS) 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 January 3, 2022.

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 write to PEO EIS, Project Manager (PM) Army Data and Analytics Platforms (ARDAP), 9351 Hall Drive, Bldg 1456, ATTN: Linda O. Jones, or call 571-595-9291.

SUPPLEMENTARY INFORMATION: *Title; Associated Form; and OMB Number:* Project Manager Army Data Analytics Platforms Climate Survey, OMB Control Number 0702-RDAP.

Needs and Uses: The PM ARDAP Climate Survey is seeking feedback from its civilian, military, and contractor personnel to assess how they feel about the organization and their work environment. The responses will enable PM ARDAP leadership to assess and determine where changes are required. Though the survey is intended to reach all personnel, this proposed collection request only covers public respondents (contractor personnel) as required by the Paperwork Reduction Act. PM ARDAP will distribute this Climate Survey using the MilSuite survey feature, which enables PM ARDAP to create a custom survey for organization-wide distribution with advanced survey statistics to capture, review, and share the responses. Respondents will access and provide their responses to the collection instrument online. They will receive a link that takes them directly to the PM ARDAP Climate Survey in MilSuite. The PM ARDAP Operations Team will review the survey responses and provide data and subsequent analysis to PM ARDAP leadership. The results will enable PM ARDAP leadership to communicate areas for improvement, actions they plan to take or have been taken, and if the changes address the area in need of improvement with its personnel. Additionally, since the survey is annual, PM ARDAP will be able to review and analyze data year to year to identify trends.

Affected Public: Individuals or households.

Annual Burden Hours: 267.5.

Number of Respondents: 535.

Responses per Respondent: 1.

Annual Responses: 535.

Average Burden per Response: 30 minutes.

Frequency: Annually.

Dated: October 29, 2021.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2021-24032 Filed 11-3-21; 8:45 am]

BILLING CODE 5001-06-P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID DoD-2021-OS-0114]

Proposed Collection; Comment Request

AGENCY: The Office of the Under Secretary of Defense for Personnel and Readiness, Department of Defense (DoD).

ACTION: Information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995*, the Office of the Under Secretary of Defense for Personnel and Readiness 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 January 3, 2022.

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 write to Defense Human Resources Activity, 4800 Mark Center

Drive, Suite 08F05, Alexandria, VA 22350, LaTarsha Yeargins, 571-372-2089.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: On-Site Installation Evaluations; OMB Control Number 0704-0610.

Needs and Uses: These information collections continue to support a high-visibility requirement directed in Secretary of Defense Memorandum, "Immediate Actions to Counter Sexual Assault and Harassment and the Establishment of a 90-Day Independent Review Commission on Sexual Assault in the Military," February 26, 2021. Immediate Action 2 directs the Under Secretary of Defense for Personnel and Readiness (USD(P&R)) to develop a plan of action and milestones to conduct high risk installation evaluations. Memorandum "Plan of Action and Milestones for High Risk Installation Evaluations," March 30, 2021 USD(P&R) approved the plan of action and milestones. The end result of the data collection will be a series of ratings for each installation to characterize the maturity of prevention at each installation (*i.e.*, how consistently prevention is prioritized, how consistently people are prepared to conduct needed prevention, and how consistently prevention is done well).

Affected Public: Individuals or households.

Annual Burden Hours: 2,938 hours.

Number of Respondents: 4,100.

Responses per Respondent: 1.

Annual Responses: 4,100.

Average Burden per Response: 43 minutes.

Frequency: On occasion.

Dated: October 29, 2021.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2021-24030 Filed 11-3-21; 8:45 am]

BILLING CODE 5001-06-P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID DoD-2021-OS-0113]

Proposed Collection; Comment Request

AGENCY: The Office of the Under Secretary of Defense for Personnel and Readiness, Department of Defense (DoD).

ACTION: Information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995*, the

Office of the Under Secretary of Defense for Personnel and Readiness 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 January 3, 2022.

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 write to Defense Human Resources Activity, 4800 Mark Center Drive, Suite 08F05, Alexandria, VA 22350, LaTarsha Yeargins, 571-372-2089.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Status of Forces Survey of Reserve Component Members; OMB Control Number 0704-0616.

Needs And Uses: The purpose of the Status of the Forces Survey of Reserve Component Members (SOFS-R) is to assess the attitudes and opinions of Reserve component members and to provide key metrics to the OUSD(P&R). Results of this survey are used to

provide direct feedback on key strategic indicators such as satisfaction and retention. These indicators provide primary data on personnel career plans, retention decisions, morale, commitment, and quality of life and historically provide the ability to evaluate the impact of policies and programs with regard to readiness and retention.

Affected Public: Individuals or households.

Annual Burden Hours: 5,505 hours.

Number of Respondents: 16,515.

Responses per Respondent: 1.

Annual Responses: 16,515.

Average Burden per Response: 20 minutes.

Frequency: Annually.

Dated: October 29, 2021.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2021-24031 Filed 11-3-21; 8:45 am]

BILLING CODE 5001-06-P

DEPARTMENT OF EDUCATION

[Docket No.: ED-2021-SCC-0128]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Guaranty Agencies Security Self-Assessment and Attestation

AGENCY: Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing an extension without change of a currently approved collection.

DATES: Interested persons are invited to submit comments on or before December 6, 2021.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this information collection request by selecting "Department of Education" under "Currently Under Review," then check "Only Show ICR for Public Comment" checkbox. Comments may also be sent to ICDocketmgr@ed.gov.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Beth Grebeldinger, 202-377-4018.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork

Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Guaranty Agencies Security Self-assessment and Attestation.

OMB Control Number: 1845-0134.

Type of Review: An extension without change of a currently approved collection.

Respondents/Affected Public: Private Sector; State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 20.

Total Estimated Number of Annual Burden Hours: 6,320.

Abstract: This is a request for an extension of the approved information collection used by Federal Student Aid (FSA) to ensure that all data collected and managed by Guaranty Agencies (GAs) in support federal student financial aid programs is secure. FSA continues to use a formal assessment program that ensures the GAs have security protocols in place to protect the confidentiality and integrity of data entrusted to FSA by students and families. This assessment will identify security deficiencies based on the federal standards described in the National Institute of Standards and Technology publications.

Dated: November 1, 2021.

Juliana Pearson,

PRA Coordinator, Strategic Collections and Clearance Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2021–24096 Filed 11–3–21; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP20–484–000; CP20–485–000]

ANR Pipeline Company; Great Lakes Transmission Limited Partnership; Notice of Availability of the Final Environmental Impact Statement for the Proposed Alberta Xpress and Lease Capacity Abandonment Project

The staff of the Federal Energy Regulatory Commission (FERC or Commission) has prepared a final environmental impact statement (EIS) for the Alberta Xpress and Lease Capacity Abandonment Projects, proposed by ANR Pipeline Company (ANR) and Great Lakes Gas Transmission Limited Partnership (GLGT) in Docket Nos. CP20–484–000 and CP20–485–000, respectively. ANR proposes to construct and operate one new greenfield compressor station (designated as the Turkey Creek Compressor Station) and modify a mainline valve in Evangeline Parish, Louisiana, and acquire a lease agreement between ANR and GLGT. ANR has executed binding precedent agreements with two shippers to transport up to 165,000 dekatherms per day of natural gas. GLGT proposes to abandon firm capacity by a lease agreement with ANR. No new construction is proposed as part of the Lease Capacity Abandonment Project; however, this is related to the application filed by ANR to construct and operate the Alberta Xpress Project.

The final EIS assesses the potential environmental effects of the construction and operation of the proposed facilities in accordance with the requirements of the National Environmental Policy Act. The final EIS is not a decision document. It presents Commission staff's independent analysis of the environmental issues for the Commission to consider when addressing the merits of all issues in this proceeding.

The final EIS responds to comments that were received on the Commission's December 4, 2020 environmental assessment (EA) and July 30, 2021 draft

EIS,¹ and discloses downstream greenhouse gas emissions for the projects. With the exception of climate change impacts, the FERC staff concludes that approval of the proposed projects, with the mitigation measures recommended in this EIS, would not result in significant environmental impacts. FERC staff continues to be unable to determine significance with regards to climate change impacts.

The final EIS incorporates the above-referenced EA, which addressed the potential environmental effects of the construction and operation of the Turkey Creek Compressor Station and modifications to a mainline valve. The Turkey Creek Compressor Station would include the following facilities:

- One 15,900 horsepower gas-fired turbine compressor;
- three inlet filter separators;
- three discharge gas cooling bays;
- 36-inch-diameter suction and discharge piping;
- 16-inch-diameter cold recycle valves and piping;
- 16-inch-diameter unit control valve and bypass piping; and
- related appurtenant facilities.

The Commission mailed a copy of the *Notice of Availability of the Final Environmental Impact Statement for the Proposed Alberta Xpress and Lease Capacity Abandonment Projects* to federal, state, and local government representatives and agencies; elected officials; environmental and public interest groups; Native American tribes; potentially affected landowners and other interested individuals and groups; and newspapers and libraries in the Alberta Xpress Project area. The final EIS is only available in electronic format. It may be viewed and downloaded from the FERC's website (www.ferc.gov), on the natural gas environmental documents page (<https://www.ferc.gov/industries-data/natural-gas/environment/environmental-documents>). In addition, the draft EIS may be accessed by using the eLibrary link on the FERC's website. Click on the eLibrary link (<https://elibrary.ferc.gov/eLibrary/search>), select "General Search," and enter the docket number in the "Docket Number" field (i.e., CP20–484 and CP20–485). Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at FercOnlineSupport@ferc.gov or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659.

Additional information about the projects are 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. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription that allows you to keep track of all formal issuances and submittals in specific dockets. 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.

Dated: October 29, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–24106 Filed 11–3–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC22–12–000.

Applicants: Calhoun Power Company, LLC, Alabama Power Company.

Description: Joint Application for Authorization Under Section 203 of the Federal Power Act of Calhoun Power Company, LLC, et al.

Filed Date: 10/29/21.

Accession Number: 20211029–5156.

Comment Date: 5 p.m. ET 11/19/21.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER20–1828–002.

Applicants: PacifiCorp.

Description: Compliance filing: OATT Order 864 Compliance Filing—Second Deficiency Response to be effective N/A.

Filed Date: 10/29/21.

Accession Number: 20211029–5177.

Comment Date: 5 p.m. ET 11/19/21.

Docket Numbers: ER21–1875–002.

Applicants: Arizona Public Service Company.

Description: Tariff Amendment: Response to Deficiency Letter to be effective 7/10/2021.

Filed Date: 10/29/21.

Accession Number: 20211029–5002.

Comment Date: 5 p.m. ET 11/19/21.

¹ The project's EA is available on eLibrary under accession no. 20201204–3004 and the draft EIS is available under accession no. 20210730–3017.

Docket Numbers: ER21–2600–001.
Applicants: Southwest Power Pool, Inc.

Description: Tariff Amendment: Deficiency Response in ER21–2600—L and O Power Cooperative Formula Rate to be effective 12/1/2021.

Filed Date: 10/29/21.

Accession Number: 20211029–5217.

Comment Date: 5 p.m. ET 11/19/21.

Docket Numbers: ER21–2931–001.

Applicants: Midcontinent

Independent System Operator, Inc.

Description: Tariff Amendment: 2021–10–29_SA 3170 Crossett Solar—EAI Substitute 1st Rev GIA (J680) to be effective 9/7/2021.

Filed Date: 10/29/21.

Accession Number: 20211029–5068.

Comment Date: 5 p.m. ET 11/19/21.

Docket Numbers: ER22–40–001.

Applicants: PSEG Power New York Inc.

Description: Tariff Amendment: Supplement to Application for Market-Based Rate Authorization to be effective 12/3/2021.

Filed Date: 10/29/21.

Accession Number: 20211029–5122.

Comment Date: 5 p.m. ET 11/19/21.

Docket Numbers: ER22–123–001.

Applicants: Hecate Energy Highland LLC.

Description: Tariff Amendment: Supplement to Application for Market-Based Rate Authorization to be effective 10/16/2021.

Filed Date: 10/29/21.

Accession Number: 20211029–5077.

Comment Date: 5 p.m. ET 11/19/21.

Docket Numbers: ER22–244–000; TS22–1–000.

Applicants: Caddo Wind, LLC, Caddo Wind, LLC.

Description: Request for Temporary Tariff Waiver, et al. of Caddo Wind, LLC.

Filed Date: 10/28/21.

Accession Number: 20211028–5155.

Comment Date: 5 p.m. ET 11/18/21.

Docket Numbers: ER22–246–000.

Applicants: New England Power Company, ISO New England Inc.

Description: § 205(d) Rate Filing: New England Power Company submits tariff filing per 35.13(a)(2)(iii): NEP; Updates to Depreciation Rates Under Appendix D to Attachment F to be effective 1/1/2022.

Filed Date: 10/29/21.

Accession Number: 20211029–5027.

Comment Date: 5 p.m. ET 11/19/21.

Docket Numbers: ER22–247–000.

Applicants: Midcontinent Independent System Operator, Inc., Great River Energy.

Description: § 205(d) Rate Filing: Midcontinent Independent System

Operator, Inc. submits tariff filing per 35.13(a)(2)(iii): 2021–10–29_SA 3724 GRE-Nexus Line TIA (CS Line) to be effective 12/31/9998.

Filed Date: 10/29/21.

Accession Number: 20211029–5049.

Comment Date: 5 p.m. ET 11/19/21.

Docket Numbers: ER22–248–000.

Applicants: New England Power Company.

Description: § 205(d) Rate Filing: 2021–10–29 Amendment to Att. 4 of TSA–NEP–22 re Updated Depreciation Rates to be effective 1/1/2022.

Filed Date: 10/29/21.

Accession Number: 20211029–5051.

Comment Date: 5 p.m. ET 11/19/21.

Docket Numbers: ER22–249–000.

Applicants: Midcontinent Independent System Operator, Inc., Great River Energy.

Description: § 205(d) Rate Filing: Midcontinent Independent System Operator, Inc. submits tariff filing per 35.13(a)(2)(iii): 2021–10–29_SA 3725 GRE-Nexus Line TIA (SVT Line) to be effective 12/31/9998.

Filed Date: 10/29/21.

Accession Number: 20211029–5053.

Comment Date: 5 p.m. ET 11/19/21.

Docket Numbers: ER22–250–000.

Applicants: Midcontinent Independent System Operator, Inc., Otter Tail Power Company.

Description: § 205(d) Rate Filing: Midcontinent Independent System Operator, Inc. submits tariff filing per 35.13(a)(2)(iii): 2021–10–29_SA 3726 OTP-Nexus Line TIA (Underwood 230 kV) to be effective 12/31/9998.

Filed Date: 10/29/21.

Accession Number: 20211029–5059.

Comment Date: 5 p.m. ET 11/19/21.

Docket Numbers: ER22–251–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: 607R41 Evergy Kansas Central, Inc. NITSA NOA to be effective 10/1/2021.

Filed Date: 10/29/21.

Accession Number: 20211029–5070.

Comment Date: 5 p.m. ET 11/19/21.

Docket Numbers: ER22–252–000.

Applicants: Midcontinent Independent System Operator, Inc., Ameren Illinois Company.

Description: § 205(d) Rate Filing: Midcontinent Independent System Operator, Inc. submits tariff filing per 35.13(a)(2)(iii): 2021–10–29_SA 2880 Att A-Proj Spec No. 7 WVPA–MJM–Butler to be effective 12/29/2021.

Filed Date: 10/29/21.

Accession Number: 20211029–5073.

Comment Date: 5 p.m. ET 11/19/21.

Docket Numbers: ER22–253–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: Revisions to Modify Generator Interconnection Procedures to Mitigate Backlog to be effective 1/15/2022.

Filed Date: 10/29/21.

Accession Number: 20211029–5085.

Comment Date: 5 p.m. ET 11/19/21.

Docket Numbers: ER22–254–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Amendment to ISA, SA No. 3831; Queue No. Z1–072 to be effective 6/14/2016.

Filed Date: 10/29/21.

Accession Number: 20211029–5091.

Comment Date: 5 p.m. ET 11/19/21.

Docket Numbers: ER22–255–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: 2236R15 Golden Spread Electric Cooperative, Inc. NITSA NOA to be effective 10/1/2021.

Filed Date: 10/29/21.

Accession Number: 20211029–5111.

Comment Date: 5 p.m. ET 11/19/21.

Docket Numbers: ER22–256–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Interim ISA, Service Agreement No. 6216; Queue No. AF1–215 to be effective 9/30/2021.

Filed Date: 10/29/21.

Accession Number: 20211029–5119.

Comment Date: 5 p.m. ET 11/19/21.

Docket Numbers: ER22–257–000.

Applicants: Pacific Gas and Electric Company.

Description: § 205(d) Rate Filing: Q3 2021 Quarterly Filing of City and County of San Francisco's WDT SA (SA 275) to be effective 9/30/2021.

Filed Date: 10/29/21.

Accession Number: 20211029–5135.

Comment Date: 5 p.m. ET 11/19/21.

Docket Numbers: ER22–258–000.

Applicants: San Diego Gas & Electric Company.

Description: § 205(d) Rate Filing: 2022 TRBAA Update to be effective 1/1/2022.

Filed Date: 10/29/21.

Accession Number: 20211029–5149.

Comment Date: 5 p.m. ET 11/19/21.

Docket Numbers: ER22–259–000.

Applicants: PPL Electric Utilities Corporation, PJM Interconnection, L.L.C.

Description: Tariff Amendment: PPL Electric Utilities Corporation submits tariff filing per 35.15: PPL submits Notice of Cancellation of SA 5419, ESCA between PPL and MAIT to be effective 10/30/2021.

Filed Date: 10/29/21.

Accession Number: 20211029–5150.

Comment Date: 5 p.m. ET 11/19/21.
Docket Numbers: ER22–260–000.
Applicants: Duke Energy Carolinas, LLC.
Description: Tariff Amendment: DEC—Notice of Cancellation of Rate Schedule No. 338 to be effective 1/1/2022.
Filed Date: 10/29/21.
Accession Number: 20211029–5186.
Comment Date: 5 p.m. ET 11/19/21.
Docket Numbers: ER22–261–000.
Applicants: Tri-State Generation and Transmission Association, Inc.
Description: § 205(d) Rate Filing: Amendment to Rate Schedule No. 331 to be effective 12/28/2021.
Filed Date: 10/29/21.
Accession Number: 20211029–5187.
Comment Date: 5 p.m. ET 11/19/21.
Docket Numbers: ER22–262–000.
Applicants: Nevada Power Company.
Description: Tariff Amendment: Notice of Cancellation of Cert of Concurrence WestConnect to be effective 1/1/2022.
Filed Date: 10/29/21.
Accession Number: 20211029–5199.
Comment Date: 5 p.m. ET 11/19/21.
Docket Numbers: ER22–263–000.
Applicants: Wisconsin Power and Light Company.
Description: § 205(d) Rate Filing: WPL Adjustment of Formula Rates for Retail Service to be effective 12/31/2021.
Filed Date: 10/29/21.
Accession Number: 20211029–5203.
Comment Date: 5 p.m. ET 11/19/21.
Docket Numbers: ER22–264–000.
Applicants: Puget Sound Energy, Inc.
Description: § 205(d) Rate Filing: NorthernGrid Attachment K Amendment to be effective 1/1/2022.
Filed Date: 10/29/21.
Accession Number: 20211029–5204.
Comment Date: 5 p.m. ET 11/19/21.
Docket Numbers: ER22–265–000.
Applicants: Puget Sound Energy, Inc.
Description: Tariff Amendment: Notice of Cancellation Rate Schedule 941 to be effective 12/31/2021.
Filed Date: 10/29/21.
Accession Number: 20211029–5205.
Comment Date: 5 p.m. ET 11/19/21.
Docket Numbers: ER22–266–000.
Applicants: Northern States Power Company, a Minnesota corporation.
Description: § 205(d) Rate Filing: 2021–10–29 NSP–CHAK–Non-Conforming SISA–694–0.0.0 to be effective 10/30/2021.
Filed Date: 10/29/21.
Accession Number: 20211029–5206.
Comment Date: 5 p.m. ET 11/19/21.
Docket Numbers: ER22–267–000.
Applicants: Puget Sound Energy, Inc.
Description: § 205(d) Rate Filing: Certificate of Concurrence to

NorthernGrid Funding Agreement to be effective 1/1/2022.
Filed Date: 10/29/21.
Accession Number: 20211029–5207.
Comment Date: 5 p.m. ET 11/19/21.
Docket Numbers: ER22–268–000.
Applicants: Northern Indiana Public Service Company LLC.
Description: § 205(d) Rate Filing: Filing of a CIAC Agreement to be effective 11/1/2021.
Filed Date: 10/29/21.
Accession Number: 20211029–5209.
Comment Date: 5 p.m. ET 11/19/21.
Docket Numbers: ER22–269–000.
Applicants: Midcontinent Independent System Operator, Inc., Michigan Electric Transmission Company, LLC.
Description: § 205(d) Rate Filing: Midcontinent Independent System Operator, Inc. submits tariff filing per 35.13(a)(2)(iii): 2021–10–29_SA 3735 METC–Jackson County Solar E&P (J1310) to be effective 10/28/2021.
Filed Date: 10/29/21.
Accession Number: 20211029–5226.
Comment Date: 5 p.m. ET 11/19/21.
 Take notice that the Commission received the following PURPA 210(m)(3) filings:
Docket Numbers: QM22–5–000.
Applicants: East Kentucky Power Cooperative, Inc.
Description: Application of East Kentucky Power Cooperative, Inc. to Terminate Its Mandatory Purchase Obligation under the Public Utility Regulatory Policies Act of 1978.
Filed Date: 10/29/21.
Accession Number: 20211029–5152.
Comment Date: 5 p.m. ET 11/26/21.
 The filings are accessible in the Commission's eLibrary system (<https://elibrary.ferc.gov/idmws/search/fercgensearch.asp>) by querying the docket number. Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding. eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: October 29, 2021.
Debbie-Anne A. Reese,
Deputy Secretary.
 [FR Doc. 2021–24110 Filed 11–3–21; 8:45 am]
BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP21–760–000.
Applicants: Kinetica Energy Express, LLC.
Description: Motion Filing: Motion to Place Suspended Tariff Records into Effect to be effective 11/1/2021.
Filed Date: 10/28/21.
Accession Number: 20211028–5123.
Comment Date: 5 p.m. ET 11/9/21.
Docket Numbers: RP22–98–000.
Applicants: Sierrita Gas Pipeline LLC.
Description: § 4(d) Rate Filing: Fuel and LU Update to be effective 12/1/2021.
Filed Date: 10/28/21.
Accession Number: 20211028–5076.
Comment Date: 5 p.m. ET 11/9/21.
Docket Numbers: RP22–99–000.
Applicants: Portland Natural Gas Transmission System.
Description: § 4(d) Rate Filing: Reservation Charge Credits to be effective 12/1/2021.
Filed Date: 10/28/21.
Accession Number: 20211028–5081.
Comment Date: 5 p.m. ET 11/9/21.
Docket Numbers: RP22–100–000.
Applicants: Texas Eastern Transmission, LP.
Description: § 4(d) Rate Filing: Negotiated Rates—Vitol 911824 eff 11–1–2021 to be effective 11/1/2021.
Filed Date: 10/28/21.
Accession Number: 20211028–5083.
Comment Date: 5 p.m. ET 11/9/21.
Docket Numbers: RP22–101–000.
Applicants: Texas Eastern Transmission, LP.
Description: § 4(d) Rate Filing: Negotiated Rates—Castleton 911826 and 911827 to be effective 11/1/2021.
Filed Date: 10/28/21.
Accession Number: 20211028–5085.
Comment Date: 5 p.m. ET 11/9/21.
Docket Numbers: RP22–102–000.
Applicants: Texas Eastern Transmission, LP.
Description: § 4(d) Rate Filing: Negotiated Rates—Nextera 911771 Perm

Rel to BUG 911805 to be effective 11/1/2021.

Filed Date: 10/28/21.

Accession Number: 20211028–5093.

Comment Date: 5 p.m. ET 11/9/21.

Docket Numbers: RP22–103–000.

Applicants: Transcontinental Gas Pipe Line Company, LLC.

Description: § 4(d) Rate Filing:

Negotiated Rates—Sentinel—National Grid NY to be effective 11/1/2021.

Filed Date: 10/28/21.

Accession Number: 20211028–5106.

Comment Date: 5 p.m. ET 11/9/21.

Docket Numbers: RP22–104–000.

Applicants: Sabine Pipe Line LLC.

Description: Compliance filing: 2021 Sabine NAESB Compliance Filing Final to be effective 6/1/2022.

Filed Date: 10/28/21.

Accession Number: 20211028–5107.

Comment Date: 5 p.m. ET 11/9/21.

Docket Numbers: RP22–105–000.

Applicants: Maritimes & Northeast Pipeline, L.L.C.

Description: § 4(d) Rate Filing:

Negotiated Rate—New Brunswick Energy 210384 Release eff 11–1–2021 to be effective 11/1/2021.

Filed Date: 10/28/21.

Accession Number: 20211028–5110.

Comment Date: 5 p.m. ET 11/9/21.

Docket Numbers: RP22–106–000.

Applicants: Texas Eastern Transmission, LP.

Description: § 4(d) Rate Filing:

Negotiated Rates—NRG 910616 Perm Release to Direct 911823 to be effective 11/1/2021.

Filed Date: 10/28/21.

Accession Number: 20211028–5153.

Comment Date: 5 p.m. ET 11/9/21.

Docket Numbers: RP22–107–000.

Applicants: Algonquin Gas Transmission, LLC.

Description: § 4(d) Rate Filing:

Negotiated Rates—Keyspan 510369 Releases eff 11–1–2021 to be effective 11/1/2021.

Filed Date: 10/28/21.

Accession Number: 20211028–5183.

Comment Date: 5 p.m. ET 11/9/21.

Docket Numbers: RP22–108–000.

Applicants: Texas Eastern Transmission, LP.

Description: § 4(d) Rate Filing:

Negotiated Rates—PSEG 911810 eff 11–1–21 to be effective 11/1/2021.

Filed Date: 10/28/21.

Accession Number: 20211028–5188.

Comment Date: 5 p.m. ET 11/9/21.

Docket Numbers: RP22–109–000.

Applicants: Algonquin Gas Transmission, LLC.

Description: § 4(d) Rate Filing:

Negotiated Rates—Brooklyn Union 806313 Releases eff 11–1–2021 to be effective 11/1/2021.

Filed Date: 10/29/21.

Accession Number: 20211029–5000.

Comment Date: 5 p.m. ET 11/10/21.

Docket Numbers: RP22–110–000.

Applicants: Columbia Gas Transmission, LLC.

Description: § 4(d) Rate Filing: OTRA Winter 2021 to be effective 12/1/2021.

Filed Date: 10/29/21.

Accession Number: 20211029–5003.

Comment Date: 5 p.m. ET 11/10/21.

Docket Numbers: RP22–111–000.

Applicants: Portland Natural Gas Transmission System.

Description: § 4(d) Rate Filing: PXP Ph III Cost Sharing Adjustment to be effective 11/1/2021.

Filed Date: 10/29/21.

Accession Number: 20211029–5026.

Comment Date: 5 p.m. ET 11/10/21.

Docket Numbers: RP22–112–000.

Applicants: Enable Mississippi River Transmission, LLC.

Description: Compliance filing: 2021 Annual Report of Penalty Revenue Credits to be effective N/A.

Filed Date: 10/29/21.

Accession Number: 20211029–5028.

Comment Date: 5 p.m. ET 11/10/21.

Docket Numbers: RP22–113–000.

Applicants: Gulf South Pipeline Company, LLC.

Description: Compliance filing: Compliance Tariff Filing to Docket No. CP19–517–000 to be effective 12/1/2021.

Filed Date: 10/29/21.

Accession Number: 20211029–5043.

Comment Date: 5 p.m. ET 11/10/21.

Docket Numbers: RP22–114–000.

Applicants: Gulf South Pipeline Company, LLC.

Description: § 4(d) Rate Filing: Cap Rel Neg Rate Agmts (Atlanta Gas 8438 to various eff 11–1–2021) to be effective 11/1/2021.

Filed Date: 10/29/21.

Accession Number: 20211029–5044.

Comment Date: 5 p.m. ET 11/10/21.

Docket Numbers: RP22–115–000.

Applicants: ETC Tiger Pipeline, LLC.

Description: § 4(d) Rate Filing: Fuel Filing on 10–29–21 to be effective 12/1/2021.

Filed Date: 10/29/21.

Accession Number: 20211029–5055.

Comment Date: 5 p.m. ET 11/10/21.

Docket Numbers: RP22–116–000.

Applicants: Fayetteville Express Pipeline LLC.

Description: § 4(d) Rate Filing: Fuel Filing on 10–29–21 to be effective 12/1/2021.

Filed Date: 10/29/21.

Accession Number: 20211029–5058.

Comment Date: 5 p.m. ET 11/10/21.

Docket Numbers: RP22–117–000.

Applicants: Algonquin Gas Transmission, LLC.

Description: § 4(d) Rate Filing: AGT FRQ 2021 Filing to be effective 12/1/2021.

Filed Date: 10/29/21.

Accession Number: 20211029–5075.

Comment Date: 5 p.m. ET 11/10/21.

Docket Numbers: RP22–118–000.

Applicants: Wyoming Interstate Company, L.L.C.

Description: § 4(d) Rate Filing: Fuel and L&U Quarterly Filing to be effective 12/1/2021.

Filed Date: 10/29/21.

Accession Number: 20211029–5081.

Comment Date: 5 p.m. ET 11/10/21.

Docket Numbers: RP22–119–000.

Applicants: Algonquin Gas Transmission, LLC.

Description: § 4(d) Rate Filing: Negotiated Rates—Consolidated Edison 510371 Releases eff 11–1–2021 to be effective 11/1/2021.

Filed Date: 10/29/21.

Accession Number: 20211029–5083.

Comment Date: 5 p.m. ET 11/10/21.

Docket Numbers: RP22–120–000.

Applicants: Cheniere Creole Trail Pipeline, L.P.

Description: § 4(d) Rate Filing: CCTPL Transportation Retainage Adjustment to be effective 12/1/2021.

Filed Date: 10/29/21.

Accession Number: 20211029–5088.

Comment Date: 5 p.m. ET 11/10/21.

Docket Numbers: RP22–121–000.

Applicants: Midship Pipeline Company, LLC.

Description: § 4(d) Rate Filing: Midship Pipeline Transportation Retainage Adjustment to be effective 12/1/2021.

Filed Date: 10/29/21.

Accession Number: 20211029–5089.

Comment Date: 5 p.m. ET 11/10/21.

Docket Numbers: RP22–122–000.

Applicants: Garden Banks Gas Pipeline, LLC.

Description: Compliance filing: GB Order 587–Z (Docket RM96–1–042)

Compliance Filing to be effective 6/1/2022.

Filed Date: 10/29/21.

Accession Number: 20211029–5098.

Comment Date: 5 p.m. ET 11/10/21.

Docket Numbers: RP22–123–000.

Applicants: Rockies Express Pipeline LLC.

Description: § 4(d) Rate Filing: REX 2021–10–29 Non-Conforming Negotiated Rate Amendment to be effective 11/1/2021.

Filed Date: 10/29/21.

Accession Number: 20211029–5102.

Comment Date: 5 p.m. ET 11/10/21.

Docket Numbers: RP22–124–000.

Applicants: Eastern Gas Transmission and Storage, Inc.

Description: § 4(d) Rate Filing: EGT—October 29, 2021 Negotiated Rate Agreements to be effective 12/1/2021.

Filed Date: 10/29/21.

Accession Number: 20211029–5106.

Comment Date: 5 p.m. ET 11/10/21.

Docket Numbers: RP22–125–000.

Applicants: Mississippi Canyon Gas Pipeline, L.L.C.

Description: Compliance filing: MCGP Order 587–Z (Docket RM96–1–042) Compliance Filing to be effective 6/22/2022.

Filed Date: 10/29/21.

Accession Number: 20211029–5114.

Comment Date: 5 p.m. ET 11/10/21.

Docket Numbers: RP22–126–000.

Applicants: Kern River Gas Transmission Company.

Description: § 4(d) Rate Filing: 2021 October Negotiated Rate Amendment to be effective 11/1/2021.

Filed Date: 10/29/21.

Accession Number: 20211029–5120.

Comment Date: 5 p.m. ET 11/10/21.

Docket Numbers: RP22–127–000.

Applicants: Transcontinental Gas Pipe Line Company, LLC.

Description: § 4(d) Rate Filing: Negotiated Rates—Leidy South—Interim Svc 2—Coterra Energy to be effective 11/1/2021.

Filed Date: 10/29/21.

Accession Number: 20211029–5139.

Comment Date: 5 p.m. ET 11/10/21.

Docket Numbers: RP22–128–000.

Applicants: Northern Natural Gas Company.

Description: § 4(d) Rate Filing: 20211029 Negotiated Rate to be effective 11/1/2021.

Filed Date: 10/29/21.

Accession Number: 20211029–5142.

Comment Date: 5 p.m. ET 11/10/21.

Docket Numbers: RP22–129–000.

Applicants: Great Lakes Gas Transmission Limited Partnership.

Description: § 4(d) Rate Filing: TCPL FT18966 Rev 5 Negotiated Rate Agreement to be effective 11/1/2021.

Filed Date: 10/29/21

Accession Number: 20211029–5154.

Comment Date: 5 p.m. ET 11/10/21.

Docket Numbers: RP22–130–000.

Applicants: Colorado Interstate Gas Company, L.L.C.

Description: § 4(d) Rate Filing: Negotiated Rate Agreement Filing (BHSC #218854) to be effective 11/1/2021.

Filed Date: 10/29/21

Accession Number: 20211029–5161.

Comment Date: 5 p.m. ET 11/10/21.

Any person desiring to intervene or protest in any of the above proceedings

must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

Filings in Existing Proceedings

Docket Numbers: RP21–1129–001.

Applicants: ANR Pipeline Company.

Description: Compliance filing: ANR Best Bid Evaluation Compliance to be effective 10/20/2021.

Filed Date: 10/28/21.

Accession Number: 20211028–5033.

Comment Date: 5 p.m. ET 11/9/21.

Any person desiring to protest in any of the above proceedings must file in accordance with Rule 211 of the Commission's Regulations (18 CFR 385.211) on or before 5:00 p.m. Eastern time on the specified comment date.

The filings are accessible in the Commission's eLibrary system (<https://elibrary.ferc.gov/idmws/search/fercgensearch.asp>) by querying the docket number. eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: October 29, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–24108 Filed 11–3–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP22–9–000]

Equitrans, L.P.; Notice of Request Under Blanket Authorization and Establishing Intervention and Protest Deadline

Take notice that on October 20, 2021, Equitrans, L.P. (Equitrans), 2200 Energy Drive, Canonsburg, Pennsylvania 15317, filed in the above referenced docket a prior notice pursuant to Section 157.205 and 157.213 of the Federal Energy Regulatory Commission's regulations under the Natural Gas Act and the blanket certificate issued by the Commission in Docket No. CP96–532–000,¹ seeking authorization to convert

two observation wells to injection/withdrawal wells in the existing Truittsburg Storage Field in Clarion County, Pennsylvania. Specifically, Equitrans proposes to add approximately 1,119 feet of 4-inch diameter well lines to convert Truittsburg wells 2483 and 2484 from observation wells to injection/withdrawal wells. The conversion of the wells is intended to increase working gas capacity at the Truittsburg Storage Field from 1,634 million cubic feet (MMcf) to 1,829 MMcf. Equitrans estimates the cost of the project to be \$739,000, all as more fully set forth in the request which is on file with the Commission and open to public inspection.

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 TTY, (202) 502–8659.

Any questions concerning this application should be directed to Matthew Eggerding, Assistant General Counsel, Equitrans, L.P., 2200 Energy Drive, Canonsburg, Pennsylvania 15317, by telephone at (412) 553–5786, or by email at meggerding@equitransmidstream.com.

Public Participation

There are three ways to become involved in the Commission's review of this project: You can file a protest to the project, you can file a motion to intervene in the proceeding, and you can file comments on the project. There is no fee or cost for filing protests, motions to intervene, or comments. The deadline for filing protests, motions to intervene, and comments is 5:00 p.m. Eastern Time on December 28, 2021. How to file protests, motions to intervene, and comments is explained below.

¹ *Equitrans, L.P.*, 85 FERC ¶ 61,089 (1998).

Protests

Pursuant to section 157.205 of the Commission's regulations under the NGA,² any person³ or the Commission's staff may file a protest to the request. If no protest is filed within the time allowed or if a protest is filed and then withdrawn within 30 days after the allowed time for filing a protest, the proposed activity shall be deemed to be authorized effective the day after the time allowed for protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request for authorization will be considered by the Commission.

Protests must comply with the requirements specified in section 157.205(e) of the Commission's regulations,⁴ and must be submitted by the protest deadline, which is December 28, 2021. A protest may also serve as a motion to intervene so long as the protestor states it also seeks to be an intervenor.

Interventions

Any person has the option to file a motion to intervene in this proceeding. Only intervenors have the right to request rehearing of Commission orders issued in this proceeding and to subsequently challenge the Commission's orders in the U.S. Circuit Courts of Appeal.

To intervene, you must submit a motion to intervene to the Commission in accordance with Rule 214 of the Commission's Rules of Practice and Procedure⁵ and the regulations under the NGA⁶ by the intervention deadline for the project, which is December 28, 2021. As described further in Rule 214, your motion to intervene must state, to the extent known, your position regarding the proceeding, as well as your interest in the proceeding. For an individual, this could include your status as a landowner, ratepayer, resident of an impacted community, or recreationist. You do not need to have property directly impacted by the project in order to intervene. For more information about motions to intervene, refer to the FERC website at <https://www.ferc.gov/resources/guides/how-to-intervene.asp>.

All timely, unopposed motions to intervene are automatically granted by operation of Rule 214(c)(1). Motions to

intervene that are filed after the intervention deadline are untimely and may be denied. Any late-filed motion to intervene must show good cause for being late and must explain why the time limitation should be waived and provide justification by reference to factors set forth in Rule 214(d) of the Commission's Rules and Regulations. A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies (paper or electronic) of all documents filed by the applicant and by all other parties.

Comments

Any person wishing to comment on the project may do so. The Commission considers all comments received about the project in determining the appropriate action to be taken. To ensure that your comments are timely and properly recorded, please submit your comments on or before December 28, 2021. The filing of a comment alone will not serve to make the filer a party to the proceeding. To become a party, you must intervene in the proceeding.

How To File Protests, Interventions, and Comments

There are two ways to submit protests, motions to intervene, and comments. In both instances, please reference the Project docket number CP22–9–000 in your submission.

(1) You may file your protest, motion to intervene, and comments by using the Commission's eFiling feature, which is located on the Commission's website (www.ferc.gov) under the link to Documents and Filings. New eFiling users must first create an account by clicking on "eRegister." You will be asked to select the type of filing you are making; first select "General" and then select "Protest", "Intervention", or "Comment on a Filing." The Commission's eFiling staff are available to assist you at (202) 502–8258 or FercOnlineSupport@ferc.gov.

(2) You can file a paper copy of your submission. Your submission must reference the Project docket number CP22–9–000.

To mail via USPS, use the following address: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

To mail via any other courier, use the following address: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

Protests and motions to intervene must be served on the applicant either by mail or email (with a link to the

document) at: Matthew Eggerding, Assistant General Counsel, Equitrans, L.P., 2200 Energy Drive, Canonsburg, Pennsylvania 15317, by telephone at (412) 553–5786, or by email at meggerding@equitransmidstream.com. Any subsequent submissions by an intervenor must be served on the applicant and all other parties to the proceeding. Contact information for parties can be downloaded from the service list at the eService link on FERC Online.

Tracking the Proceeding

Throughout the proceeding, additional information about the project will be available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC website at www.ferc.gov using the "eLibrary" link as described above. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. 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. For more information and to register, go to www.ferc.gov/docs-filing/esubscription.asp.

Dated: October 29, 2021.

Debbie-Anne A. Reese,
Deputy Secretary.

[FR Doc. 2021–24107 Filed 11–3–21; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL 9104–02–OA]

Announcement of the Board of Directors for the National Environmental Education Foundation; Correction

AGENCY: U.S. Environmental Protection Agency (EPA).

ACTION: Notice of appointment and re-appointment; correction.

SUMMARY: The National Environmental Education and Training Foundation (doing business as The National Environmental Education Foundation or "NEEF") was created as a private 501(c)(3) non-profit organization. It was established by Congress as a common ground upon which leaders from business and industry, all levels of

² 18 CFR 157.205.

³ Persons include individuals, organizations, businesses, municipalities, and other entities. 18 CFR 385.102(d).

⁴ 18 CFR 157.205(e).

⁵ 18 CFR 385.214.

⁶ 18 CFR 157.10.

government, public interest groups, and others can work cooperatively to raise a greater national awareness of environmental issues beyond traditional classrooms.

DATES: Appointments are effective on January 13, 2022.

FOR FURTHER INFORMATION CONTACT: For information regarding this Notice of Appointment, please contact Hiram Lee Tanner III. (202) 564-4988, Director for Office of Environmental Education, U.S. EPA 1200 Pennsylvania Avenue NW, Washington, DC 20460.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of October 15, 2021, in the FR Doc. 2021-22494 on page 57422, column 3 correct paragraph 2 to read:

Per NEEA, the EPA Administrator appoints and reappoints eligible individuals to serve on NEEF's Board of Directors. The Administrator announces the following four-year appointments to NEEF's Board of Directors, effective 90 days after publication of the original notice:

- Dr. Robert D. Bullard, Texas Southern University
- Sally Cole, Apple
- Omar Mitchell, National Hockey League
- Arturo Garcia-Costas, The New York Community Trust

Mr. Kevin Butt, Toyota Motor North America, Inc., will be re-appointed for an additional four-year term.

Hiram Tanner,

Director, Office of Environmental Education.

[FR Doc. 2021-24007 Filed 11-3-21; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-EPA-HQ-OECA-2021-0763; FRL-9204-01-OECA]

Withdrawal of Two Answers to Frequent Questions About Property Management Companies and the Toxic Substances Control Act Lead-Based Paint Renovation, Repair, and Painting Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice and opportunity for public comment.

SUMMARY: The EPA intends to withdraw two Frequently Asked Questions (FAQs) concerning property management companies (PMCs) and their compliance responsibilities under the Toxic

Substances Control Act (TSCA) Lead Renovation, Repair and Painting (RRP) Rule. This notice explains the rationale for the withdrawal, the impact on the regulated community, how EPA will exercise its enforcement discretion, and invites public comment. The requirements of the RRP rule are intended to protect people, especially children, from the hazardous health effects of lead from lead-based paint.

DATES: The EPA intends to withdraw FQ 23002-13650 and 23002-18348 (the "PMC FQs"), found below and at <https://www.epa.gov/lead/fqs-rrp-rule> on March 21, 2022. However, due to the significant public interest in the issues addressed in this notice, the EPA is providing an opportunity for public comment on the EPA's intended action. The EPA is requesting comments by December 6, 2021 to identify any relevant information that could change the EPA's decision to withdraw these two FQs. Following the comment period and the Agency's consideration of comments received by that date, the EPA intends to post a memorandum that states whether the withdrawal will take effect as planned. The EPA would make the memorandum available on its website at: www.epa.gov/lead, and in the public comment docket for this notice at Docket EPA-HQ-OECA-2021-0763. By providing advance notice of the planned withdrawal of the FQs in 135 days from publication in the **Federal Register**, the EPA is providing more than sufficient time for PMCs to obtain any needed certification under the Lead RRP rule.

ADDRESSES: You may send comments, identified by Docket ID No. EPA-HQ-OECA-2021-0763, by any of the following methods:

- **Federal eRulemaking Portal:** <https://www.regulations.gov/> (our preferred method). Follow the online instructions for submitting comments.
- **Agency Website:** www.epa.gov/lead. Follow the online instructions for submitting comments.
- **Mail:** U.S. Environmental Protection Agency, EPA Docket Center, OECA Docket, Mail Code 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460.
- **Hand Delivery/Courier:** EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004. The Docket Center's hours of operations are 8:30 a.m.-4:30 p.m., Monday-Friday (except Federal Holidays).

Instructions: All submissions received must include the Docket ID No. for this notice. Comments received may be posted without change to <https://>

www.regulations.gov/, including any personal information provided. For detailed instructions on sending comments and additional information on the notice, see the "Public Participation" heading of the **SUPPLEMENTARY INFORMATION** section of this document. Out of an abundance of caution for members of the public and our staff, the EPA Docket Center and Reading Room are open to the public by appointment only to reduce the risk of transmitting COVID-19. Our Docket Center staff also continues to provide remote customer service via email, phone, and webform. Hand deliveries and couriers may be received by scheduled appointment only. For further information on EPA Docket Center services and the current status, please visit us online at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT:

Aimee Hessert, Federal Facilities Enforcement Office (MC 2261A), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 564-0993; email address: hessert.aimee@epa.gov; and Amos Presler, Office of Civil Enforcement (MC 2249A), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 564-1076; email address: presler.amos@epa.gov. Comments or questions submitted by email must include "Docket EPA-HQ-OECA-2021-0763" in the subject line of the email message.

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Written Comments

Submit your comments, identified by Docket ID No. EPA-HQ-OECA-2021-0763, at <https://www.regulations.gov> (our preferred method), or the other methods identified in the **ADDRESSES** section. Once submitted, comments cannot be edited or removed from the docket. The EPA may publish any comment received to its public docket. Do not submit to EPA's docket at <https://www.regulations.gov> any information you consider to be Proprietary Business Information (PBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the web, cloud, or other file sharing system). For

additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <https://www.epa.gov/dockets/commenting-epa-dockets>.

Due to public health concerns related to COVID-19, the EPA Docket Center and Reading Room are open to the public by appointment only. Our Docket Center staff also continues to provide remote customer service via email, phone, and webform. For further information and updates on EPA Docket Center services, please visit us online at <https://www.epa.gov/dockets>.

The EPA continues to carefully and continuously monitor information from the Centers for Disease Control and Prevention (CDC), local area health departments, and our Federal partners so that we can respond rapidly as conditions change regarding COVID-19.

II. General Information

A. Does this action affect you?

This announcement matters to you if you are a PMC, if you are employed by a PMC, if you live in target housing managed by a PMC, or if you work with PMCs on renovation, repair or painting activities covered by the EPA's RRP rule. Target housing includes residential dwellings constructed before 1978. This notice also matters to you if you have a child under the age of 6 years who regularly visits a "child-occupied facility," such as a daycare or a kindergarten, in a pre-1978 building managed by a PMC.

B. Intended Action

This Notice by the Environmental Protection Agency (EPA) announces it intends to withdraw two Frequently Asked Questions ("FQs") concerning property managers and property management companies (collectively, "property management companies" or "PMCs") and their compliance responsibilities under the Lead-based Paint Renovation, Repair, and Painting Rule ("RRP rule"), section 402(c) of the Toxic Substances Control Act (TSCA), 40 CFR part 745, subpart E, including the pre-renovation information distribution requirements promulgated under TSCA section 406(b) and codified at 40 CFR 745.84. The FQs are viewable on the EPA website: www.epa.gov/lead/fqs-rrp-rule.

The first of the PMC FQs to be withdrawn indicated the EPA's prior statement that a PMC did not need to obtain firm certification for itself or renovator certification for an employee

if none of its employees "do the work" of the renovation:

Question (23002-13650): A property management company performs most of the clerical functions of the business, and hires plumbers, electricians, carpenters, etc., for its renovation needs. Does the property management company need firm certification?

Answer: A property management company acts as an agent for the landlord and has the same responsibilities as the landlord under the RRP rule. Therefore, if the property management company uses its own employees to do the work, the property management company must be a certified firm and one of the employees must be a certified renovator. If the property management company hires a renovation firm to perform the renovation, the property management company does not need firm or renovator certification, but the firm the property management company hires must be certified and must perform the renovation using a certified renovator that directs and provides on-the-job training to any workers that are not certified renovators.

The second of the two PMC FQs explained how the EPA would exercise its enforcement discretion under circumstances in which a certified firm hired by the PMC fails to comply with a requirement of the RRP rule:

Question (23002-18348): If a property management company hires a certified firm to perform a renovation and the firm violates the RRP rule, for example, by failing to distribute the necessary materials or keep proper records, which entity is subject to enforcement action, the property manager or the certified firm?

Answer: It is the certified firm's responsibility to comply with the requirements of the RRP rule, and any enforcement action taken would be against the firm.

With the withdrawal of FQ 23002-13650 and FQ 23002-18348, the EPA would assess compliance by PMCs with the RRP rule, as it would for any other entity, according to the broadly applicable language of the RRP rule: That no firm may perform, offer, or claim to perform renovations without certification from EPA in target housing or child-occupied facilities (unless the renovation qualifies for a specified exception). *See, e.g.,* 40 CFR 745.81(a)(2)(ii). Furthermore, the EPA will evaluate compliance and appropriate enforcement actions on the basis of each case's individual facts and circumstances, and the EPA may exercise its enforcement discretion regarding PMC obligations.

As stated in the introduction to the current FQs document (available at <https://www.epa.gov/lead/answers-frequent-questions-about-epas-lead-renovation-repair-and-painting-rrp-rule>), the FQs present the agency's

preliminary responses, may be periodically revised, and do not necessarily bind the EPA to a specific application of the RRP rule. This notice, like the PMC FQs, is intended solely for guidance and does not alter any statutory or regulatory requirements and does not create binding obligations.

For information on how to get certified, please see <https://www.epa.gov/lead/renovation-repair-and-painting-program-contractors>.

C. Background

The RRP rule is intended to protect residents of pre-1978 homes from lead-based paint disturbed in the course of renovation, repair or painting activities. Compliance with the RRP rule's requirements protects people from the hazardous health effects of lead, especially children six years old and younger and pregnant women, both of whom are most susceptible to the effects of lead. Even low levels of lead in the blood of children can result in: Behavior and learning problems; lower IQ and hyperactivity; slowed growth; hearing problems; and anemia. In rare cases, ingestion of lead can cause seizures, coma and even death. Lead accumulates in the body over time, where it is stored in the bones along with calcium. During pregnancy, lead is released from the pregnant mother's bones, along with calcium, and can pass from the mother, exposing the fetus or the breastfeeding infant to lead. This can result in serious effects to the developing fetus and infant. It can cause the baby to be born too early or too small; hurt the baby's brain, kidneys, and nervous system; increase the likelihood of learning or behavioral problems; and put the mother at risk for miscarriage.

Congress recognized almost thirty years ago, upon enactment of the legislation that included TSCA Title IV, that lead in paint was responsible for "low-level lead poisoning [that was] widespread among American children, afflicting as many as 3,000,000 children under age 6, with minority and low-income communities disproportionately affected." 42 U.S.C. 4851. Disproportionate risks of lead exposure in minority and low-income communities persist today.¹ Withdrawal of the PMC FQs is important for the safety of all who live in PMC-managed

¹ Hauptman, et al., *Individual- and Community-Level Factors Associated with Detectable and Elevated Blood Lead Levels in US Children: Results From a National Clinical Laboratory*, JAMA Pediatrics (published online September 27, 2021) (finding statistically significant associations between detectable or elevated blood lead levels and zip codes with concentrations of poverty, Black populations, or Hispanic populations, and other community factors).

housing, and it is vitally important to the health of children under the age of 6 years, particularly in communities burdened by exposure to high levels of lead-based paint in pre-1978 housing. Communities with environmental justice concerns often include a higher proportion of rental housing. PMCs manage a significant portion of the nation's rental housing market, and each PMC often manages a large number of rental housing units. For example, the largest 50 PMCs alone control 3.4 million units.² PMCs also manage approximately 205,000 family housing projects, which comprise 99% of privatized military housing. More than 3.18 million children under the age of 6 years live in pre-1980 rental housing.³ A portion of these children may be at risk of exposure to lead-based paint hazards.

D. RRP Rule Applicability

The RRP rule broadly applies to renovation, repair or painting activities performed for compensation that disturb painted surfaces in target housing and child occupied facilities.

When the EPA developed the RRP rule, as required by section 402(c) of TSCA, it defined the scope of the RRP rule based on the circumstances of the renovation, repair and painting activity, rather than the person or entity performing the renovation. The RRP rule “applies to all renovations performed for compensation in target housing and child-occupied facilities. . . .” 40 CFR 745.82(a). The purpose of this broad application, as stated in the regulation is “to ensure” that “individuals performing renovations . . . are properly trained; renovators and firms performing these renovations are certified; and the work practices in [the regulation] are followed. . . .” § 745.80(b). Work practice requirements, such as work-area containment, and a prohibition on certain work practices, such as open-flame burning, minimize exposure to lead-based paint hazards.

The regulations provide that “no firm may perform, offer, or claim to perform renovations without certification from EPA . . . in target housing or child-occupied facilities [unless an exception applies].” § 745.81(a)(2)(ii). The regulations broadly define “firms” to include: “a company, partnership, corporation, sole proprietorship or individual doing business, association, or other business entity; a Federal, State, Tribal or local government agency; or a nonprofit organization.” § 745.83.

E. Basis for EPA's PMC FQs

In an effort to help the public understand and comply with the RRP rule, the EPA posted answers to frequent questions on its website at <https://www.epa.gov/lead/fqs-rrp-rule> (“FQ document”). When the EPA added the PMC FQs to the FQ document in 2010, it did not have experience with implementation of the RRP rule and the PMC industry's response to it. PMC FQ 23002–13650 states, “if the property management company hires a renovation firm to perform the renovation, the property management company does not need firm or renovator certification.” The FQ, which as noted above is not binding, analogized PMCs to landlords and provided that a PMC that did not use its own employees “to do the work” would not have enforceable obligations under the RRP rule and, for example, would not need to ensure that lead-safe work practices were followed. The FQ did not elaborate on the phrase “do the work.” At the time the FQ was written, EPA generally did not think that a PMC that hired a renovation firm to perform a renovation would itself be doing work such that it also would be performing or offering to perform the renovation for compensation. Therefore, EPA did not think the PMC would need to comply with the RRP rule and need to be a certified firm. Consistent with this prior interpretation, FQ 23002–18348 states that any enforcement action taken would be against the renovation firm, not the PMC. EPA now has experience implementing the RRP rule and understands there are circumstances where a PMC hires a renovation firm to perform the renovation, and also engages in activities such that the PMC also performs or offers to perform the renovation, and these circumstances are described in more detail in this notice.

F. EPA's Experience Implementing the RRP Rule Supports Withdrawal of the PMC FQs

The EPA has gained experience implementing the RRP rule since 2010 and, based on this experience, has a

better understanding of the activities commonly undertaken by PMCs. As explained below, the EPA has concluded that it is not appropriate to make categorical assumptions about PMC compliance obligations and that these obligations should be determined based on the facts and circumstances of each individual case. While PMCs may in some instances and in some circumstances act as agents of a landlord, unlike landlords they are not property owners, but instead are a distinct type of entity that performs services for compensation. In the EPA's experience, PMCs often do not hire certified renovation firms. Furthermore, the EPA has found many circumstances where a PMC that hires a renovation firm for a renovation also performs or offers to perform the renovation for compensation in target housing. For example, in some cases, the PMC might offer to perform renovation, repair, or painting activities through its contractual agreements with the building owner, and in other cases the PMC might perform an element of the renovation for compensation.

Given the EPA's understanding of these circumstances, the EPA intends to assess compliance by PMCs with the RRP rule, just as it would for any other entity, in accordance with the broadly applicable language of the RRP rule: That no firm may perform, offer, or claim to perform regulated renovations without certification from the EPA in target housing or child-occupied facilities. *See, e.g.*, 40 CFR 745.81(a)(2)(ii). Consistent with the requirements in the RRP rule, the EPA will evaluate compliance and appropriate enforcement actions on the basis of each case's individual facts and circumstances, and the EPA may exercise its enforcement discretion regarding PMC obligations.

G. Examples of PMCs' Varying Levels of Involvement With Renovations

The following discussion is intended to help elaborate on how the RRP rule may apply to PMCs when they hire a renovation firm. In some cases, the PMC might offer to perform renovation, repair, or painting activities through its contractual agreements with the building owner, and in other cases the PMC might perform an element of the renovation for compensation.

When a PMC enters into a business relationship with the property owner, the PMC typically agrees to perform various property management services. In some circumstances, a PMC's services may be strictly limited to leasing and rent collection. That circumstance would be unlikely to give rise to facts

² National Multifamily Housing Council (NMHC) (tallying 3,405,227 rental units under management by 50 PMCs). <https://www.nmhc.org/research-insight/the-nmhc-50/top-50-lists/2019-managers-list/>.

³ American Housing Survey Table, 2019 National—Household Demographics—All Occupied Units—Tenure Filter: Renter—Year Built Variable (2019) (rental filtered sum of pre-1980 households (columns I–M) with one child under 6 years (rows 170–71, 176–77, 182–83) plus doubled sum of pre-1980 households of two or more children under 6 years old (rows 172,73, 178–79, 184–85) yields a minimum estimate of 3,188,000 children under 6 years old in pre-1980 rental housing). Spreadsheet is derived from the Custom AHS Table tool maintained by the U.S. Census at <https://www.census.gov/programs-surveys/ahs>.

indicating that a PMC “performed” a renovation.

More often, a PMC agrees to provide—and is compensated for—property management services that include maintenance, repair, painting, renovations, or other activities that disturb painted surfaces and may be subject to the RRP rule and require a certified renovator. In such agreements, oral contracts, or written contracts, the agreement obligates the PMC to perform the renovation. Whether the PMC uses its own employees to perform the work or hires an outside firm to perform the work, the PMC remains obligated by such an agreement with the property owner (and typically is compensated for fulfilling such obligations) to ensure that the renovation is performed.

Specification of such “renovation” responsibilities in a written contract between a property owner and a PMC is not essential to establishing RRP rule applicability to the PMC, especially if other facts establish that the PMC offered to perform or actually did perform some other action necessary to ensure the performance of a renovation activity.

When a PMC hires a firm for renovation, repair or painting activities, the PMC, as part of the business relationship with the property owner, is typically compensated for managing certain activities that are necessary or even integral to the performance of the renovation, repair or painting activity, including (but not limited to):

- Soliciting and evaluating contractor bids;
- Applying for permits, as appropriate;
- Granting contractors access to the property;
- Overseeing contractor work on the property;
- Informing tenants of renovation activity;
- Verifying completion of renovation activity; or
- Remitting payment to the contractors.

The PMC may even oversee or supervise the outside renovation firms, individuals and contractors who are not the PMC’s employees but are doing activities that are recognized as part of the renovation in the RRP rule. The PMC may also coordinate work schedules of the various outside contractors.

Compensation of a PMC by the property owner for any of these or similar activities may establish that a PMC is performing a renovation for

compensation and must comply with the RRP rule, even if the PMC uses an independent contractor instead of its own employees to do the specific activities that disturb paint surfaces. Consistent with the requirements in the RRP rule, the EPA will evaluate compliance and appropriate enforcement actions on the basis of each case’s individual facts and circumstances, and the EPA may exercise its enforcement discretion regarding PMC obligations.

H. Why Withdrawal of the PMC FQs Is Preferable

The EPA has over ten years of experience with the PMC FQs and has concluded, as discussed above, that these FQs have contributed to non-compliance with the RRP rule in rental property managed by PMCs.

EPA’s experience also has shown that PMCs routinely hire smaller, uncertified firms to conduct RRP activities. Collectively these hiring decisions by PMCs have an outsized impact on worksite compliance at properties managed by PMCs as the numerous contractors for renovation, repair and painting activities are often small and transitory. Withdrawing the PMC FQs signals that EPA plans to hold both the PMCs and the contractors they hire responsible for compliance if the circumstances indicate that both entities performed or offered to perform renovations for compensation in target housing or child-occupied facilities.

Withdrawal of the PMC FQs and the discussion in this notice helps to increase the impact and effectiveness of the RRP Rule and improve compliance in rental properties managed by PMCs. The EPA seeks to explain the circumstances that may give rise to compliance obligations for PMCs under the RRP Rule. We also aim to identify the potential enforcement consequences for a PMC that performs or offers to perform renovations for compensation without considering its role in RRP rule compliance.

I. Assessing Compliance for PMCs

The EPA is cognizant that PMCs relying on the EPA’s PMC FQs may have declined to obtain RRP certification themselves or ensure the RRP compliance of contractors they hired. Therefore, through this notice, the EPA is informing the public and PMCs that EPA intends to withdraw FQs 23002–13650 and 23002–18348 and intends, upon withdrawal, to assess compliance by PMCs that are performing or offering

to perform renovations for compensation—either by using their own employees or hiring an outside firm—according to the same requirements placed upon any other entity that performs or offers to perform a renovation for compensation in target housing or child-occupied facilities.

Consistent with the RRP rule, any individual or entity (including PMCs) is subject to the RRP rule requirements when they perform or offer to perform renovation, repair or painting activities for compensation in housing and child-occupied facilities built before 1978, and therefore must be a certified firm.

Requirements for certified firms include, among other things: Obtaining firm certification; providing owners and occupants with the EPA’s *Renovate Right* pamphlet; assigning a certified renovator to the RRP activity (or ensuring assignment of a contractor’s certified renovator); ensuring all workers onsite are certified or receive on-the-job training from a certified renovator; ensuring use of lead-safe work practices and clean-up; ensuring documentation of compliance of lead-safe work practices that minimize the release of lead-based paint hazards such as paint chips and dust containing lead; and providing that documentation to the EPA and to EPA-authorized state programs upon request.

By providing advance notice of the planned withdrawal of the FQs in 135 days, the EPA is providing more than sufficient time for PMCs to obtain any needed certification under the Lead RRP rule. For information on how to get certified, please see <https://www.epa.gov/lead/renovation-repair-and-painting-program-contractors>.

Michael S. Regan,
Administrator.

[FR Doc. 2021–24010 Filed 11–3–21; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice of Termination of Receiverships

The Federal Deposit Insurance Corporation (FDIC or Receiver), as Receiver for each of the following insured depository institutions, was charged with the duty of winding up the affairs of the former institutions and liquidating all related assets. The Receiver has fulfilled its obligations and made all dividend distributions required by law.

NOTICE OF TERMINATION OF RECEIVERSHIPS

Fund	Receivership name	City	State	Termination date
10136	Bank USA, NA	Phoenix	AX	11/01/2021
10137	Community Bank of Lemont	Lemont	IL	11/01/2021
10138	North Houston Bank	Houston	TX	11/01/2021
10141	Citizens National Bank	Teague	TX	11/01/2021
10533	Resolute Bank	Maumee	OH	11/01/2021

The Receiver has further irrevocably authorized and appointed FDIC-Corporate as its attorney-in-fact to execute and file any and all documents that may be required to be executed by the Receiver which FDIC-Corporate, in its sole discretion, deems necessary, including but not limited to releases, discharges, satisfactions, endorsements, assignments, and deeds. Effective on the termination dates listed above, the Receiverships have been terminated, the Receiver has been discharged, and the Receiverships have ceased to exist as legal entities.

(Authority: 12 U.S.C. 1819)

Federal Deposit Insurance Corporation.

Dated at Washington, DC, on November 1, 2021.

James P. Sheesley,

Assistant Executive Secretary.

[FR Doc. 2021–24058 Filed 11–3–21; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL ELECTION COMMISSION

Sunshine Act Notice

TIME AND DATE: Wednesday, November 10, 2021 at 3 p.m.

PLACE: Virtual Hearing. Note: Because of the covid-19 pandemic, we will conduct the hearing virtually. If you would like to access the hearing, see the instructions below.

STATUS: This hearing will be open to the public. To access the virtual hearing, go to the commission's website www.fec.gov and click on the banner to be taken to the hearing page.

MATTER TO BE CONSIDERED: Audit Hearing; Mike Braun for Indiana.

CONTACT PERSON FOR MORE INFORMATION: Judith Ingram, Press Officer; Telephone: (202) 694–1220.

Authority: Government in the Sunshine Act, 5 U.S.C. 552b.

Laura E. Sinram,

Acting Secretary and Clerk of the Commission.

[FR Doc. 2021–24285 Filed 11–2–21; 4:15 pm]

BILLING CODE 6715–01–P

FEDERAL ELECTION COMMISSION

Sunshine Act Meeting

TIME AND DATE: Tuesday, November 9, 2021 at 10 a.m. and its continuation at the conclusion of the open meeting on November 10, 2021.

PLACE: 1050 First Street NE, Washington, DC (This meeting will be a virtual meeting).

STATUS: This meeting will be closed to the public.

MATTERS TO BE CONSIDERED: Compliance matters pursuant to 52 U.S.C. 30109.

Matters relating to internal personnel decisions, or internal rules and practices.

Information the premature disclosure of which would be likely to have a considerable adverse effect on the implementation of a proposed Commission action.

Matters concerning participation in civil actions or proceedings or arbitration.

CONTACT PERSON FOR MORE INFORMATION: Judith Ingram, Press Officer, Telephone: (202) 694–1220.

Vicktoria J. Allen,

Acting Deputy Secretary of the Commission.

[FR Doc. 2021–24243 Filed 11–2–21; 4:15 pm]

BILLING CODE 6715–01–P

FEDERAL ELECTION COMMISSION

Sunshine Act Meeting

TIME AND DATE: Wednesday, November 10, 2021 at 10:00 a.m.

PLACE: Virtual meeting. Note: Because of the COVID–19 pandemic, we will conduct the open meeting virtually. If you would like to access the meeting, see the instructions below.

STATUS: This meeting will be open to the public. To access the virtual meeting, go to the commission's website www.fec.gov and click on the banner to be taken to the meeting page.

MATTERS TO BE CONSIDERED:

Draft Advisory Opinion 2021–12: Congressman Adam Schiff and Schiff for Congress

Draft Advisory Opinion 2021–10: Retail Benefits, Inc.

Draft Advisory Opinion 2021–11: DSCC and DCCC

Management and Administrative Matters

CONTACT PERSON FOR MORE INFORMATION: Judith Ingram, Press Officer. Telephone: (202) 694–1220.

Authority: Government in the Sunshine Act, 5 U.S.C. 552b.

Laura E. Sinram,

Acting Secretary and Clerk of the Commission.

[FR Doc. 2021–24157 Filed 11–2–21; 11:15 am]

BILLING CODE 6715–01–P

FEDERAL RESERVE SYSTEM

Agency Information Collection

Activities: Announcement of Board Approval Under Delegated Authority and Submission to OMB

AGENCY: Board of Governors of the Federal Reserve System.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) is adopting a proposal to extend for three years, without revision, FR HMDA LAR, the Reporting, Recordkeeping, and Disclosure Requirements Associated with the CFPB's Home Mortgage Disclosure Act Loan/Application Register required by Regulation C.

FOR FURTHER INFORMATION CONTACT: Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551, (202) 452–3829.

Office of Management and Budget (OMB) Desk Officer for the Federal Reserve Board, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395–6974.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve and assign OMB control numbers to

collections of information conducted or sponsored by the Board. Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. The OMB inventory, as well as copies of the PRA Submission, supporting statements, and approved collection of information instrument(s) are available at <https://www.reginfo.gov/public/do/PRAMain>. These documents are also available on the Federal Reserve Board's public website at <https://www.federalreserve.gov/apps/reportforms/review.aspx> or may be requested from the agency clearance officer, whose name appears above.

Final Approval Under OMB Delegated Authority of the Extension for Three Years, Without Revision, of the Following Information Collection

Report title: Reporting, Recordkeeping, and Disclosure Requirements Associated with the CFPB's Home Mortgage Disclosure Act Loan/Application Register required by Regulation C.

Agency form number: FR HMDA LAR.

OMB control number: 7100-0247.

Frequency: Annually and quarterly.

Respondents: State member banks and their subsidiaries, subsidiaries of bank holding companies, U.S. branches and agencies of foreign banks (other than federal branches, federal agencies, and insured state branches of foreign banks), commercial lending companies owned or controlled by foreign banks, and organizations operating under section 25 or 25A of the Federal Reserve Act.

Estimated number of respondents: Reporting—Tier 1 Annual Reporter, 3; Tier 1 Quarterly Reporter, 1; Tier 2, 131; Tier 2 Partial Reporter, 308; and Tier 3 Partial Reporter, 33; Recordkeeping—Tier 1 Annual Reporter, 3; Tier 1 Quarterly Reporter, 1; Tier 2, 439; and Tier 3, 33; and Disclosure—Tier 1 Annual Reporter, 3; and Tier 1 Quarterly Reporter, 1.

Estimated average hours per response: Reporting—Tier 1 Annual Reporter, 5,969; Tier 1 Quarterly Reporter, 6,903; Tier 2, 1,232; Tier 2 Partial Reporter, 986; and Tier 3 Partial Reporter, 64; Recordkeeping—Tier 1 Annual Reporter, 4,130; Tier 1 Quarterly Reporter, 4,130; Tier 2, 83; and Tier 3, 27; and Disclosure—Tier 1 Annual Reporter, 5; and Tier 1 Quarterly Reporter, 5.

Estimated annual burden hours: Reporting—Tier 1 Annual Reporter, 17,907; Tier 1 Quarterly Reporter, 27,612; Tier 2, 161,392; Tier 2 Partial Reporter, 303,688; and Tier 3 Partial

Reporter, 2,112; Recordkeeping—Tier 1 Annual Reporter, 12,390; Tier 1 Quarterly Reporter, 16,520; Tier 2, 36,437; and Tier 3, 891; and Disclosure—Tier 1 Annual Reporter, 15; and Tier 1 Quarterly Reporter, 20.

General description of report: The Home Mortgage Disclosure Act (HMDA) was enacted in 1975 and is implemented by Regulation C. Generally, the HMDA requires certain depository and non-depository institutions that make certain mortgage loans to collect, report, and disclose data about originations and purchases of mortgage loans, as well as loan applications that do not result in originations (for example, applications that are denied or withdrawn). The HMDA was enacted to provide regulators and the public with loan data that can be used to (1) help determine whether financial institutions are serving the housing needs of their communities, (2) assist public officials in distributing public-sector investments so as to attract private investment to areas where it is needed, and (3) assist in identifying possible discriminatory lending patterns and enforcing anti-discrimination statutes.¹ Supervisory agencies, state and local public officials, and members of the public use the data to aid in the enforcement of the Community Reinvestment Act, the Equal Credit Opportunity Act, and the Fair Housing Act and to aid in identifying areas for residential redevelopment and rehabilitation.

Legal authorization and confidentiality: The FR HMDA LAR is authorized pursuant to section 304(j) of the HMDA, which requires that the Consumer Financial Protection Bureau (CFPB) prescribe by regulation the form of loan application register information that must be reported by covered financial institutions. Section 1003.5 of Regulation C implements this statutory provision, and requires covered financial institutions to submit reports to their appropriate federal agency. Section 304(h)(2)(A) of the HMDA designates the Board as the appropriate agency with respect to the entities described above. The FR HMDA LAR is mandatory.

The HMDA requires the information collected on the FR HMDA LAR to be made available to the general public in the form required under regulations prescribed by the CFPB. The CFPB is authorized to redact or modify the scope of the information before it is publicly disclosed to protect the privacy of loan applicants and to protect depository

institutions from liability under any federal or state privacy law. The redacted information may be kept confidential under exemption 6 of the Freedom of Information Act, which protects from release information that, if disclosed, would "constitute a clearly unwarranted invasion of personal privacy."²

Current actions: On July 19, 2021, the Board published a notice in the **Federal Register** (86 FR 38090) requesting public comment for 60 days on the extension, without revision, of the Reporting, Recordkeeping, and Disclosure Requirements Associated with the CFPB's Home Mortgage Disclosure Act Loan/Application Register required by Regulation C. The comment period for this notice expired September 17, 2021. The Board did not receive any comments.

Board of Governors of the Federal Reserve System, October 27, 2021.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2021-23805 Filed 11-3-21; 8:45 am]

BILLING CODE 6210-01-P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (Act) (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the applications are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at <https://www.federalreserve.gov/foia/request.htm>. Interested persons may express their views in writing on the standards enumerated in paragraph 7 of the Act.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th

¹ See 12 CFR 1003.1(b).

² 5 U.S.C. 552(b)(6).

Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than November 19, 2021.

A. Federal Reserve Bank of Minneapolis (Chris P. Wangen, Assistant Vice President), 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291. Comments can also be sent electronically to MA@mpls.frb.org:

1. *Richard M. Wall, Eden Prairie, Minnesota, Elizabeth Wall Lee, Sunfish Lake, Minnesota, and John K. Wall, Wayzata, Minnesota*; to retain voting shares of Highland Bancshares, Inc., and thereby indirectly retain voting shares of Highland Bank, both of Saint Michael, Minnesota.

In addition, Richard M. Wall, as trustee to the following trusts: The 2012 Grantor Trust for Richard M. Wall and Family dated 12/26/12, the Emilie Grace Wall 2020 Irrevocable Trust dated 12/26/20, the Ericka Marie Wall 2020 Irrevocable Trust dated 12/26/20, and the Julianna Karin Wall 2020 Irrevocable Trust dated 12/26/20; John K. Wall, as trustee to the following trusts: The 2012 Grantor Trust for John K. Wall and Family dated 12/26/12, the Lauren Wall 2020 Irrevocable Trust dated 12/26/20, and the Jack Wall 2020 Irrevocable Trust dated 12/26/20; and Elizabeth Wall Lee, as trustee to the following trusts: The 2012 Grantor Trust for Elizabeth W. Lee and Family dated 12/26/12, the Kevin Connor Lee 2020 Irrevocable Trust dated 12/26/20, and the Shannon Elizabeth Lee 2020 Irrevocable Trust dated 12/26/20, all of Minneapolis, Minnesota; to join the Wall Family Control Group, a group acting in concert, to acquire voting shares of Highland Bancshares, Inc., and thereby indirectly acquire voting shares of Highland Bank.

B. Federal Reserve Bank of St. Louis (Holly A. Rieser, Manager) P.O. Box 442, St. Louis, Missouri 63166–2034. Comments can also be sent electronically to Comments.applications@stls.frb.org:

1. *The Samuel D. Gohn Irrevocable Trust, Kenneth Larry Joplin, trustee, both of West Plains, Missouri*; to join the Gohn Family Control Group, a group acting in concert, to acquire voting shares of West Plains Bancshares, Inc., and thereby indirectly acquire voting shares of West Plains Bank and Trust Company, both of West Plains, Missouri.

Board of Governors of the Federal Reserve System, November 1, 2021.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2021–24111 Filed 11–3–21; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Notice, request for comment.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) invites comment on a proposal to extend for three years, with revision the Recordkeeping and Disclosure Requirements Associated with Loans Secured by Real Estate Located in Flood Hazard Areas Pursuant to Regulation H (FR H–2; OMB 7100–0280) of the Board's rules.

DATES: Comments must be submitted on or before January 3, 2022.

ADDRESSES: You may submit comments, identified by FR H–2, by any of the following methods:

- *Agency website:* <https://www.federalreserve.gov/>. Follow the instructions for submitting comments at <https://www.federalreserve.gov/apps/foia/proposedregs.aspx>.

- *Email:* regs.comments@federalreserve.gov. Include the OMB number or FR number in the subject line of the message.

- *FAX:* (202) 452–3819 or (202) 452–3102.

- *Mail:* Ann E. Misback, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW, Washington, DC 20551.

All public comments are available from the Board's website at <https://www.federalreserve.gov/apps/foia/proposedregs.aspx> as submitted, unless modified for technical reasons or to remove personally identifiable information at the commenter's request. Accordingly, comments will not be edited to remove any confidential business information, identifying information, or contact information. Public comments may also be viewed electronically or in paper in Room 146, 1709 New York Avenue NW, Washington, DC 20006, between 9:00 a.m. and 5:00 p.m. on weekdays. For security reasons, the Board requires that visitors make an appointment to inspect comments. You may do so by calling (202) 452–3684. Upon arrival, visitors will be required to present valid government-issued photo identification and to submit to security screening in order to inspect and photocopy comments.

Additionally, commenters may send a copy of their comments to the Office of Management and Budget (OMB) Desk

Officer for the Federal Reserve Board, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT:

Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551, (202) 452–3829.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. In exercising this delegated authority, the Board is directed to take every reasonable step to solicit comment. In determining whether to approve a collection of information, the Board will consider all comments received from the public and other agencies.

During the comment period for this proposal, a copy of the proposed PRA OMB submission, including the draft reporting form and instructions, supporting statement, and other documentation, will be made available on the Board's public website at <https://www.federalreserve.gov/apps/reportforms/review.aspx> or may be requested from the agency clearance officer, whose name appears above. Final versions of these documents will be made available at <https://www.reginfo.gov/public/do/PRAMain>, if approved.

Request for Comment on Information Collection Proposal

The Board invites public comment on the following information collection, which is being reviewed under authority delegated by the OMB under the PRA. Comments are invited on the following:

a. Whether the proposed collection of information is necessary for the proper performance of the Board's functions, including whether the information has practical utility;

b. The accuracy of the Board's estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

c. Ways to enhance the quality, utility, and clarity of the information to be collected;

d. Ways to minimize the burden of information collection on respondents, including through the use of automated

collection techniques or other forms of information technology; and

e. Estimates of capital or startup costs and costs of operation, maintenance, and purchase of services to provide information.

At the end of the comment period, the comments and recommendations received will be analyzed to determine the extent to which the Board should modify the proposal.

Proposal Under OMB Delegated Authority To Extend for Three Years, With Revision, the Following Information Collection

Report title: Recordkeeping and Disclosure Requirements Associated with Loans Secured by Real Estate Located in Flood Hazard Areas Pursuant to Section 208.25 of Regulation H.

Agency form number: FR H–2.

OMB control number: 7100–0280.

Frequency: On occasion.

Respondents: State member banks (SMBs).

Estimated number of respondents: Recordkeeping: Private flood insurance (Sections 208.25(c)(3)(iii) and (iv)), 11,171; Retention of standard Federal Emergency Management Agency (FEMA) form (Section 208.25(f)(2)), 728; Notice of special flood insurance (Section 208.25(i)), 728; Disclosure: Notice of special flood hazards and availability of federal disaster relief assistance with escrow notice, as applicable (Sections 208.25(i) and (e), as applicable), 728; Notice to FEMA of servicer (Section 208.25(j)(1)), 728; Notice to FEMA of change of servicer (Section 208.25(j)(2)), 728; Notice to borrowers of lapsed mandated flood insurance (Section 208.25(g)), 728; Purchase of flood insurance on the borrower's behalf (Section 208.25(g)), 728; Notice to borrowers of lapsed mandated flood insurance due to remapping (Section 208.25(g)), 728; Purchase of flood insurance on the borrower's behalf due to remapping (Section 208.25(g)), 728; One-time notice for any designated loan outstanding on July 1 of the year SMB no longer qualifies for small lender exception, 12.

Estimated average time per response: Recordkeeping: Private flood insurance (Sections 208.25(c)(3)(iii) and (iv)), 15 minutes; Retention of standard FEMA form (Section 208.25(f)(2)), 2.5 minutes; Notice of special flood insurance (Section 208.25(i)), 2.5 minutes; Disclosure: Notice of special flood hazards and availability of federal disaster relief assistance with escrow notice, as applicable (Sections 208.25(i) and (e), as applicable), 5 minutes; Notice to FEMA of servicer (Section

208.25(j)(1)), 5 minutes; Notice to FEMA of change of servicer (Section 208.25(j)(2)), 5 minutes; Notice to borrowers of lapsed mandated flood insurance (Section 208.25(g)), 5 minutes; Purchase of flood insurance on the borrower's behalf (Section 208.25(g)), 15 minutes; Notice to borrowers of lapsed mandated flood insurance due to remapping (Section 208.25(g)), 5 minutes; Purchase of flood insurance on the borrower's behalf due to remapping (Section 208.25(g)), 15 minutes; One-time notice for any designated loan outstanding on July 1 of the year SMB no longer qualifies for small lender exception, 40 hours.

Estimated annual burden hours: Recordkeeping: Private flood insurance (Sections 208.25(c)(3)(iii) and (iv)), 2,793; Retention of standard FEMA form (Section 208.25(f)(2)), 12,255; Notice of special flood insurance (Section 208.25(i)), 2,457; Disclosure: Notice of special flood hazards and availability of federal disaster relief assistance with escrow notice, as applicable (Sections 208.25(i) and (e), as applicable), 4,914; Notice to FEMA of servicer (Section 208.25(j)(1)), 4,914; Notice to FEMA of change of servicer (Section 208.25(j)(2)), 2,487; Notice to borrowers of lapsed mandated flood insurance (Section 208.25(g)), 971; Purchase of flood insurance on the borrower's behalf (Section 208.25(g)), 728; Notice to borrowers of lapsed mandated flood insurance due to remapping (Section 208.25(g)), 485; Purchase of flood insurance on the borrower's behalf due to remapping (Section 208.25(g)), 728; One-time notice for any designated loan outstanding on July 1 of the year SMB no longer qualifies for small lender exception, 480.

General description of report: In general, the federal flood insurance statutes and Regulation H—Membership of State Banking Institutions in the Federal Reserve System (12 CFR 208) provide that a lender shall not make, increase, extend, or renew a loan secured by a building or mobile home located in a special flood hazard area unless the secured property is covered by flood insurance for the term of the loan. With respect to the recordkeeping and disclosure provisions, the regulation generally requires state member banks to retain certain flood hazard documentation and to notify borrowers and servicers regarding properties in flood hazard areas and requirements related to flood insurance. State member banks also must notify FEMA of the identity of, and any change in, the servicer of a loan secured by improved property in a special flood hazard area.

Proposed revisions: The Board proposes to revise the FR H–2 information collection to account for the recordkeeping provision in section 208.25(i) of Regulation H that had not been previously cleared by the Board under the PRA. When a state member bank makes, increases, extends, or renews a loan secured by a building or a mobile home located or to be located in a special flood hazard area, Regulation H requires that the bank mail or deliver a written notice to the borrower and to the servicer in all cases indicating whether flood insurance is available under the National Flood Insurance Program (NFIP) for the collateral securing the loan. The state member bank must retain a record of the receipt of the notices by the borrower and the servicer for the period of time the bank owns the loan.

Legal authorization and confidentiality: Section 102 of the Flood Disaster Protection Act of 1973, as amended,¹ and section 1364 of the National Flood Insurance Act, as amended,² authorize the Board to impose the disclosure and recordkeeping requirements in section 208.25 of Regulation H. The obligation to comply is mandatory.

Because the Federal Reserve does not collect information from the FR H–2, confidentiality issues generally would not arise. In the event the records are obtained by the Board as part of the examination or supervision of a financial institution, this information may be considered confidential pursuant to exemption 8 of the Freedom of Information Act, which protects information contained in “examination, operating, or condition reports” obtained in the bank supervisory process.³

Board of Governors of the Federal Reserve System, October 27, 2021.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2021–23802 Filed 11–3–21; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Notice, request for comment.

¹ 42 U.S.C. 4012a.

² 42 U.S.C. 4104a.

³ 5 U.S.C. 552(b)(8). The Board also has the authority to require reports from state member banks. (12 U.S.C. 248(a) and 324).

SUMMARY: The Board of Governors of the Federal Reserve System (Board) invites comment on a proposal to extend for three years, without revision, FR 2248-Domestic Finance Company Report of Consolidated Assets and Liabilities.

DATES: Comments must be submitted on or before January 3, 2022.

ADDRESSES: You may submit comments, identified by FR 2248, by any of the following methods:

- **Agency website:** <https://www.federalreserve.gov/>. Follow the instructions for submitting comments at <https://www.federalreserve.gov/apps/foia/proposedregs.aspx>.

- **Email:** regs.comments@federalreserve.gov. Include the OMB number 7100–0005 or FR–2248 in the subject line of the message.

- **FAX:** (202) 452–3819 or (202) 452–3102.

- **Mail:** Ann E. Misback, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW, Washington, DC 20551.

All public comments are available from the Board's website at <https://www.federalreserve.gov/apps/foia/proposedregs.aspx> as submitted, unless modified for technical reasons or to remove personally identifiable information at the commenter's request. Accordingly, comments will not be edited to remove any confidential business information, identifying information, or contact information. Public comments may also be viewed electronically or in paper in Room 146, 1709 New York Avenue NW, Washington, DC 20006, between 9:00 a.m. and 5:00 p.m. on weekdays. For security reasons, the Board requires that visitors make an appointment to inspect comments. You may do so by calling (202) 452–3684. Upon arrival, visitors will be required to present valid government-issued photo identification and to submit to security screening in order to inspect and photocopy comments.

Additionally, commenters may send a copy of their comments to the Office of Management and Budget (OMB) Desk Officer for the Federal Reserve Board, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve

System, Washington, DC 20551, (202) 452–3829.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. In exercising this delegated authority, the Board is directed to take every reasonable step to solicit comment. In determining whether to approve a collection of information, the Board will consider all comments received from the public and other agencies.

During the comment period for this proposal, a copy of the proposed PRA OMB submission, including the draft reporting form and instructions, supporting statement, and other documentation, will be made available on the Board's public website at <https://www.federalreserve.gov/apps/reportforms/review.aspx> or may be requested from the agency clearance officer, whose name appears above. Final versions of these documents will be made available at <https://www.reginfo.gov/public/do/PRAMain>, if approved.

Request for Comment on Information Collection Proposal

The Board invites public comment on the following information collection, which is being reviewed under authority delegated by the OMB under the PRA. Comments are invited on the following:

- Whether the proposed collection of information is necessary for the proper performance of the Board's functions, including whether the information has practical utility;

- The accuracy of the Board's estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

- Ways to enhance the quality, utility, and clarity of the information to be collected;

- Ways to minimize the burden of information collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

- Estimates of capital or startup costs and costs of operation, maintenance, and purchase of services to provide information.

At the end of the comment period, the comments and recommendations received will be analyzed to determine the extent to which the Board should modify the proposal.

Proposal Under OMB Delegated Authority To Extend for Three Years, Without Revision, the Following Information Collection

Report title: Domestic Finance Company Report of Consolidated Assets and Liabilities.

Agency form number: FR 2248.

OMB control number: 7100–0005.

Frequency: Monthly, quarterly, as needed.

Respondents: Finance companies.¹

Estimated number of respondents: Monthly, 150; Quarterly, 150; Addendum, 150.

Estimated average minutes per response: Monthly, 20; Quarterly, 30; Addendum, 10.

Estimated annual burden hours: Monthly, 400; Quarterly, 300; Addendum, 50.

General description of report: The FR 2248 is collected monthly as of the last calendar day of the month from a stratified sample² of finance companies. Each monthly report collects balance sheet data on major categories of consumer and business credit receivables and on major short-term liabilities. For quarter-end months (March, June, September, and December), additional asset and liability items are collected to provide a full balance sheet. A supplemental section collects data on securitized assets. Board staff may ask either quantitative or qualitative questions through the use of a special addendum section no more than twice per year. The data are used to construct universe estimates of finance company holdings, which are published in the monthly statistical releases Finance Companies (G.20) and Consumer Credit (G.19) and in the quarterly statistical release Financial Accounts of the United States (Z.1).³

Legal authorization and confidentiality: The FR 2248 is authorized by sections 2A and 12A of the Federal Reserve Act (FRA). Section

¹ Finance companies include companies in which 50 percent or more of assets are held in any of the following types of loan or lease assets: (1) Liens on real estate, defined as outstanding balances on loans or leases, for any purpose, secured by liens on real estate; (2) loans and leases not secured by real estate, such as business loans and leases, defined as outstanding balances on loans and on leases for commercial and industrial purposes to sole proprietorships, partnerships, corporations, and other business enterprises; or consumer loans and leases defined as outstanding balances on loans and on leases for household, family, and other personal expenditures.

² Potential universe of respondents is identified by the quinquennial Census of Finance Companies (FR 3033p) and Survey of Finance Companies (FR 3033s) (OMB No. 7100–0277). More details can be found in the OMB supporting statement.

³ See <https://www.federalreserve.gov/econresdata/statisticsdata.htm>.

2A of the FRA requires that the Board and the Federal Open Market Committee (FOMC) maintain long-run growth of the monetary and credit aggregates commensurate with the economy's long run potential to increase production, so as to promote effectively the goals of maximum employment, stable prices, and moderate long-term interest rates.⁴ Section 12A of the FRA further requires the FOMC to implement regulations relating to the open market operations conducted by Federal Reserve Banks with a view to accommodating commerce and business and with regard to their bearing upon the general credit situation of the country.⁵ The Board and FOMC use the information obtained through the FR 2248 to discharge these responsibilities. The FR 2248 is voluntary.

Although the Board releases aggregate data derived from the FR 2248 in the monthly G.20 and G.19 statistical releases, and in the quarterly Z.1 statistical release, individual finance company information provided by each respondent is generally treated as confidential. Information collected on the FR 2248 is likely to constitute nonpublic commercial or financial information, which is both customarily and actually treated as private by the respondent. Accordingly, such information may be kept confidential by the Board pursuant to exemption 4 of the Freedom of Information Act.⁶ If it should be determined that any information collected on the FR 2248 must be released, respondents would be notified.

Board of Governors of the Federal Reserve System, October 27, 2021.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2021-23803 Filed 11-3-21; 8:45 am]

BILLING CODE 6210-01-P

FEDERAL RESERVE SYSTEM

Agency Information Collection

Activities: Announcement of Board Approval Under Delegated Authority and Submission to OMB

AGENCY: Board of Governors of the Federal Reserve System.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) is adopting a proposal to extend for three years, with revision, FR 27—New Hire Information Collection.

DATES: The revisions are effective December 6, 2021.

FOR FURTHER INFORMATION CONTACT:

Federal Reserve Board Clearance Officer—Nuha Elmaghribi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551, (202) 452-3829.

Office of Management and Budget (OMB) Desk Officer for the Federal Reserve Board, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395-6974.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. The OMB inventory, as well as copies of the PRA Submission, supporting statements, and approved collection of information instrument(s) are available at <https://www.reginfo.gov/public/do/PRAMain>. These documents are also available on the Federal Reserve Board's public website at <https://www.federalreserve.gov/apps/reportforms/review.aspx> or may be requested from the agency clearance officer, whose name appears above.

Final Approval Under OMB Delegated Authority of the Extension for Three Years, With Revision, of the Following Information Collection

Report title: New Hire Information Collection.

Agency form number: FR 27.

OMB control number: 7100-0375.

Effective Date of Revisions: December 6, 2021.

Frequency: As needed.

Respondents: The FR 27 panel comprises individuals who are new hires to the Board but have not yet become employees.

Estimated number of respondents:

Regular hire: 312; intern hire: 122; federal transfer: 10.

Estimated average hours per response:

Regular hire: 1; intern hire: 0.75; federal transfer: 1.08.

Estimated annual burden hours:

Regular hire: 312; intern hire: 92; federal transfer: 11.

General description of report: This information collection provides for the electronic collection of certain personnel information from new hires using a secure web-based portal, the "New Hire Portal," before the first day

of employment of a new hire. As part of the onboarding process for new hires, a Human Resources professional at the Board identifies the necessary information that must be collected from the new hire, which is dependent upon whether the person will be starting as a full- or part-time employee, including a Governor or Board officer (Regular Hire) or starting as an intern (Intern Hire), or whether the Regular Employee is transferring from another federal agency (Federal Transfer). The new hire is then sent an email asking him or her to provide the information described below through the New Hire Portal prior to their official start date.

The New Hire Portal is broken out into different sections and each section corresponds to the hardcopy forms that new employees previously filled out and provide to the Board during or after the first day of new employee orientation (NEO). Thus, the information collection involves a new hire electronically providing this personnel information and filling out the applicable sections of the New Hire Portal before their first day of orientation. The sections of the portal that each new hire is asked to complete electronically depends upon the type of position that the new hire has been offered at the Board.

Legal authorization and confidentiality: The New Hire Information Collection is authorized pursuant to sections 10(3), 10(4), 11(l), and 11(q) of the Federal Reserve Act, which provide the Board broad authority over employment of staff and security of its building.¹ In addition, Executive Order 9397 (Nov. 22, 1943) authorizes Federal agencies to use an individual's social security number to identify individuals in agency records.

Providing information collected as part of the New Hire Information Collection is voluntary. However, if certain information requested as part of the New Hire Information Collection is not provided by the new hire, the hiring process cannot be completed.²

¹ 12 U.S.C. 243, 244, 248(l), and 248(q).

² The voluntary provision of the following information is optional and is not required to complete the hiring process: Education information (e.g., name of educational institution, major, degree, year of graduation), race, ethnicity, and the identity of and relationship to any relatives who are also employed at the Board. Although a new hire is required to provide the name and contact information of one "primary" emergency contact, providing a "second" emergency contact is optional and is not required to complete the hiring process. A new hire can also voluntarily provide an alternative mailing address, if it is different from his or her current address. Lastly, although not required to complete the hiring process, information on dependents is required to obtain certain benefits

Continued

⁴ 12 U.S.C. 225a.

⁵ 12 U.S.C. 263.

⁶ 5 U.S.C. 552(b)(4).

Generally, information collected as part of the New Hire Information Collection may be kept confidential from the public under exemption 6 of the Freedom of Information Act (FOIA), which protects information that “would constitute a clearly unwarranted invasion of personal privacy.”³ However, the release of information such as the educational history of the new hire or the start date of employment would not likely constitute a clearly unwarranted invasion of personal privacy and may be disclosed under the FOIA.

Determinations regarding disclosure to third parties of any confidential portions of the information collection that are considered exempt under the FOIA will be made in accordance with the Privacy Act.⁴ Relevant Privacy Act statements are provided when a respondent logs in to the portal and before the respondent is asked to provide any information. The Board may make disclosures in accordance with the Privacy Act’s routine use disclosure provision, which permits the disclosure of a record for a purpose which is compatible with the purpose for which the record was collected.⁵

Such routine uses are listed in specific systems of records notices, which apply to this information collection and which can be found in: (1) The System of Records Notice for BGFRS-1, FRB-Recruiting and Placement Records, located at: <https://www.federalreserve.gov/files/BGFRS-1-recruiting-and-placement-records.pdf>; (2) the System of Records Notice for BGFRS-4, FRB-General Personnel Records, located at: <https://www.federalreserve.gov/files/BGFRS-4-general-personnel-records.pdf>; (3) the System of Records Notice for BGFRS-7, FRB—Payroll and Leave Records, located at: <https://www.federalreserve.gov/files/BGFRS-7-payroll-and-leave-records.pdf>; (4) the System of Records Notice for BGFRS-24, FRB—EEO General Files, located at: <https://www.federalreserve.gov/files/BGFRS-24-eo-general-files.pdf>; and/or (5) the System of Records Notice for BGFRS-34, FRB—ESS Staff Identification Card File, located at: <https://www.federalreserve.gov/files/BGFRS-34-ess-staff-identification-card-file.pdf>.

Current actions: On May 25, 2021, the Board published a notice in the **Federal Register** (86 FR 28107) requesting

public comment for 60 days on the extension with revision, of the New Hire Information Collection (FR 27). The revisions remove certain fields from the information collected on this form regarding direct deposits. The comment period for this notice expired on July 26, 2021. The Board did not receive any comments. The revisions will be implemented as proposed.

Board of Governors of the Federal Reserve System, October 27, 2021.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2021-23804 Filed 11-3-21; 8:45 am]

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FEDERAL TRADE COMMISSION

Enforcement Policy Statement Regarding Negative Option Marketing

AGENCY: Federal Trade Commission.

ACTION: Commission policy statement.

SUMMARY: The Federal Trade Commission (“FTC” or “Commission”) has issued a policy statement to provide guidance regarding its enforcement of various statutes and FTC regulations addressing negative option marketing and operating. This Statement is intended to assist the business community and practitioners by providing specific guidance on the Commission’s interpretation of existing law as it applies to negative option practices. This Statement may also assist the courts in developing an appropriate framework for interpreting and applying the various statutes and regulations addressing negative option marketing discussed herein.

DATES: The Commission announced the issuance of the Statement on October 29, 2021.

FOR FURTHER INFORMATION CONTACT: Tom Dahdouh (202-326-2552), Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION:

I. Introduction and Background

The Federal Trade Commission (“FTC” or “Commission”) issues this Policy Statement to provide guidance regarding its enforcement of various statutes and FTC regulations addressing negative option marketing and operating.¹ This Statement is intended

to assist the business community and practitioners by providing specific guidance on the Commission’s interpretation of existing law as it applies to negative option practices. This Statement may also assist the courts in developing an appropriate framework for interpreting and applying the various statutes and regulations addressing negative option marketing discussed herein.

Negative option offers come in a variety of forms, but all share a central feature: Each contains a term or condition under which the seller may interpret a consumer’s silence or failure to take affirmative action to reject a good or service or to cancel the agreement as acceptance or continuing acceptance of the offer.² Typically, negative option arrangements include, but are not limited to, automatic renewals, continuity plans, free-to-pay or fee-to-pay conversions, and prenotification plans. Automatic renewals allow sellers (e.g., a magazine publisher) to unilaterally renew consumers’ subscriptions when they expire, unless consumers affirmatively cancel their subscriptions by a certain date. Continuity plans allow consumers to agree in advance to receive periodic shipments of goods or provision of services (e.g., bottled water delivery), which they continue to receive until they cancel the agreement. Free trial marketing (e.g., free-to-pay conversions) provides consumers the opportunity to receive goods or services for free (or at a nominal fee) for a trial period. After the trial period, sellers can automatically begin charging a fee (or higher fee) unless consumers affirmatively cancel or return the goods or services. Finally, under prenotification plans³ (e.g., book-of-the-month clubs), sellers provide periodic notices offering goods to participating consumers and then send—and charge for—those goods only if the consumers

practice violates one or more existing statutory or regulatory requirements. In addition, this Policy Statement does not preempt federal, state, or local laws. Compliance with those laws, however, will not necessarily preclude Commission law enforcement action under the FTC Act or other statutes. Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this Policy Statement as not a “major rule,” as defined by 5 U.S.C. 804(2).

² The Commission’s Telemarketing Sales Rule (16 CFR part 310) defines a negative option feature as a provision in an offer or agreement to sell or provide any goods or services “under which the customer’s silence or failure to take an affirmative action to reject goods or services or to cancel the agreement is interpreted by the seller as acceptance of the offer.” 16 CFR 310.2(w).

³ The Commission’s Rule on the “Use of Prenotification Negative Option Plans” (16 CFR part 425) only covers this type of negative option marketing.

(such as continuing health insurance benefits for the child or spouse of a new employee who is transferring from another federal agency).

³ 5 U.S.C. 552(b)(6).

⁴ 5 U.S.C. 552a(b).

⁵ 5 U.S.C. 552a(a)(7) and (b)(3)).

¹ This Policy Statement elaborates on principles announced by the Commission in individual cases and rules issued over the course of many years. This Policy Statement does not confer any rights on any person and does not operate to bind the FTC or the public. In any enforcement action, the Commission must prove the challenged act or

take no action to decline the offer. The periodic announcements and shipments can continue indefinitely.⁴

Negative option programs are widespread in the marketplace and can provide substantial benefits for sellers and consumers. At the same time, consumers suffer costs when marketers fail to make adequate disclosures, bill consumers without their consent, or make cancellation difficult or impossible. Over the years, unfair or deceptive negative option practices have remained a persistent source of consumer harm, often saddling shoppers with recurring payments for products and services they did not intend to purchase or did not want to continue to purchase.⁵ To address this problem, the Commission and states regularly bring cases challenging a variety of harmful negative option practices. These matters involve a range of deceptive or unfair practices, including inadequate disclosures of hidden charges in ostensibly “free” offers and other products or services, enrollment without consumer consent, and inadequate or overly burdensome cancellation and refund procedures.⁶ In addition, the Commission receives thousands of complaints each year related to negative option marketing. The number of ongoing cases and high volume of complaints demonstrate there

is prevalent, unabated consumer harm in the marketplace.

The FTC’s enforcement actions primarily rely on Section 5 of the FTC Act (15 U.S.C. 45(a)), the Restore Online Shoppers’ Confidence Act (“ROSCA”) (15 U.S.C. 8401 through 8405), and the Telemarketing Sales Rule (16 CFR part 310). However, the Rule on the Use of Prenotification Negative Option Plans (16 CFR part 425), the Electronic Fund Transfer Act (“EFTA”) (15 U.S.C. 1693 through 1693r), and the Postal Reorganization Act (*i.e.*, the Unordered Merchandise Statute) (39 U.S.C. 3009) also address various aspects of negative option marketing.

Section 5 of the FTC Act: Section 5 of the FTC Act, which prohibits unfair or deceptive acts or practices, is the core consumer protection statute enforced by the Commission, and therefore, has traditionally served as the primary mechanism for addressing deceptive negative option claims.⁷ In its guidance and cases, the FTC has highlighted four basic Section 5 requirements negative option marketing must follow to comply with Section 5.⁸ First, marketers must clearly and conspicuously disclose the material terms of a negative option offer including, at a minimum, key terms such as the existence of the negative option offer, the offer’s total cost, and

how to cancel the offer.⁹ Second, sellers must disclose these material terms before consumers agree to the purchase.¹⁰ Third, marketers must obtain consumers’ express informed consent to such offers.¹¹ Finally, marketers must not erect unreasonable barriers to cancellation or impede the effective operation of promised cancellation procedures, and must honor cancellation requests that comply with such procedures.¹² Although these basic guidelines are useful, the legality of a particular negative option depends on an individualized assessment of the advertisement’s net impression and the marketer’s business practices.¹³

ROSCA: Enacted by Congress in 2010 to address ongoing problems with online negative option marketing, ROSCA prohibits charging or attempting to charge consumers for goods or services sold on the internet through any negative option feature¹⁴ unless the marketer: (1) Clearly and conspicuously discloses all material terms of the transaction¹⁵ before obtaining the consumer’s billing information; (2) obtains a consumer’s express informed

⁹ See, e.g., *FTC v. JAB Ventures*; *FTC v. Complete Weightloss Center*; *FTC v. NutraClick, LLC*.

¹⁰ See, e.g., *FTC v. JAB Ventures*; *Complete Weightloss Center*; *FTC v. Berkeley Premium Nutraceutical*; *FTC v. Think All Publ’g*. Disclosures earlier in the transaction may be necessary to avoid deception. See e.g., *FTC’s Dot Com Disclosures* guidance.

¹¹ E.g., *FTC v. Neovi, Inc.*, 604 F.3d 1150, 1157–59 (9th Cir. 2010), amended by 2010 WL 2365956 (9th Cir. June 15, 2010); *FTC v. Amazon.com, Inc.*, No. C14–1038–JCC, 2016 WL 10654030, at *8 (W.D. Wash. Apr. 26, 2016); *FTC v. Ideal Fin. Sols., Inc.*, No. 2:13–CV–00143–JAD, 2015 WL 4032103, at *8 (D. Nev. June 29, 2015); *FTC v. BunZai Media Group, Inc.*

¹² See, e.g., *FTC v. Universal Premium Services*; *FTC v. Remote Response*; *FTC v. Berkeley Premium Nutraceuticals*; *FTC v. Hispanexo*; *FTC v. Age of Learning, Inc.*

¹³ See, e.g., *Negative Options: A Report by the Staff of the FTC’s Division of Enforcement*, 28.

¹⁴ 15 U.S.C. 8403. ROSCA incorporates the definition of “negative option feature” from the Commission’s Telemarketing Sales Rule, 16 CFR 310.2(w). ROSCA also contains a finding that “Third party sellers used a free trial period to enroll members, after which they periodically charged consumers until consumers affirmatively canceled the memberships. This use of “free-to-pay conversion” and “negative option” sales took advantage of consumers’ expectations that they would have an opportunity to accept or reject the membership club offer at the end of the trial period.” 15 U.S.C. 8401(8). Finally, in addition to addressing negative option marketing, ROSCA contains provisions related to third party “post transaction” offers. See, e.g., 15 U.S.C. 8402.

¹⁵ The Commission has brought several cases alleging a failure to disclose adequately the terms of the negative option feature. See, e.g., *FTC v. NutraClick II*; *FTC v. Triangle Media Corporation*; *FTC v. AAFE Products Corp.* The Commission recently alleged failure to disclose a material term of the underlying service that was necessary to prevent deception violated this provision of ROSCA. *In re: MoviePass, Inc.*, No. C–4751 (October 5, 2021).

⁴ In addition, some negative option offers include upsell or bundled offers, where sellers use consumers’ billing data to sell additional products from the same seller or pass consumers’ billing data to a third party for their sales. An upsell occurs when a consumer completes a first transaction and then receives a second solicitation for an additional product or service. A bundled offer occurs when a seller packages two or more products or services together so they cannot be purchased separately.

⁵ See, e.g., n. 6 *infra*.

⁶ Recent examples of these matters include: *FTC v. JDI Dating, Ltd.*, No. 1:14–cv–08400 (N.D. Ill. 2014); *FTC, State of Illinois, and State of Ohio v. One Technologies, LP*, No. 3:14–cv–05066 (N.D. Cal. 2014); *FTC v. Health Formulas, LLC*, No. 2:14–cv–01649–RFB–GWF (D. Nev. 2016); *FTC v. BunZai Media Group, Inc.*, No. 2:15–cv–04527–GW–PLA (C.D. Cal. 2015); *FTC v. NutraClick LLC*, No. 2:16–cv–06819–DMG–JPR (C.D. Cal. 2016) (*NutraClick I*); *FTC v. DOTAuthority.com, Inc.*, No. 0:16–cv–62186–WJZ (S.D. Fla. 2016); *FTC v. XXL Impressions*, No. 1:17–cv–00067–NT (D. Me. 2017); *FTC v. AAFE Products Corp.*, No. 3:17–cv–00575 (S.D. Cal. 2017); *FTC v. RevMountain, LLC*, No. 2:17–cv–02000–APG–GWF (D. Nev. 2017); *FTC v. Pact, Inc.*, No. 2:17–cv–01429 (W.D. Wash. 2017); *FTC v. Tarr*, No. 3:17–cv–02024–LAB–KSC (S.D. Cal. 2017); *FTC v. Credit Bureau Center, LLC*, No. 17–cv–00194 (N.D. Ill. 2017); *FTC v. AdoreMe, Inc.*, No. 1:17–cv–09083 (S.D.N.Y. 2017); *FTC v. Triangle Media Corp.*, No. 3:18–cv–01388–LAB–LL (S.D. Cal. 2018); *In re: UrthBox, Inc.*, No. C–4676 (FTC 2019); *FTC v. Elite IT Partners, Inc.*, No. 2:19–cv–00125–RJS (D. Utah 2019); *FTC v. Apex Capital Group, LLC*, No. 2:18–cv–09573–JFW–JPR (C.D. Cal. 2018); *FTC v. AH Media*, No. 3:19–cv–04022–JD (N.D. Cal. 2019); *FTC v. Age of Learning, Inc.*, No. 2:20–cv–07996 (C.D. Cal. 2020); *FTC v. NutraClick, LLC*, No. 2:20–cv–08612 (C.D. Cal. 2020) (*NutraClick II*).

⁷ Section 5 specifically states “unfair or deceptive acts or practices in or affecting commerce . . . are . . . declared unlawful.” The FTC Act defines “unfair or deceptive acts or practices” to include such acts or practices involving foreign commerce that cause or are likely to cause reasonably foreseeable injury within the United States or involve material conduct occurring within the United States (15 U.S.C. 45(a)(4)(A)). It also defines “unfair” practices as those that cause or are likely “to cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or to competition” (15 U.S.C. 45(n)).

⁸ See *Negative Options: A Report by the Staff of the FTC’s Division of Enforcement*, 26–29 (Jan. 2009), <https://www.ftc.gov/sites/default/files/documents/reports/negative-options-federal-trade-commission-workshop-analyzing-negative-option-marketing-report-staff/p064202negativeoptionreport.pdf>. In discussing the principal Section 5 requirements related to negative options, the report cites to the following pre-ROSCA cases, *FTC v. JAB Ventures*, No. CV08–04648 (C.D. Cal. 2008); *FTC v. Complete Weightloss Center*, No. 1:08cv00053 (D.N.D. 2008); *FTC v. Berkeley Premium Nutraceuticals*, No. 1:06cv00051 (S.D. Ohio 2006); *FTC v. Think All Publ’g*, No. 4:07cv11 (E.D. Tex. 2006); *FTC v. Hispanexo*, No. 1:06cv424 (E.D. Va. 2006); *FTC v. Consumerinfo.com*, No. SACV05–801 (C.D. Cal. 2005); *FTC v. Conversion Mktg.*, No. SACV04–1264 (C.D. Cal. 2004); *FTC v. Mantra Films*, No. CV03–9184 (C.D. Cal. 2003); *FTC v. Preferred Alliance*, No. 103–CV0405 (N.D. Ga. 2003); *United States v. Prochnow*, No. 1:02–CV–0917 (N.D. Ga. 2002); *FTC v. Ultralife Fitness, Inc.*, No. 2:08–cv–07655–DSF–PJW (C.D. Cal. 2008); *In the Matter of American Isuzu Motors*, No. C–3712 (FTC 1997); *FTC v. Universal Premium Services*, No. CV06–0849 (C.D. Cal. 2006); *FTC v. Remote Response*, No. 06–20168 (S.D. Fla. 2006); and *FTC’s Dot Com Disclosures* guidance.

consent before charging the consumer's account;¹⁶ and (3) provides simple mechanisms for the consumer to stop recurring charges.¹⁷

ROSCA also addresses offers made by, or on behalf of, third-party sellers during, or immediately following, a transaction with an initial merchant. Specifically, ROSCA prohibits post-transaction, third-party sellers¹⁸ from charging or attempting to charge consumers unless the seller: (1) Before obtaining billing information, clearly and conspicuously discloses the offer's material terms; and (2) receives the consumer's express informed consent by obtaining the consumer's name, address, contact information, as well as the full account number to be charged, and requiring the consumer to perform an additional affirmative action indicating consent.¹⁹ ROSCA also prohibits initial merchants from disclosing billing information to any post-transaction third-party seller for use in any internet-based sale of goods or services.²⁰

Furthermore, ROSCA provides a violation of that Act is a violation of a Commission trade regulation rule under Section 18 of the FTC Act.²¹ Thus, the Commission may seek a variety of remedies for violations of ROSCA, including civil penalties under Section 5(m)(1)(A) of the FTC Act;²² injunctive relief under Section 13(b) of the FTC Act;²³ and consumer redress, such as damages, and other relief under Section 19 of the FTC Act.²⁴ Although Congress charged the Commission with enforcing ROSCA, it did not direct the FTC to promulgate implementing regulations.²⁵

Telemarketing Sales Rule: The TSR prohibits deceptive telemarketing acts or practices, including those involving negative option offers, and certain types of payment methods common in

deceptive negative option marketing. Specifically, the TSR requires telemarketers to disclose all material terms and conditions of the negative option feature, including the need for affirmative consumer action to avoid the charges, the date (or dates) the charges will be submitted for payment, and the specific steps the customer must take to avoid the charges. It also prohibits telemarketers from misrepresenting such information and contains specific requirements related to payment authorization.²⁶ Finally, the TSR prohibits the use of payment methods often used in deceptive marketing, including negative options, such as remotely created checks.²⁷ The rule, however, only applies to negative option offers made over the telephone.

Prenotification Plan Rule: The Commission promulgated the "Use of Prenotification Negative Option Plans" Rule ("Prenotification Plan Rule") (16 CFR part 425).²⁸ The Prenotification Plan Rule requires sellers of such plans to clearly and conspicuously disclose their plan's material terms before consumers subscribe. It enumerates seven material terms sellers must disclose: (1) How subscribers must notify the seller if they do not wish to purchase the selection; (2) any minimum purchase obligations; (3) the subscribers' right to cancel; (4) whether billing charges include postage and handling; (5) that subscribers have at least ten days to reject a selection; (6) that, if any subscriber is not given ten days to reject a selection, the seller will credit the return of the selection and postage to return the selection, along with shipping and handling; and (7) the frequency with which announcements and forms will be sent.²⁹ In addition, sellers must provide particular periods during which they will send introductory merchandise, give consumers a specified period to respond to announcements, provide instructions for rejecting merchandise in announcements, and promptly honor written cancellation requests.³⁰

The Prenotification Plan Rule applies only to plans like book-of-the-month clubs in which sellers provide periodic notices offering goods to participating consumers and then send—and charge for—those goods only if the consumers take no action to decline the offer. These types of plans, however, account for only a small fraction of current negative option marketing. Therefore, the rule does not reach most modern negative option marketing.³¹

Other Relevant Requirements: EFTA³² and the Unordered Merchandise Statute³³ also contain provisions relevant to negative option marketing. EFTA prohibits sellers from imposing recurring charges on a consumer's debit cards or bank accounts without written authorization. The Unordered Merchandise Statute provides that mailing unordered merchandise, or a bill for such merchandise, constitutes an unfair method of competition and an unfair trade practice in violation of Section 5 of the FTC Act.

II. Principles for Negative Option Marketing

Given the number of applicable statutory and regulatory requirements and the ongoing problems in the marketplace, the Commission now issues the following enforcement guidance based on its enforcement history.³⁴ This guidance covers three areas commonly addressed by the Commission in its negative option cases: Disclosures, consent, and cancellation. These principles convey the Commission's current views on the application of relevant statutes and regulations to negative option marketing

¹⁶ See, e.g., *FTC v. BunZai Media Group, Inc.*; *FTC v. Health Formulas, LLC*; and *FTC v. JDI Dating, Ltd.*

¹⁷ See, e.g., *FTC v. Age of Learning, Inc.*; *FTC v. AdoreMe, Inc.*; and *FTC, State of Illinois, and State of Ohio v. One Technologies.*

¹⁸ ROSCA defines "post-transaction third-party seller" as a person other than the initial merchant who sells any good or service on the internet and solicits the purchase on the internet through an initial merchant after the consumer has initiated a transaction with the initial merchant. 15 U.S.C. 8402(d)(2).

¹⁹ 15 U.S.C. 8402(a).

²⁰ 15 U.S.C. 8402(b).

²¹ 15 U.S.C. 8404. Section 18 of the FTC Act is 15 U.S.C. 57a.

²² 15 U.S.C. 45(m)(1)(A).

²³ 15 U.S.C. 53(b).

²⁴ 15 U.S.C. 57b(a)(1) and (b).

²⁵ ROSCA states a violation "of this chapter or any regulation prescribed under this chapter shall be treated as a violation of a rule under section 18 of the Federal Trade Commission Act (15 U.S.C. 57a) regarding unfair or deceptive acts or practices." 15 U.S.C. 8404(a).

²⁶ 16 CFR part 310.3(a).

²⁷ 80 FR 77520 (December 14, 2015). The TSR Notice of Proposed Rulemaking (78 FR 41200 (July 9, 2013)) noted negative option cases where the defendants used unauthorized remotely created checks. E.g., *FTC v. FTM Promotions, Inc.*, Civ. No. 8:07–1279 (M.D. Fla. Dec. 30, 2008) (Stip. Perm. Inj.) (defendants allegedly caused more than \$171 million in unauthorized charges to consumers' accounts for bogus travel and buyers' clubs in part by using unauthorized remotely created checks).

²⁸ The Commission issued the rule after finding some negative option marketers committed unfair and deceptive practices that violated Section 5 of the Act. 15 U.S.C. 45.

²⁹ 16 CFR 425.1(a)(1)(i) through 425.1(a)(1)(vii).

³⁰ 16 CFR 425.1(a)(2) and (3); § 425.1(b).

³¹ The Prenotification Plan Rule defines "negative option plan" narrowly to apply only to prenotification plans. 16 CFR 425.1(c)(1). In 1998, the Commission clarified the rule's application to such plans in all media, stating it "covers all promotional materials that contain a means for consumers to subscribe to prenotification negative option plans, including those that are disseminated through newer technologies . . ." 63 FR 44555, 44561 (Aug. 20, 1998). In 2017, the Commission estimated fewer than 100 sellers ("clubs") were subject to the current rule's requirements. 82 FR 38907, 38908 (Aug. 16, 2017).

³² 15 U.S.C. 1693 through 1693r.

³³ 39 U.S.C. 3009.

³⁴ In an October 2, 2019 document (84 FR 52393), the Commission sought comment on the need for amendments to the "Rule Concerning the Use of Prenotification Negative Option Plans" (i.e., "Negative Option Rule" (16 CFR part 425)) to help consumers avoid recurring payments for products and services they did not intend to order and to allow them to cancel such payments without unwarranted obstacles. The Commission will continue to closely monitor compliance with the rules and laws applicable to negative option marketing, and is still considering various options in the rule review proceeding for the Negative Option Rule.

and, as such, should help marketers in their compliance efforts and better understand how the Commission enforces the law.

Disclosures: ROSCA³⁵ requires marketers to clearly and conspicuously disclose the material terms of the transaction.³⁶ Pursuant to longstanding precedent, any express claim or deliberately implied claim is presumed to be material.³⁷ Moreover, the FTC's cases for failure to disclose under Section 5 of the FTC Act are generally consistent with ROSCA.³⁸ Those terms at minimum should include:

- Any material terms related to the underlying product or service that are necessary to prevent deception, regardless of whether that term directly relates to the terms of the negative option offer;³⁹
- That consumers will be charged⁴⁰ for the good or service, or that those charges will increase after any applicable trial period ends, and, if applicable, that the charges will be on a recurring basis, unless the consumer timely takes steps to prevent or stop such charges;
- Each deadline (by date or frequency) by which the consumer must act in order to stop the charges;
- The amount (or range of costs) the consumer will be charged or billed and, if applicable, the frequency of such charges a consumer will incur unless the consumer takes timely steps to prevent or stop those charges;
- The date (or dates) each charge will be submitted for payment; and

- All information necessary to cancel the contract.

These disclosures must be clear and conspicuous.⁴¹ To meet this standard, offers should be difficult to miss (*i.e.*, easily noticeable) or unavoidable and easily understandable by ordinary consumers, including:

- In any communication that is solely visual or solely audible, the disclosure should be made through the same means through which the communication is presented. In any communication made through both visual and audible means, such as a television advertisement, the disclosure should be presented simultaneously in both the visual and audible portions of the communication even if the representation requiring the disclosure is made in only one means.
- A visual disclosure, by its size, contrast, location, the length of time it appears, and other characteristics, should stand out from any accompanying text or other visual elements so it is easily noticed, read, and understood.
- An audible disclosure, including by telephone or streaming video, should be delivered in a volume, speed, and cadence sufficient for ordinary consumers to easily hear and understand it.
- In any communication using an interactive electronic medium, such as the internet or software, the disclosure should be unavoidable. A disclosure is not clear and conspicuous if a consumer needs to take any action, such as clicking on a hyperlink or hovering over an icon, to see it.
- The disclosure should use diction and syntax understandable to ordinary consumers and should appear in each language in which the representation that requires the disclosure appears.
- The disclosure should comply with these requirements in each medium through which it is received, including all electronic devices and face-to-face communications.
- The disclosure should not be contradicted or mitigated by, or inconsistent with, anything else in the communication.⁴²
- When the representation or sales practice targets a specific audience,

such as children, the elderly, or the terminally ill, “ordinary consumers” includes reasonable members of that group.

Additionally, if the disclosures are in writing (including on the internet), they should:

- if related to the negative option feature, appear immediately adjacent to the means of recording the consumer's consent for the negative option feature;
- if not related to the negative option feature, appear before consumers make a decision to buy (*e.g.*, before they “add to shopping cart”); and
- not contain any other information that interferes with, detracts from, contradicts, or otherwise undermines the ability of consumers to read and understand the disclosures, including any information not directly related to the material terms and conditions of any negative option feature.

For all telephone and other oral offers, the disclosures should not contain any other information that interferes with, detracts from, contradicts, or otherwise undermines the ability of consumers to understand the disclosures, including any information not directly related to the material terms and conditions of any negative option feature.

Consent:⁴³ ROSCA, judicial decisions applying Section 5, and cases brought by the Commission under those laws make clear marketers should obtain the consumer's express informed consent before charging the consumer.⁴⁴ To attain express informed consent, the negative option seller should:

- obtain the consumer's acceptance of the negative option feature offer separately from any other portion of the entire transaction;
- not include any information that interferes with, detracts from, contradicts, or otherwise undermines the ability of consumers to provide their express informed consent to the negative option feature;⁴⁵
- obtain the consumer's unambiguously affirmative consent to the negative option feature;⁴⁶

³⁵ Any reference to ROSCA in these principles applies only to internet transactions, consistent with that statute's coverage.

³⁶ Of course, sellers fail to disclose adequately material terms if the disclosed terms are not truthful and substantiated.

³⁷ See, *e.g.*, *FTC Statement on Deception*, 103 F.T.C. 174, 182 (1984) (appended to *Cliffdale Assocs., Inc.*, 103 F.T.C. 110 (1984)); *Thompson Medical Co.*, 104 F.T.C. 648, 816 (1984).

³⁸ The Commission has consistently brought cases for deceptive and pure omissions of material fact. See, *e.g.*, *FTC v. Roca Labs, Inc.*, 345 F. Supp. 3d 1375, 1390 (M.D. Fla. 2018); *FTC v. NPB Advert., Inc.*, 218 F. Supp. 3d 1352, 1361 (M.D. Fla. 2016); *FTC v. Am. Standard Credit Sys., Inc.*, 874 F. Supp. 1080, 1088 (C.D. Cal. 1994); *FTC v. BlueHippo Funding, LLC*, 762 F.3d 238, 241 (2d Cir. 2014). But see, *In re International Harvester*, 104 F.T.C. 949, 1059 (1984) (Not all omissions are deceptive or unfair. “The number of facts that may be material to consumers—and on which they may have prior misconceptions—is literally infinite.”)

³⁹ The Commission recently alleged a negative option seller's failure to disclose it was impeding access to its movie subscription service violates ROSCA. *In the Matter of MoviePass, Inc.*

⁴⁰ “Charge,” “Charged,” or “Charging,” for the purposes of this Policy Statement, means any attempt to collect money or other consideration from a consumer, including but not limited to causing Billing Information to be submitted for payment, including against the consumer's credit card, debit card, bank account, telephone bill, or other account.

⁴¹ *Supra* at nn. 9 and 15.

⁴² An example of an inadequate disclosure is one where the consumer sees an offer upfront, in an electronic or written advertisement or on the landing page of a website, which is materially different from the terms of the offer presented in later stages, such as later web pages, of the ordering process. See, *e.g.*, *FTC v. E.M.A. Nationwide, Inc.*, 767 F.3d 611, 633 (6th Cir. 2014); *FTC v. Fed. Loan Modification Law Ctr., LLP*, No. SA-CV-09-401-CJC (MLGx) (C.D. Cal. 2010); *FTC v. Grant Connect, LLC*, 827 F. Supp. 2d 1199, 1214 (D. Nev. 2011).

⁴³ Negative option sellers covered by the Telemarketing Sales Rule should also ensure they are complying with the consent requirements in 16 CFR 310.4 specifically applicable to transactions involving a free-to-pay conversion and preacquired account information.

⁴⁴ *Supra* at nn. 11 and 16.

⁴⁵ Such information could appear on the product page itself (*e.g.*, extraneous language that interferes with the consumer's ability to provide consent) or in another location (*e.g.*, a separate web page containing information materially contradicting the information on the consent page).

⁴⁶ A “pre-checked box” does not constitute affirmative consent. In addition, the seller should clearly disclose the name of the billing entity authorized by the consumer's consent.

- obtain the consumer's unambiguously affirmative consent to the entire transaction; and

- be able to verify the consumer's consent.

Cancellation: ROSCA requires negative option sellers to provide a simple, reasonable means for consumers to cancel their contracts.⁴⁷ To meet this standard, negative option sellers should provide cancellation mechanisms at least as easy to use as the method the consumer used to initiate the negative option feature. For example, to ensure compliance with this simple cancellation mechanism requirement, negative option sellers should not subject consumers to new offers or similar attempts to save the negative option arrangement that impose unreasonable delays on consumers' cancellation efforts.⁴⁸ In addition, negative option sellers should provide their cancellation mechanisms at least through the same medium (such as website or mobile application) the consumer used to consent to the negative option feature. The negative option seller should provide, at a minimum, the simple mechanism over the same website or web-based application the consumer used to purchase the negative option feature. If the seller also provides for telephone cancellation, it should provide, at a minimum, a telephone number, and answer all calls to this number during normal business hours, within a short time frame, and ensure the calls are not lengthier or otherwise more burdensome than the telephone call the consumer used to consent to the negative option feature.

Finally, to comply with Section 5, a seller's cancellation procedures for negative option features should be effective. Sellers should not impede the effective operation of promised cancellation procedures, and should honor cancellation requests that comply with such procedures. In implementing effective cancellation procedures, marketers should not, among other things: Hang up on consumers who call to cancel; place them on hold for an unreasonably long time; provide false information about how to cancel; or misrepresent the reasons for delays in processing consumers' cancellation

requests.⁴⁹ If ROSCA applies, sellers must comply with both that statute and Section 5 of the FTC Act.

By direction of the Commission,
Commissioner Wilson dissenting.

April J. Tabor,
Secretary.

Concurring Statement of Commissioner Noah Joshua Phillips

I support the Commission's decision to issue an enforcement policy regarding negative option marketing. Negative option marketing—a ubiquitous feature of businesses from newspapers to water bottle delivery to video streaming—is currently covered by a patchwork of laws and regulations: Section 5 of the FTC Act, the Restore Online Shoppers' Confidence Act, the Telemarketing Sales Rule, the Rule on the Use of Prenotification Negative Option Plans, the Electronic Fund Transfer Act, and the Unordered Merchandise Statute. This policy statement sets forth a framework to explain what the Commission expects of participants in this space, apprising marketers of their obligations and informing consumers of their rights.

Drawing upon decisions by federal courts and the Commission about negative options, the policy statement lays out expectations concerning disclosures, consent from consumers, and how marketers must handle the consumer's ability to cancel. ROSCA, for example, requires a seller to provide “simple mechanisms for a consumer to stop recurring charges”.¹ The policy statement explains how the Commission interprets that, including a cancellation mechanism that is as easy to accomplish as signing up, whilst preserving the opportunity for a business to make an offer to induce a consumer to stay.² If you have ever signed up for something online but had to wait on hold on the telephone to cancel, this policy is for you.

Commissioner Wilson takes no issue with the substance of the policy statement itself, but instead is concerned about superseding the rulemaking process. Where the issuance of a statement supplants the rulemaking process effectively to declare a new “rule” solely by guidance and without notice and comment, I share that

reservation.³ Where, as here, the Commission is explaining its view of obligations under existing authorities, I think it better to pursue a lighter, less “regulatory” touch in the first instance. The Commission can pursue rulemaking later, if, and when, we determine a rule change is necessary.

Negative option marketing rulemaking implicates the requirements of the Magnuson-Moss Warranty-Federal Trade Commission Improvement Act. Even though the Commission has begun this process,⁴ this kind of rulemaking sensibly includes regulatory guardrails that have certain timing constraints and could require the consumption of substantial agency resources. The policy statement provides immediate guidance to industry, without the wait. If followed, there may be no need for a new rule. Apprising industry of its obligations, and saving consumers money they might otherwise lose because of problematic negative option marketing practices, is a win for both.

Dissenting Statement of Commissioner Christine S. Wilson

Today the Commission issues a Policy Statement Regarding Negative Option Marketing to “provide guidance regarding its enforcement of various statutes and FTC regulations addressing negative option marketing and operating.” The Commission takes this step even though we have an open rulemaking on precisely the topics covered in the Policy Statement.¹ Prior to the arrival of new agency leadership, the FTC had issued policy guidance during the pendency of a related rulemaking on only one occasion, and

³ See Dissenting Statement of Commissioner Noah Joshua Phillips Regarding the Policy Statement on Breaches by Health Apps and Other Connected Devices (Sept. 15, 2021), at <https://www.ftc.gov/public-statements/2021/09/dissenting-statement-commissioner-noah-joshua-phillips-regarding-policy>. The Health Breach Notification Rule is governed by Administrative Procedures Act rulemaking requirements, and the FTC's ongoing rulemaking efforts are directed to an existing rule. The policy statement subverted the rulemaking process by declaring something illegal where the Commission had never done so before, in a situation where I do not believe the underlying statute applies. The circumstances here are different, in part because, in the negative option marketing space, there is no comprehensive rule that covers all marketing in all media. In the HBNR context, my concern was heightened by a policy statement that, *inter alia*, undermined two rulemaking processes and contradicted standing guidance from the agency.

⁴ Advance Notice of Proposed Rulemaking, 84 FR 52393 (Oct. 2, 2019) (seeking comment on need for amendments to the Rule Concerning the Use of Prenotification Negative Option Plans (16 CFR part 425)) to help consumers avoid recurring payments for products and services they did not intend to order and to allow them to cancel such payments without unwarranted obstacles).

¹ See 84 FR 52393 (Oct. 2, 2019).

⁴⁷ *Supra* at 17.

⁴⁸ While a request to consider an offer or discount would not amount to an unreasonable delay, multiple requests for a consumer to listen to additional offers, lengthy pitches, or ignoring a consumer's request to decline further offers could amount to an unreasonable delay.

⁴⁹ See, e.g., *FTC v. Universal Premium Services; FTC v. Remote Response; FTC v. Hispanexo; FTC v. Berkeley Premium Nutraceuticals*.

¹ 15 U.S.C. 8403.

² The moment at which a consumer is about to cancel may be the moment when they can get the best deal. Cf. A.O. Hirschman, *Exit, Voice, and Loyalty* (1970).

in that instance noted its intention to refrain from enforcement actions in the area.² But today's initiative marks the third time in as many months new agency leadership has issued expansive policy directives while related rulemakings proceed.³ Publishing guidance during the pendency of a related rulemaking short-circuits the receipt of public input and conveys disdain for our stakeholders. I believe this practice does not constitute good government, so I dissent.

The FTC currently enforces several statutes that address negative option marketing,⁴ including the Restore Online Shoppers' Confidence Act,⁵ the Telemarketing Sales Rule,⁶ the Use of Prenotification Negative Plans Rule,⁷ the Postal Reorganization Act (also known as the Unordered Merchandise Rule),⁸ and the Electronic Funds Transfer Act.⁹ In addition, the FTC has brought numerous cases challenging negative option practices not covered by these statutes using Section 5 of the FTC Act.¹⁰ Thus, there is a significant body of law in the form of FTC consents and litigated cases involving negative option practices.

In 2019, the Commission published a **Federal Register** Notice seeking comment on whether the Commission should expand its Prenotification Negative Option Rule to cover all types of negative option marketing, noting

deceptive practices persist and the current regulatory patchwork does not provide a consistent framework for businesses.¹¹ We received 17 comments from business groups, consumer groups, and state attorneys general in response to that request for comment, representing a range of views and containing substantive and insightful information.

The Policy Statement acknowledges the ongoing rulemaking and states the Commission "will continue to closely monitor compliance with the rules and laws applicable to negative option marketing, and is still considering various options in the rule review proceeding for the Negative Option Rule." A good government approach would be to publish this proposed guidance in the **Federal Register** with a discussion of how it comports with or differs from the comments we received in the rulemaking and seek comment on the proposed guidance.

Particularly given Chair Khan's stated goal of "democratizing" the FTC, one could be forgiven for viewing this as the best way in which to proceed. Alternatively, we could assimilate the feedback we received, close the rulemaking, and then publish this guidance. But the former approach is preferable—having determined as a unanimous Commission to embark on this rulemaking, rendering it moot at this early stage is akin to the elimination of opportunities for public input that the majority undertook in its changes to the Rules of Practice.¹²

There is no question the Commission has the authority to issue policy statements explaining its interpretation of the rules and laws it enforces. Moreover, this practice is a beneficial one: The FTC's business guidance facilitates transparency with respect to agency priorities and policy preferences, educates the business community, and drives compliance with the law. Our Division of Consumer and Business Education has received numerous awards for its publications, and I found FTC guidance documents helpful for client counseling purposes when I was in private practice.¹³ Here, I agree this

Policy Statement provides information that will be useful to businesses, and I largely support the guidance contained in the document. I believe, however, the Commission should either provide this guidance within the context of the open rulemaking or close the rulemaking and then issue the guidance.

For these reasons, I dissent.

[FR Doc. 2021–24094 Filed 11–3–21; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–E–2124]

Determination of Regulatory Review Period for Purposes of Patent Extension; SEVENFACT

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

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for SEVENFACT 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 biological 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 January 3, 2022. 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 May 3, 2022. 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 January 3, 2022. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 3, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service

² See Enforcement Policy Statement Regarding Certain Imported Textile, Wool, and Fur Products (Jan. 3, 2013), <https://www.ftc.gov/news-events/press-releases/2013/01/ftc-announces-enforcement-policy-statement-retailers-directly>; see also 76 FR 68690 (Nov. 7, 2001); Press Release, FTC Seeks Public Input in Review of Textile Labeling Rules (Nov. 1, 2011), <https://www.ftc.gov/news-events/press-releases/2011/11/ftc-seeks-public-input-review-textile-labeling-rules>.

³ See Christine S. Wilson, FTC Comm'r, Dissenting Statement of Commissioner Christine S. Wilson Regarding the Policy Statement on Breaches by Health Apps and Other Connected Devices at 6 (Sept. 15, 2021), <https://www.ftc.gov/public-statements/2021/09/dissenting-statement-commissioner-christine-s-wilson-regarding-policy> (describing issuance of Policy Statement on Breaches by Health Apps and Other Connected Devices during a related rulemaking; also describing rescission of agency guidance on treatment of debt in premerger notification context during a rulemaking covering precisely that issue).

⁴ The Enforcement Policy Statement Regarding Negative Option Marketing explains that while negative options can take various forms, the central feature is "each contains a term or condition under which the seller may interpret a consumer's silence or failure to take affirmative action to reject a good or service or to cancel the agreement as acceptance or continuing acceptance of the offer."

⁵ 15 U.S.C. 8401 through 8405.

⁶ 16 CFR 310.

⁷ 16 CFR 425.

⁸ 39 U.S.C. 3009.

⁹ 15 U.S.C. 1693 through 1693r.

¹⁰ See 84 FR 52393, 52395–96 (Oct. 2, 2019) (ANPRM describing the cases the Commission has brought under Section 5 of the FTC Act).

¹¹ 84 FR 52393, 52394 (Oct. 2, 2019).

¹² 86 FR 38542 (July 22, 2021); see also Press Release, FTC Votes to Update Rulemaking Procedures, Sets Stage for Stronger Deterrence of Corporate Misconduct (July 1, 2021), <https://www.ftc.gov/news-events/press-releases/2021/07/ftc-votes-update-rulemaking-procedures-sets-stage-stronger>.

¹³ While in private practice, I also found informative the business guidance provided by expert FTC staff during speeches and panels. Unfortunately, our staff has been prohibited from delivering public remarks since Chair Khan's arrival in June.

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-E-2124 for "Determination of Regulatory Review Period for Purposes of Patent Extension; SEVENFACT." 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 or biologic 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 biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological 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 biological 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 biologic product SEVENFACT (coagulation factor VIIa (recombinant)-jncw (eptacog beta)). SEVENFACT is indicated for the treatment and control of bleeding episodes occurring in adults and adolescents (12 years of age and older) with hemophilia A or B with inhibitors. Subsequent to this approval, the USPTO received a patent term restoration application for SEVENFACT (U.S. Patent No. 9,029,316) from Laboratoire Francais du Fractionnement et des Biotechnologies S.A. (LFB S.A.), and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated January 4, 2021, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of SEVENFACT 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 SEVENFACT is 2,785 days. Of this time, 1,518 days occurred during the testing phase of the regulatory review period, while 1,267 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 (21 U.S.C. 355(i))*

became effective: August 18, 2012. The applicant claims August 17, 2012, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was August 18, 2012, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* October 13, 2016. FDA has verified the applicant's claim that the biologics license application (BLA) for SEVENFACT (BLA 125641) was initially submitted on October 13, 2016.

3. *The date the application was approved:* April 1, 2020. FDA has verified the applicant's claim that BLA 125641 was approved on April 1, 2020.

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 482 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: October 28, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–24065 Filed 11–3–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2020–E–1327 and FDA–2020–E–1333]

Determination of Regulatory Review Period for Purposes of Patent Extension; ADAKVEO

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 ADAKVEO and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications 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 biological 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 January 3, 2022. 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 May 3, 2022. 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 January 3, 2022. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 3, 2022. 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:

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- 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 Nos. FDA–2020–E–1327 and FDA–2020–E–1333 for “Determination of Regulatory Review Period for Purposes of Patent Extension; ADAKVEO.” 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 or biologic 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 biological products, the testing phase

begins when the exemption to permit the clinical investigations of the biological product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological 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 biological 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 biologic product ADAKVEO (crizanlizumab-tmca). ADAKVEO is indicated to reduce the frequency of vaso-occlusive crises in adults and pediatric patients aged 16 years and older with sickle cell disease. Subsequent to this approval, the USPTO received a patent term restoration application for ADAKVEO (U.S. Patent Nos. 8,377,440 and 9,556,266) from Novartis AG, and the USPTO requested FDA’s assistance in determining this patent’s eligibility for patent term restoration. In a letter dated July 14, 2020, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of ADAKVEO 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 ADAKVEO is 3,152 days. Of this time, 2,968 days occurred during the testing phase of the regulatory review period, while 184 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 (21 U.S.C. 355(i)) became effective:* April 1, 2011. FDA has verified the applicant’s claim that the date the investigational new drug application became effective was on April 1, 2011.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42*

U.S.C. 262): May 16, 2019. FDA has verified the applicant’s claim that the biologics license application (BLA) for ADAKVEO (BLA 761128) was initially submitted on May 16, 2019.

3. *The date the application was approved:* November 15, 2019. FDA has verified the applicant’s claim that BLA 761128 was approved on November 15, 2019.

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 applications for patent extension, this applicant seeks 1,323 or 601 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: October 28, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021-24070 Filed 11-3-21; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket Nos. FDA–2020–E–2052, FDA–2020–E–2042, and FDA–2020–E–2045]

Determination of Regulatory Review Period for Purposes of Patent Extension; AKLIEF

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

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for AKLIEF and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications 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 January 3, 2022. 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 May 3, 2022. 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 January 3, 2022. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 3, 2022. 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 Nos. FDA–2020–E–2052, FDA–2020–E–2042, and FDA–2020–E–2045 for “Determination of Regulatory Review Period for Purposes of Patent Extension; AKLIEF.” 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, AKLIEF (trifarotene), which is indicated for topical treatment of acne vulgaris in patients 9 years of age and older. Subsequent to this approval, the USPTO received patent term restoration applications for AKLIEF (U.S. Patent Nos. 7,807,708; 8,227,507; and 8,470,871) from Galderma Research & Development, and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated December 14, 2020, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of AKLIEF 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 AKLIEF is 3,137 days. Of this time, 2,771 days occurred during the testing phase of the regulatory review period, while 366 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 5, 2011. The applicant claims June 8, 2011, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was March 5, 2011, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* October 4, 2018. FDA has verified the applicant's claim that the new drug application (NDA) for AKLIEF (NDA 211527) was initially submitted on October 4, 2018.

3. *The date the application was approved:* October 4, 2019. FDA has verified the applicant's claim that NDA 211527 was approved on October 4, 2019.

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 applications for patent extension, this applicant seeks 5 years, or 1,498 days, or 1,329 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: October 29, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–24077 Filed 11–3–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–E–1326]

Determination of Regulatory Review Period for Purposes of Patent Extension; SCENESSE

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 SCENESSE 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 January 3, 2022. 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 May 3, 2022. 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 January 3, 2022. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 3, 2022. 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-E-1326 for “Determination of Regulatory Review Period for Purposes of Patent Extension; SCENESSE.” 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 or biologic 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, SCENESSE (afamelanotide acetate) indicated to increase pain-free light exposure in adult patients with a history of phototoxic reactions from erythropoietic protoporphyria. Subsequent to this approval, the USPTO received a patent term restoration application for

SCENESSE (U.S. Patent No. 8,334,265) from Clinuvel Pharmaceuticals Limited, and the USPTO requested FDA’s assistance in determining the patent’s eligibility for patent term restoration. In a letter dated May 26, 2020, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of SCENESSE 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 SCENESSE is 3,914 days. Of this time, 3,579 days occurred during the testing phase of the regulatory review period, while 335 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:* January 21, 2009. FDA has verified the applicant’s claim that the date the investigational new drug application became effective was on January 21, 2009.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* November 8, 2018. The applicant claims June 21, 2018, as the date the new drug application (NDA) for SCENESSE (NDA 210797) was initially submitted. However, FDA records indicate that NDA 210797, submitted on June 21, 2018, was incomplete. The completed NDA was then submitted on November 8, 2018, which is considered to be the initially submitted date.

3. *The date the application was approved:* October 8, 2019. FDA has verified the applicant’s claim that NDA 210797 was approved on October 8, 2019.

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 1,481 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: October 28, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–24074 Filed 11–3–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–6784]

Manufacture of Blood Components Using a Pathogen Reduction Device in Blood Establishments: Questions and Answers; 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 entitled “Manufacture of Blood Components Using a Pathogen Reduction Device in Blood Establishments: Questions and Answers; Guidance for Industry.” The guidance document provides blood establishments that collect or process blood and blood components with recommendations for implementing a pathogen reduction device for the manufacture of pathogen-reduced blood components. The guidance, in a question-and-answer format, addresses the most frequently asked questions concerning implementation of the INTERCEPT® Blood System for Platelets and Plasma. The guidance also provides

recommendations to licensed manufacturers on reporting the manufacturing changes associated with implementation of a pathogen reduction device. The guidance announced in this notice finalizes the draft document entitled “Implementation of Pathogen Reduction Technology in the Manufacture of Blood Components in Blood Establishments: Questions and Answers; Draft Guidance for Industry,” dated December 2017.

DATES: The announcement of the guidance is published in the **Federal Register** on November 4, 2021.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–

2017–D–6784 for “Manufacture of Blood Components using a Pathogen Reduction Device in Blood

Establishments: Questions and Answers; Guidance for Industry.” 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 the guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), 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 the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Tami Belouin, 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 document entitled “Manufacture of Blood Components Using a Pathogen Reduction Device in Blood Establishments: Questions and Answers; Guidance for Industry.” The guidance document provides blood establishments that collect or process blood and blood components with recommendations for implementing a pathogen reduction device for the manufacture of pathogen-reduced blood components. The guidance, in a question-and-answer format, addresses the most frequently asked questions on this topic. The guidance also provides recommendations to licensed manufacturers on reporting the manufacturing changes associated with implementation of a pathogen reduction device under 21 CFR 601.12.

The recommendations in the guidance apply to blood establishments that intend to manufacture pathogen-reduced platelet and plasma products using an FDA approved pathogen reduction device. Currently, the INTERCEPT® Blood System has been approved for the manufacture of certain pathogen-reduced platelet and plasma products. If the product platforms for this FDA approved device change, or FDA approves another pathogen reduction device with a similar intended use in the future, the Agency will consider providing additional recommendations to blood establishments.

In the **Federal Register** of December 27, 2017 (82 FR 61304), FDA announced the availability of the draft document entitled “Implementation of Pathogen Reduction Technology in the Manufacture of Blood Components in Blood Establishments: Questions and Answers; Draft Guidance for Industry.” FDA received a few comments on the draft guidance. The comments addressed various issues, including the

indications for use of the INTERCEPT® Blood System for Platelets and Plasma; sampling plans for quality control and validation of the manufacturing process in blood establishments; labeling of pathogen reduced blood components; submissions to FDA for changes to an approved application; and requirements for licensure of pathogen reduced blood components. One comment raised a concern that the guidance addresses a single product. FDA made changes to the guidance to reflect revised labeling for the INTERCEPT® Blood System, and to improve clarity of the recommendations, including those related to quality control and submissions to FDA. Additionally, FDA changed the title of the guidance to clarify that the purpose of the guidance is to provide recommendations for implementing a pathogen reduction device in blood establishments, as opposed to providing recommendations regarding the clinical use of products. However, FDA did not make substantive changes to the guidance in response to the public comments. The guidance announced in this notice finalizes the draft guidance dated December 2017.

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 the manufacture of blood components using a pathogen reduction device in blood establishments. 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 collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338; the collections of information in 21 CFR parts 606 and 630 have been approved under OMB control number 0910–0116.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics-regulatory-guidances>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: October 29, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–24073 Filed 11–3–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–E–5390]

Determination of Regulatory Review Period for Purposes of Patent Extension; DENG VAXIA

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 DENG VAXIA 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 biological 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 January 3, 2022. 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 May 3, 2022. 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 January 3, 2022. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 3, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the

instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2019-E-5390 for "Determination of Regulatory Review Period for Purposes of Patent Extension; DENG VAXIA." 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 or biologic 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 biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological product becomes effective

and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological 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 biological 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 biologic product DENG VAXIA (dengue tetravalent vaccine, Live). DENG VAXIA is indicated for the prevention of dengue disease caused by dengue virus serotypes 1, 2, 3 and 4. DENG VAXIA is approved for use in individuals 9 through 16 years of age with laboratory-confirmed previous dengue infection and living in endemic areas. Subsequent to this approval, the USPTO received a patent term restoration application for DENG VAXIA (U.S. Patent No. 8,142,795) from Sanofi Pasteur, and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated December 26, 2019, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of DENG VAXIA 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 DENG VAXIA is 5,710 days. Of this time, 5,466 days occurred during the testing phase of the regulatory review period, while 244 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 (21 U.S.C. 355(i)) became effective:* September 14, 2003. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on September 14, 2003.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42*

U.S.C. 262): August 31, 2018. The applicant claims August 30, 2018, as the date the biologics license application (BLA) for DENGXVAXIA (BLA 125682) was initially submitted. However, FDA records indicate that BLA 125682 was submitted on August 31, 2018.

3. *The date the application was approved*: May 1, 2019. FDA has verified the applicant's claim that BLA 125682 was approved on May 1, 2019.

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 1,248 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: October 28, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–24067 Filed 11–3–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–E–2023]

Determination of Regulatory Review Period for Purposes of Patent Extension; RECARBRIO

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

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for RECARBRIO 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 January 3, 2022. 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 May 3, 2022. 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 January 3, 2022. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 3, 2022. 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>.

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- 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–E–2023 for “Determination of Regulatory Review Period for Purposes of Patent Extension; RECARBRIO.” 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 or biologic 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, RECARBRIO. RECARBRIO is a combination of cilastatin, imipenem, and relebactam indicated in patients 18 years of age and older who have limited or no alternative treatment options for the treatment of the following infections caused by susceptible gram-negative bacteria: Complicated urinary tract infections, including pyelonephritis, and complicated intra-abdominal infections. Approval of these indications is based on limited clinical safety and efficacy data for RECARBRIO. Subsequent to this approval, the USPTO received a patent term restoration application for RECARBRIO (U.S. Patent No. 8,487,093) from Merck Sharp & Dohme Corp., and the USPTO requested FDA’s assistance in determining the patent’s eligibility for patent term restoration. In a letter dated January 4, 2021, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of RECARBRIO represented the first permitted commercial marketing or use of relebactam, one of the three active ingredients in 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 RECARBRIO is 3,200 days. Of this time, 2,957 days occurred during the testing phase of the regulatory review period, while 243 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:* October 13, 2010. FDA has verified the applicant’s claim that the date the investigational new drug application became effective was on October 13, 2010.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* November 16, 2018. FDA has verified the applicant’s claim that the new drug application (NDA) for

RECARBRIO (NDA 212819) was initially submitted on November 16, 2018.

3. *The date the application was approved:* July 16, 2019. FDA has verified the applicant’s claim that NDA 212819 was approved on July 16, 2019.

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 1,218 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: October 28, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021-24068 Filed 11-3-21; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-D-0775]

Content of Premarket Submissions for Device Software Functions; Draft Guidance for Industry and Food and Drug Administration Staff; 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 the draft guidance entitled “Content of Premarket Submissions for Device Software Functions.” This guidance document is intended to provide information regarding the recommended documentation sponsors should include in premarket submissions for FDA’s evaluation of the safety and effectiveness of device software functions, which are functions that meet the definition of a device under the Federal Food, Drug, and Cosmetic Act (FD&C Act). When final, this document will replace FDA’s “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices” issued on May 11, 2005, and it will update FDA’s thinking related to the documentation FDA recommends sponsors include for the review of device software functions in premarket 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 February 2, 2022 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-2021-D-0775 for “Content of Premarket Submissions for Device Software Functions.” 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)).

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 “Content of Premarket Submissions for Device Software Functions” 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; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), 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 request.

FOR FURTHER INFORMATION CONTACT:

Bakul Patel, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5458, Silver Spring, MD 20993-0002, 301-796-5528; 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, 240-402-7911.

SUPPLEMENTARY INFORMATION:**I. Background**

The purpose of this draft guidance is to describe FDA’s thinking on the recommended documentation sponsors should include in premarket submissions for FDA’s evaluation of the safety and effectiveness of device software functions. This thinking recognizes recent changes to the Federal Food, Drug, and Cosmetic Act (FD&C Act) made by the 21st Century Cures Act (Pub. L. 114-255), which amended section 520 of the FD&C Act (21 U.S.C. 360) and excludes certain software functions from the device definition. It also considers the rapidly evolving nature of digital health and recent FDA-recognized consensus standards related to software.

This draft guidance identifies the software information generally necessary for evaluating the safety and effectiveness of a device in a premarket submission. The recommendations in this draft guidance also may help facilitate FDA's premarket review. This draft guidance describes information that typically would be generated and documented during software development, verification, and design validation. The least burdensome approach was applied to identify the minimum amount of information that, based on our experience, would generally be needed to support a premarket submission for a device that uses software. During premarket review, FDA may request additional information that is needed to evaluate the submission.

When final, this document will replace FDA's "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued on May 11, 2005, and it will update FDA's thinking related to the documentation recommended for the review of device software functions in premarket submissions.

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 "Content of Premarket Submissions for Device Software Functions." 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. 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>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents> or <https://www.fda.gov/vaccines-blood->

biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances. Persons unable to download an electronic copy of "Content of Premarket Submissions for Device Software Functions" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 337 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations, guidance, and forms have been approved by OMB as listed in the following table:

21 CFR part; guidance; or FDA form	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
814, subpart H	Humanitarian Device Exemption	0910–0332
812	Investigational Device Exemption	0910–0078
"De Novo Classification Process (Evaluation of Automatic Class III Designation)".	De Novo classification process	0910–0844
800, 801, and 809	Medical Device Labeling Regulations	0910–0485
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation	0910–0073

Dated: October 29, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–24061 Filed 11–3–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–1112]

Agency Information Collection Activities; Proposed Collection; Comment Request; Interstate Shellfish Dealer's Certificate and Other Records Related to Participation in the National Shellfish Sanitation Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of the Interstate Shellfish Dealer's Certificate as well as the collection of other records related to participation in the National Shellfish Sanitation Program (NSSP).

DATES: Submit either electronic or written comments on the collection of information by January 3, 2022.

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 January 3, 2022. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 3, 2022. 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

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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>.

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- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2021-N-1112 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Interstate Shellfish Dealer's Certificate and Other Records Related to Participation in the National Shellfish Sanitation Program." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The

second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrahi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information

is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Interstate Shellfish Dealer's Certificate and Other Records Related to Participation in the National Shellfish Sanitary Program

OMB Control Number 0910-0021—*Extension*

Under section 243 of the Public Health Service Act (42 U.S.C. 243), FDA is required to cooperate with and aid State and local authorities in the enforcement of their health regulations and are authorized to assist States in the prevention and suppression of communicable diseases. Under this authority, FDA participates with State regulatory agencies, some foreign nations, and the U.S. molluscan shellfish industry in the NSSP.

The NSSP is a voluntary, cooperative program to promote the safety of molluscan shellfish by providing for the classification and patrol of shellfish growing waters and for the inspection and certification of shellfish dealers. Each participating State and foreign nation monitors its molluscan shellfish production and issues certificates for those dealers that meet the State or foreign shellfish control authority's criteria. Each participating State and nation provides a certificate of its certified shellfish dealers to FDA on Form FDA 3038, "Interstate Shellfish Dealer's Certificate" (available at <https://www.fda.gov/media/72094/download>). FDA uses this information to publish the "Interstate Certified Shellfish Shippers List (ICSSL)," a monthly comprehensive listing of all molluscan shellfish dealers certified under the cooperative program (available at <https://www.fda.gov/food/federalstate-food-programs/interstate-certified-shellfish-shippers-list>). If FDA did not collect the information necessary to compile this list, participating States would not be able to identify and prevent the distribution in the United States of shellfish processed by uncertified dealers. Consequently, the NSSP would not be able to control

the distribution of uncertified and possibly unsafe shellfish in interstate commerce. Without the ICSSL, the effectiveness of the NSSP would be nullified. The ICSSL is also used to identify U.S. shellfish dealers eligible to obtain health certificates and export to certain countries or regions.

FDA has been collecting information to construct the ICSSL since 2001. FDA is seeking to add one new data field to the Form FDA 3038, the “FDA Establishment Identifier” (FEI number). The FEI number is a unique number assigned by FDA to identify FDA-regulated facilities. FDA will explore whether the FEI can be used to retrieve data on shellfish dealers from existing FDA systems, which could reduce the number of required data elements that firms have to submit on Form FDA 3038.

The information collection also includes providing certain documents demonstrating compliance with the NSSP. When a competent authority in another country conducts an evaluation to determine whether the U.S. food safety control measures for molluscan shellfish are equivalent to their system

of controls, the competent authority may require FDA to provide information and records demonstrating compliance with the provisions of the NSSP. Only those firms that comply with the NSSP would be permitted to export molluscan shellfish to a country whose competent authority determined that the U.S. system of controls is equivalent to their own controls. If approved, FDA will use this information to support the export of U.S. shellfish to countries whose competent authorities have determined the U.S. system of food safety controls to be equivalent to their own system of controls by demonstrating that the exporter is in compliance with the U.S. system of controls specified in the NSSP.

For example, to implement the European Commission’s (EC) determination that the U.S. system of food safety controls for raw bivalve molluscan shellfish is equivalent to the European Union’s (EU) system of controls, the EC is requiring FDA to provide documentation collected from NSSP-participating shellfish control authorities with firms seeking to export raw molluscan shellfish to the EU. This

documentation includes, but is not limited to:

- A list of growing areas with an Approved classification;
- the most recent sanitary survey for each growing area with an Approved classification; and
- the most recent inspection report for each firm seeking to export shellfish to the EU.

The examples above are illustrative. Some competent authorities may require additional information to conduct an equivalence assessment or to implement an equivalence determination, or both. We plan to provide respondents with information about the specific documentation that is required for each equivalence assessment. For those competent authorities that recognize the U.S. system as equivalent, additional documentation may be needed to implement that determination.

Description of Respondents:

Respondents to this collection are participating State and local regulatory agencies and foreign nations.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity	Form FDA No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Submission of Interstate Shellfish Dealer’s Certificate	3038	40	57	2,280	0.10 (6 minutes)	228
Submission of Other Records Related to Participation in the NSSP.	N/A	13	1	13	0.25 (15 minutes)	3.25
Total						231.25

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate. This estimate is based on our experience with this information collection and the number of certificates received in the past 3 years, which has remained constant.

Dated: October 28, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–24063 Filed 11–3–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Biodefense Science Board

AGENCY: Office of the Assistant Secretary for Preparedness and Response (ASPR), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The National Biodefense Science Board (NBSB or the Board) is authorized under Section 319M of the Public Health Service (PHS) Act, as added by section 402 of the Pandemic and All-Hazards Preparedness Act of 2006 and amended by section 404 of the Pandemic and All-Hazards Preparedness Reauthorization Act. The Board is governed by the Federal Advisory Committee Act (5 U.S.C. app.), which sets forth standards for the formation and use of advisory committees. The NBSB provides expert advice and guidance on scientific, technical, and other matters of special interest to the Department of Health and Human Services (HHS) regarding current and future chemical, biological, nuclear, and radiological agents, whether naturally occurring, accidental, or deliberate. Authority to manage and operate the NBSB, including to receive

advice and recommendations from the Board, has been delegated by the Secretary of HHS to the Assistant Secretary for Preparedness and Response (ASPR). The NBSB will meet in public (virtually) on December 16, 2021, to provide advice and recommendations to ASPR regarding the development of the 2023–2026 National Health Security Strategy and to discuss other matters of current importance for public health emergency preparedness, response, and recovery. A more detailed agenda will be available on the NBSB meeting website <https://www.phe.gov/nbsb>.

Procedures for Public Participation: Members of the public may attend the meeting via a toll-free phone number or Zoom teleconference, which requires pre-registration. The meeting link to pre-register will be posted on the meeting website <https://www.phe.gov/nbsb>. Members of the public may provide written comments or submit

questions for consideration by the NBSB at any time via email to NBSB@hhs.gov.

Additionally, the NBSB invites those who are involved in or represent a relevant biodefense or health security industry, serve as faculty or conduct research at an academic institution, occupy a relevant health profession, or work for a hospital system or health care consumer organization; or those who serve in a state, Tribal, territorial or local government agency to request up to seven minutes to address the Board in person via Zoom. Requests to provide remarks to the NBSB during the public meeting must be sent to NBSB@hhs.gov by midnight on October 10, 2021. In that request, please provide the name, title, and position of the individual who will be speaking and a brief description of the planned topic. Presenters who are selected for the public meeting will have audio only during the meeting, thoughlides, documents, and other presentation material may be sent ahead; those will be provided directly to the board members. Topics and presentations with an obvious commercial bias, to include any form of advertising, marketing, or solicitation, will not be accepted.

FOR FURTHER INFORMATION CONTACT:
CAPT Christopher L. Perdue, MD, MPH,
(202) 480-7226, NBSB Designated
Federal Officer, Washington, DC, Office
NBSB@hhs.gov.

Dawn O'Connell,

Assistant Secretary for Preparedness and Response.

[FR Doc. 2021-23971 Filed 11-3-21; 8:45 am]

BILLING CODE 4150-37-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Domestic Violence Prevention: Forensic Healthcare Services

Announcement Type: New.

Funding Announcement Number:
HHS-2022-IHS-FHC-0001.

Assistance Listing (Catalog of Federal Domestic Assistance or CFDA) Number:
93.653.

Key Dates

Application Deadline Date: February 2, 2022.

Earliest Anticipated Start Date: March 21, 2022.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) is accepting applications for grants that

will develop and/or expand Forensic Healthcare (FHC) services. This program was first established by the Omnibus Appropriations Act of 2009, Public Law 111-8, 123 Stat. 524, 735, as a component of the Domestic Violence Prevention Initiative, and continued in the annual appropriations acts since that time. This program is authorized under the Snyder Act, 25 U.S.C. 13; and the Indian Health Care Improvement Act, 25 U.S.C. 1665a, 1665m. This program is described in the Assistance Listings located at <https://sam.gov/content/home> (formerly known as Catalog of Federal Domestic Assistance) under 93.653.

Background

The Division of Behavioral Health (DBH) serves as the primary source of national advocacy, policy development, management and administration of behavioral health, alcohol and substance abuse, and family violence prevention programs. Domestic and sexual violence including child maltreatment are a public health concern among the American Indian/Alaska Native (AI/AN) population. American Indians and Alaska Natives experience high rates of sexual violence according to a 2016 publication from the Department of Justice. Previously, forensic health care functions were funded under Purpose Area 2 of the Domestic Violence Prevention (DVP) program, formerly known as the Domestic Violence Prevention Initiative. This announcement separates forensic health care functions into a distinct program. The FHC program will address access to health care needed for AI/AN victims of domestic and sexual violence. The IHS supports comprehensive efforts to develop and/or expand FHC services to provide treatment, intervention, and prevention in order to address the needs of victims impacted by domestic violence, sexual assault, stalking, sexual exploitation/human trafficking, and child maltreatment. The FHC program is aligned with the national DVP goals, <https://www.ihs.gov/dvpi/aboutdvp/>.

Purpose

The purpose of this IHS grant is to provide access to treatment for AI/AN victims of domestic and sexual violence by supporting the development of and/or expansion of FHC services that are culturally appropriate and trauma-informed. The intent is to impact FHC services in each IHS Area (provided by Tribes, Tribal organizations and Urban Indian organizations). This also includes promoting treatment, intervention, and prevention efforts for the social, spiritual, and emotional well-

being of victims, including victims of child maltreatment. To address domestic and sexual violence, including victims of sexual exploitation/human trafficking, applicants are encouraged to use Multidisciplinary Team (MDT) and Sexual Assault Response Team (SART) approaches. Using these types of team approaches is crucial—especially among local, state, and Federal agencies that includes health care providers, law enforcement, child protective services, social services, legal services, domestic violence coalitions, behavioral health services, and victim advocacy. The MDT/SART are community-based approaches in responding to sexual assault, intimate partner violence, and sexual abuse victims. Without the advantage of a team approach method, a program is more likely to fail. Improving collaboration through formal inter-agency agreements can improve the response time for sexual assault victims.

II. Award Information

Funding Instrument—Grant

Estimated Funds Available

The total funding identified for fiscal year (FY) 2022 is approximately \$2,500,000. Individual award amounts for the first budget year are anticipated to be \$250,000. The funding available for competing and subsequent continuation awards issued under this announcement is subject to the availability of appropriations and budgetary priorities of the agency. The IHS is under no obligation to make awards that are selected for funding under this announcement.

Anticipated Number of Awards

Approximately 10 awards will be issued under this program announcement with up to one award set aside for an eligible Urban Indian organization.

Period of Performance

The period of performance is for 5 years.

III. Eligibility Information

1. Eligibility

To be eligible for this new FY 2022 funding opportunity, applicants must be one of the following as defined by 25 U.S.C. 1603:

- A federally recognized Indian Tribe as defined by 25 U.S.C. 1603(14). The term "Indian Tribe" means any Indian Tribe, band, nation, or other organized group or community, including any Alaska Native village or group, or regional or village corporation as defined in or established pursuant to the

Alaska Native Claims Settlement Act (85 Stat. 688) [43 U.S.C. 1601 *et seq.*], which is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians.

- A Tribal organization as defined by 25 U.S.C. 1603(26). The term “Tribal organization” has the meaning given the term in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304(l)): “Tribal organization” means the recognized governing body of any Indian Tribe; any legally established organization of Indians which is controlled, sanctioned, or chartered by such governing body or which is democratically elected by the adult members of the Indian community to be served by such organization and which includes the maximum participation of Indians in all phases of its activities: Provided that, in any case where a contract is let or grant made to an organization to perform services benefiting more than one Indian Tribe, the approval of each such Indian Tribe shall be a prerequisite to the letting or making of such contract or grant. Applicant shall submit letters of support and/or Tribal Resolutions from the Tribes to be served.

- An Urban Indian organization, as defined by 25 U.S.C. 1603(29). The term “Urban Indian organization” means a nonprofit corporate body situated in an urban center, governed by an urban Indian controlled board of directors, and providing for the maximum participation of all interested Indian groups and individuals, which body is capable of legally cooperating with other public and private entities for the purpose of performing the activities described in 25 U.S.C. 1653(a). Applicants must provide proof of nonprofit status with the application, *e.g.*, 501(c)(3).

The program office will notify any applicants deemed ineligible.

Note: Please refer to Section IV.2 (Application and Submission Information/ Subsection 2, Content and Form of Application Submission) for additional proof of applicant status documents required, such as Tribal Resolutions, proof of nonprofit status, etc.

2. Cost Sharing or Matching

The IHS does not require matching funds or cost sharing for grants or cooperative agreements.

3. Other Requirements

Applications with budget requests that exceed the highest dollar amount outlined under Section II Award Information, Estimated Funds Available,

or exceed the period of performance outlined under the Section II Award Information, Period of Performance, are considered not responsive and will not be reviewed. The Division of Grants Management (DGM) will notify the applicant.

Additional Required Documentation

Tribal Resolution

The DGM must receive an official, signed Tribal Resolution prior to issuing a Notice of Award (NoA) to any applicant selected for funding. An Indian Tribe or Tribal organization that is proposing a project affecting another Indian Tribe must include resolutions from all affected Tribes to be served. However, if an official, signed Tribal Resolution cannot be submitted with the application prior to the application deadline date, a draft Tribal Resolution must be submitted with the application by the deadline date in order for the application to be considered complete and eligible for review. The draft Tribal Resolution is not in lieu of the required signed resolution but is acceptable until a signed resolution is received. If an application without a signed Tribal Resolution is selected for funding, the applicant will be contacted by the Grants Management Specialist (GMS) listed in this funding announcement and given 90 days to submit an official, signed Tribal Resolution to the GMS. If the signed Tribal Resolution is not received within 90 days, the award will be forfeited.

Tribes organized with a governing structure other than a Tribal council may submit an equivalent document commensurate with their governing organization.

Proof of Nonprofit Status

Organizations claiming nonprofit status must submit a current copy of the 501(c)(3) Certificate with the application.

IV. Application and Submission Information

1. Obtaining Application Materials

The application package and detailed instructions for this announcement are available at <https://www.Grants.gov>.

Please direct questions regarding the application process to Mr. Paul Gettys at (301) 443-2114 or (301) 443-5204.

2. Content and Form Application Submission

Mandatory documents for all applicants include:

- Abstract (one page) summarizing the project.
- Application forms:

1. SF-424, Application for Federal Assistance.

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

3. SF-424B, Assurances—Non-Construction Programs.

- Project Narrative (not to exceed 15 pages). See Section IV.2.A, Project Narrative, for additional instructions.

1. Background information on the organization.

2. Proposed scope of work, objectives, and activities that provide a description of what the applicant plans to accomplish.

- Budget Justification and Narrative (not to exceed four pages). See Section IV.2.B, Budget Narrative for instructions.

- Work plan with timeline, limit one page.

- Tribal Resolution(s) or Tribal Letter of Support (only required for Tribes and Tribal organizations).

- Letters of Commitment.

1. For all applicants: From local organizational partners.

2. For all applicants: From community partners.

3. For Tribal organizations: From the board of directors (or relevant equivalent).

4. For Urban Indian organizations: From the board of directors (or relevant equivalent).

- 501(c)(3) Certificate where applicable.

- Biographical sketches for all Key Personnel.

- Contractor/Consultant resumes or qualifications and scope of work.

- Disclosure of Lobbying Activities (SF-LLL), if applicant conducts reportable lobbying.

- Certification Regarding Lobbying (GG-Lobbying Form).

- Copy of current Negotiated Indirect Cost rate (IDC) agreement (required in order to receive IDC).

- Organizational Chart (optional).

- Documentation of current Office of Management and Budget (OMB) Financial Audit.

Acceptable forms of documentation include:

1. Email confirmation from Federal Audit Clearinghouse (FAC) that audits were submitted; or

2. Face sheets from audit reports.

Applicants can find these on the FAC website at <https://harvester.census.gov/facdissem/Main.aspx>.

Public Policy Requirements

All Federal public policies apply to IHS grants and cooperative agreements. Pursuant to 45 CFR 80.3(d), an individual shall not be deemed subjected to discrimination by reason of

their exclusion from benefits limited by Federal law to individuals eligible for benefits and services from the IHS. See <https://www.hhs.gov/grants/grants/grants-policies-regulations/index.html>.

Requirements for Project and Budget Narratives

A. Project Narrative

This narrative should be a separate document that is no more than 15 pages and must: (1) Have consecutively numbered pages; (2) use black font 12 points or larger; (3) be single-spaced; and (4) be formatted to fit standard letter paper (8½ x 11 inches).

Be sure to succinctly answer all questions listed under the evaluation criteria (refer to Section V.1, Evaluation Criteria) and place all responses and required information in the correct section noted below or they will not be considered or scored. If the narrative exceeds the page limit, the application will be considered not responsive and not be reviewed. The 15-page limit for the narrative does not include the work plan with timeline, standard forms, Tribal Resolutions, budget, budget justifications, narratives, and/or other items or requested attachments.

There are four parts to the Project Narrative:

Part 1—Statement of Need

Part 2—Program Plan

Part 3—Organizational Capacity

Part 4—Program Evaluation

Part 1: Statement of Need (Limit—2 Pages)

The project narrative must include the statement of need that addresses the nature and scope of the problem (e.g., limited or no access to forensic health care). Refer to Section V.1.A, Evaluation Criteria—Statement of Need for details.

Part 2: Program Plan (Limit—9 Pages)

Describe the proposed program plan, an outline of goal(s), proposed implementation of the required five objectives and activities. Refer to Section V.1.B, Evaluation Criteria—Program Plan for details.

Part 3: Organizational Capacity (Limit—2 Pages)

Describe the applicant's management capability and experience in administering grants. Refer to Section V.1.C, Evaluation Criteria—Organizational Capacity.

Part 4: Program Evaluation (Limit—2 Pages)

Describe how you plan to collect data for the proposed project activities and identify what type of evaluation method will be used. Applicants are encouraged

to partner with their Tribal Epidemiology Center (TEC) or Urban Epidemiology Center (for urban applicants) and should describe their plan for coordination and collaboration with the TEC. Refer to Section V.1.D, Evaluation Criteria—Program Evaluation.

B. Budget Narrative (Limit—4 Pages)

Provide a budget narrative that explains the amounts requested for each line item of the budget from the SF-424A (Budget Information for Non-Construction Programs). The budget narrative document can include a more detailed spreadsheet than is provided by the SF-424A. The budget narrative should specifically describe how each item will support the achievement of proposed objectives. Be very careful about showing how each item in the "Other" category is justified. For subsequent budget years (see Multi-Year Project Requirements in Section V.1, Application Review Information, Evaluation Criteria), the narrative should highlight the changes from the first year or clearly indicate that there are no substantive budget changes during the period of performance. Do NOT use the budget narrative to expand the project narrative.

3. Submission Dates and Times

Applications must be submitted through *Grants.gov* by 11:59 p.m. Eastern Time on the Application Deadline Date. Any application received after the application deadline will not be accepted for review. *Grants.gov* will notify the applicant via email if the application is rejected.

If technical challenges arise and assistance is required with the application process, contact *Grants.gov* Customer Support (see contact information at <https://www.grants.gov>). If problems persist, contact Mr. Paul Gettys (Paul.Gettys@ihs.gov), Acting Director, DGM, by telephone at (301) 443-2114 or (301) 443-5204. Please be sure to contact Mr. Gettys at least 10 days prior to the application deadline. Please do not contact the DGM until you have received a *Grants.gov* tracking number. In the event you are not able to obtain a tracking number, call the DGM as soon as possible.

The IHS will not acknowledge receipt of applications.

4. Intergovernmental Review

Executive Order 12372 requiring intergovernmental review is not applicable to this program.

5. Funding Restrictions

- Pre-award costs are allowable up to 90 days before the start date of the award provided the costs are otherwise allowable if awarded. Pre-award costs are incurred at the risk of the applicant.
- The available funds are inclusive of direct and indirect costs.
- Only one grant will be awarded per applicant.

6. Electronic Submission Requirements

All applications must be submitted via *Grants.gov*. Please use the <https://www.Grants.gov> website to submit an application. Find the application by selecting the "Search Grants" link on the homepage. Follow the instructions for submitting an application under the Package tab. No other method of application submission is acceptable.

If the applicant cannot submit an application through *Grants.gov*, a waiver must be requested. Prior approval must be requested and obtained from Mr. Paul Gettys, Acting Director, DGM. A written waiver request must be sent to GrantsPolicy@ihs.gov with a copy to Paul.Gettys@ihs.gov. The waiver request must: (1) Be documented in writing (emails are acceptable) before submitting an application by some other method, and (2) include clear justification for the need to deviate from the required application submission process.

Once the waiver request has been approved, the applicant will receive a confirmation of approval email containing submission instructions. A copy of the written approval must be included with the application that is submitted to the DGM. Applications that are submitted without a copy of the signed waiver from the Acting Director of the DGM will not be reviewed. The Grants Management Officer of the DGM will notify the applicant via email of this decision.

Applications submitted under waiver must be received by the DGM no later than 5:00 p.m. Eastern Time on the Application Deadline Date. Late applications will not be accepted for processing. Applicants that do not register for both the System for Award Management (SAM) and *Grants.gov* and/or fail to request timely assistance with technical issues will not be considered for a waiver to submit an application via alternative method.

Please be aware of the following:

- Please search for the application package in <https://www.Grants.gov> by entering the Assistance Listing (CFDA) number or the Funding Opportunity Number. Both numbers are located in the header of this announcement.

- If you experience technical challenges while submitting your application, please contact *Grants.gov* Customer Support (see contact information at <https://www.Grants.gov>).

- Upon contacting *Grants.gov*, obtain a tracking number as proof of contact. The tracking number is helpful if there are technical issues that cannot be resolved and a waiver from the agency must be obtained.

- Applicants are strongly encouraged not to wait until the deadline date to begin the application process through *Grants.gov* as the registration process for SAM and *Grants.gov* could take up to 20 working days.

- Please follow the instructions on *Grants.gov* to include additional documentation that may be requested by this funding announcement.

- Applicants must comply with any page limits described in this funding announcement.

- After submitting the application, the applicant will receive an automatic acknowledgment from *Grants.gov* that contains a *Grants.gov* tracking number. The IHS will not notify the applicant that the application has been received.

Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS)

Applicants and grantee organizations are required to obtain a DUNS number and maintain an active registration in the SAM database. The DUNS number is a unique 9-digit identification number provided by D&B that uniquely identifies each entity. The DUNS number is site specific; therefore, each distinct performance site may be assigned a DUNS number. Obtaining a DUNS number is easy, and there is no charge. To obtain a DUNS number, please access the request service through <https://fedgov.dnb.com/webform>, or call (866) 705-5711.

The Federal Funding Accountability and Transparency Act of 2006, as amended ("Transparency Act"), requires all HHS recipients to report information on sub-awards. Accordingly, all IHS grantees must notify potential first-tier sub-recipients that no entity may receive a first-tier sub-award unless the entity has provided its DUNS number to the prime grantee organization. This requirement ensures the use of a universal identifier to enhance the quality of information available to the public pursuant to the Transparency Act.

System for Award Management (SAM)

Organizations that are not registered with SAM must have a DUNS number first, then access the SAM online registration through the SAM home page

at <https://sam.gov> (U.S. organizations will also need to provide an Employer Identification Number from the Internal Revenue Service that may take an additional 2–5 weeks to become active). Please see *SAM.gov* for details on the registration process and timeline. Registration with the SAM is free of charge but can take several weeks to process. Applicants may register online at <https://sam.gov>.

Additional information on implementing the Transparency Act, including the specific requirements for DUNS and SAM, are available on the DGM Grants Management, Policy Topics web page at <https://www.ihs.gov/dgm/policytopics/>.

V. Application Review Information

Possible points assigned to each section are noted in parentheses. The project narrative and budget narrative should include only the first year of activities; information for multi-year projects should be included as a separate document. See "Multi-year Project Requirements" at the end of this section for more information. The project narrative should be written in a manner that is clear to outside reviewers unfamiliar with prior related activities of the applicant. It should be well organized, succinct, and contain all information necessary for reviewers to understand the project fully. Attachments requested in the criteria do not count toward the page limit for the narratives. Points will be assigned to each evaluation criteria adding up to a total of 100 possible points. Points are assigned as follows:

1. Evaluation Criteria

A. Statement of Need (20 Points)

The project narrative must include a statement of need that describes the background knowledge and context on the issue of the problem (e.g., limited and/or lack of access to care for victims of AI/AN) affected by domestic and sexual violence, including children, and victims of sexual exploitation/human trafficking. The applicant should use data to provide evidence that the problem exists, describe the size of the problem, and the effects of the problem on the target population. The data documenting need may come from a variety of qualitative and quantitative sources. Examples of data sources to be included are local epidemiologic data from Trends in Indian Health and State data, national data from My Tribal Area by the U.S. Census Bureau; Centers for Disease Control and Prevention reports; Department of Justice; and Substance Abuse and Mental Health Services

Administration, National Survey on Drug Use and Health.

1. Describe the needs and conditions of your priority population.

2. Describe the need to support the development of and/or expansion of FHC services.

3. Provide demographics of the community (e.g., race, ethnicity, federally recognized Tribe, language, age, socioeconomic status, and other relevant factors, such as literacy).

4. Provide incidence and prevalence rates on domestic and sexual violence including children.

5. Describe the existing service gaps, barriers, and other systemic challenges related to the need for program planning and capacity building.

B. Program Plan (35 Points)

Using the five objectives, describe the purpose of the proposed program plan in the narrative, a work plan, and timeline that clearly outlines the goal(s), five objectives, and activities.

Objective 1: Strengthen or increase access to quality medical Forensic Healthcare to victims of domestic and sexual violence including children.

1. Describe your plan to create a MDT and SART team from local, state, and Federal agencies that includes health care providers, law enforcement, child protective services, social service, legal service, coalitions, behavioral health, and victim advocacy.

2. Describe your plan to establish health system policies for sexual assault and domestic violence, including child maltreatment, and sexual exploitation/human trafficking.

3. Describe your plan to incorporate culturally-sensitive screening processes and trauma-informed forensic examinations.

4. Describe your plan to create a quality assessment and performance improvement mechanism to provide professional review of service quality.

Objective 2: Foster coalitions and networks to improve coordination and collaboration among partners to ensure adequate services exist either on-site or by referral for victims of domestic and sexual violence, sexual exploitation/human trafficking, and child maltreatment 24 hours per day/7 days per week year round.

1. Describe your plan to create a MDT and SART team to ensure adequate services exist either on-site or by referral for victims of domestic and sexual violence 24/7 year round.

2. Describe your plan to establish partnerships among local, state, and Federal agencies to strengthen the system of care.

Objective 3: Promote education, training, and community resources.

1. Describe your plan to raise awareness about availability of forensic examination and the benefits of examinations for sexual assault, sexual abuse, and intimate partner violence examinations.

2. Describe your plan to train health care workforce at the systems level and support initial and ongoing forensic examiner education (*e.g.*, intimate partner violence, strangulation, trauma-informed care, traumatic brain injury, sexual assault, child maltreatment, elder abuse, sexual exploitation/human trafficking).

3. Describe the project plan to identify and disseminate relevant local resources and information to be shared with victims and/or local partners regarding seeking services that require immediate attention (*e.g.*, care coordination services that increase access to timely forensic examination services, including follow-up visits, and access to HIV, STD, pregnancy prophylaxis, and aftercare services).

4. Describe your plan to create public health messages about access and availability of forensic health care services being offered using the following resources: Radio; TV; billboards; advertisements; patient education brochures; and social media.

5. Describe how your project will increase educational awareness and services that address Missing and Murdered AI/ANs, including support services for family members of victims (*e.g.*, community support groups, trainings on ambiguous and traumatic loss, and community-based trainings that highlight at-risk groups and protection and prevention activities).

Objective 4: Integrate at least one program/intervention that is an evidence-based practice, or known as a promising practice, and may be integrated or coordinated with traditional practices and/or faith-based services to facilitate the social and emotional well-being of victims and their families.

1. Describe your chosen practice that is appropriate to achieve the desired outcomes.

2. Describe your plan to modify/adapt your proposed practice to meet the goal(s) and objectives of the project and why changes will improve the outcomes.

3. Describe your training needs or plans to successfully implement the proposed practice.

Objective 5: Develop a process and a formal plan for sustainability of these objectives and activities beyond the life of this grant.

1. Describe your plan for sustainability of these objectives and activities beyond the life of the grant.

C. Organizational Capacity and Staffing/Administration (15 Points)

1. Describe your management's capability and experience in administering grants and projects, and identify your department/division that will administer this project.

2. Describe your experience in creating and implementing a MDT and SART team to expand FHC services.

3. Describe your program's experience and capacity to provide FHC services to the community.

4. Describe the resources available for your proposed project (*e.g.*, facilities, equipment, information technology systems, and financial management systems).

5. Describe how your project continuity will be maintained if/when there is a change in the operational environment (*e.g.*, staff turnover, change in project leadership, change in elected officials) to ensure project stability over the life of the grant.

6. Describe the staff positions showing the role and level of effort (percent) committed for each position. Forensic health care services require a coordinated response, however successful grant applicants should identify and include a position description for the project lead/full-time coordinator who will serve as the primary point of contact. For example, if the project lead also serves as the forensic nurse examiner, please indicate the expected percent of time that will be committed to grant objectives and outcomes. Include a biographical sketch for those individuals in key positions that are identified and currently on staff. Each biographical sketch should not exceed one page and should be submitted as Other Attachments. Do not include any of the following in the biographical sketch:

- Personally Identifiable Information (*i.e.*, SSN, home address, etc.);
- Resumes; or
- Curriculum Vitae.

D. Program Evaluation (20 Points)

Program Evaluation will require grantee submission of annual progress reports through a web-based Behavioral Health Reporting portal system. Applicants are expected to collect data within their communities on prevalence rates of domestic violence, sexual assault, sexual exploitation/human trafficking, and child maltreatment. Progress reports will include the compilation of quantitative data (*e.g.*, number served; screenings completed,

etc.) and qualitative or narrative (text) data. Reporting elements may include data from local community-based and evidence-based programs pertaining to activities, processes, and outcomes such as performance measures and other data relevant to evaluation outcomes including intended results (*i.e.*, impact and outcomes).

In addition to the annual progress reports, the IHS will compile and provide aggregate program statistics including associated service unit-level Government Performance Results Act (GPRA) health care facility data available in the National Data Warehouse. Each applicant should prioritize screening efforts as an effective tool in identifying women at risk of domestic violence so that these individuals can be referred for appropriate services. Therefore, the IHS will monitor and collect available service unit GPRA data reporting the proportion of AI/AN women ages 14–46 who have been screened for domestic violence/intimate partner violence for all health care facilities associated with the awardee. For additional information regarding the IHS GPRA, see <https://www.ihs.gov/crs/gprareporting/>. Comprehensive information about CRS software and logic is available at <https://www.ihs.gov/crs/>.

1. Describe your plan on gathering data, including data related to evidence-based programs and interventions proposed, how variables will be measured and what method will be used, and how the data will be used for quality improvement and sustainability of program.

2. Describe your plan on collaborating with your regional TEC to complete evaluation efforts.

3. Describe how you will prioritize screening efforts as a tool in identifying AI/AN women ages 14–46 who are at risk for intimate partner violence/domestic violence (IPV/DV) so that these individuals can be referred for appropriate services and data can be collected for IHS GPRA measures related to IPV/DV.

4. Describe how you will prioritize screening efforts as a tool in identifying AI/AN who are at risk for sexual exploitation/human trafficking so that these individuals can be referred for appropriate services.

5. Describe your plan to establish necessary data-sharing agreements that will be used in support of these activities.

6. Describe your plan to collect data on number of examinations and refusals, screening for strangulation and traumatic brain injuries, and sexual exploitation/human trafficking.

E. Budget and Budget Narrative (10 Points)

The budget must match the program and work plan described in the program narrative for the first budget year expenses only.

1. Create a budget narrative and a line item budget that are aligned with your goal(s), objectives, and activities listed in the program and work plan described in the project narrative for Year 1.

2. Include travel funds for your project director and coordinator to attend the first grantee meeting.

Multi-Year Project Requirements

Applications must include a brief project narrative and budget (one additional page per year) addressing the developmental plans for each additional year of the project. This attachment will not count as part of the project narrative or the budget narrative.

Additional documents can be uploaded as Other Attachments in *Grants.gov*. These can include:

- Work plan, timeline, and logic model for the program plan.
- Position descriptions for key staff.
- Consultant or contractor proposed scope of work and letter of commitment (if applicable).
- Current Indirect Cost Rate Agreement.
- Organizational chart.
- Abstract.
- Map of area identifying project location(s).

2. Review and Selection

Each application will be prescreened for eligibility and completeness as outlined in the funding announcement. Applications that meet the eligibility criteria shall be reviewed for merit by the Objective Review Committee (ORC) based on evaluation criteria. Incomplete applications and applications that are not responsive to the administrative thresholds (budget limit, project period limit) will not be referred to the ORC and will not be funded. The applicant will be notified of this determination.

Applicants must address all program requirements and provide all required documentation.

3. Notifications of Disposition

All applicants will receive an Executive Summary Statement from the IHS DBH within 30 days of the conclusion of the ORC outlining the strengths and weaknesses of their application. The summary statement will be sent to the Authorizing Official identified on the face page (SF-424) of the application.

A. Award Notices for Funded Applications

The NoA is the authorizing document for which funds are dispersed to the approved entities and reflects the amount of Federal funds awarded, the purpose of the grant, the terms and conditions of the award, the effective date of the award, and the budget/project period. Each entity approved for funding must have a user account in GrantSolutions in order to retrieve the NoA. Please see the Agency Contacts list in Section VII for the systems contact information.

B. Approved but Unfunded Applications

Approved applications not funded due to lack of available funds will be held for one year. If funding becomes available during the course of the year, the application may be reconsidered.

Note: Any correspondence other than the official NoA executed by an IHS grants management official announcing to the project director that an award has been made to their organization is not an authorization to implement their program on behalf of the IHS.

VI. Award Administration Information

1. Administrative Requirements

Awards issued under this announcement are subject to, and are administered in accordance with, the following regulations and policies:

A. The criteria as outlined in this program announcement.

B. Administrative Regulations for Grants:

- Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards currently in effect or implemented during the period of award, other Department regulations and policies in effect at the time of award, and applicable statutory provisions. At the time of publication, this includes 45 CFR part 75, at <https://www.govinfo.gov/content/pkg/CFR-2020-title45-vol1/pdf/CFR-2020-title45-vol1-part75.pdf>.
- Please review all HHS regulatory provisions for Termination at 45 CFR 75.372, at https://www.ecfr.gov/cgi-bin/retrieveECFR?gp&SID=2970eec67399fab1413ede53d7895d99&mc=true&n=pt45.1.75&r=PART&ty=HTML&se45.1.75_1372#se45.1.75_1372.

C. Grants Policy:

- HHS Grants Policy Statement, Revised January 2007, at <http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgrs107.pdf>.

D. Cost Principles:

- Uniform Administrative Requirements for HHS Awards, “Cost Principles,” at 45 CFR part 75 subpart E.

E. Audit Requirements:

- Uniform Administrative Requirements for HHS Awards, “Audit Requirements,” at 45 CFR part 75 subpart F.

F. As of August 13, 2020, 2 CFR 200 was updated to include a prohibition on certain telecommunications and video surveillance services or equipment. This prohibition is described in 2 CFR 200.216. This will also be described in the terms and conditions of every IHS grant and cooperative agreement awarded on or after August 13, 2020.

2. Indirect Costs

This section applies to all recipients that request reimbursement of indirect costs (IDC) in their application budget. In accordance with HHS Grants Policy Statement, Part II-27, the IHS requires applicants to obtain a current IDC rate agreement and submit it to the DGM prior to the DGM issuing an award. The rate agreement must be prepared in accordance with the applicable cost principles and guidance as provided by the cognizant agency or office. A current rate covers the applicable grant activities under the current award's budget period. If the current rate agreement is not on file with the DGM at the time of award, the IDC portion of the budget will be restricted. The restrictions remain in place until the current rate agreement is provided to the DGM.

Per 45 CFR 75.414(f) Indirect (F&A) costs, “any non-Federal entity (NFE) [i.e., applicant] that has never received a negotiated indirect cost rate, . . . may elect to charge a de minimis rate of 10 percent of modified total direct costs which may be used indefinitely. As described in Section 75.403, costs must be consistently charged as either indirect or direct costs, but may not be double charged or inconsistently charged as both. If chosen, this methodology once elected must be used consistently for all Federal awards until such time as the NFE chooses to negotiate for a rate, which the NFE may apply to do at any time.”

Electing to charge a de minimis rate of 10 percent only applies to applicants that have never received an approved negotiated indirect cost rate from HHS or another cognizant federal agency. Applicants awaiting approval of their indirect cost proposal may request the 10 percent de minimis rate. When the applicant chooses this method, costs included in the indirect cost pool must

not be charged as direct costs to the grant.

Available funds are inclusive of direct and appropriate indirect costs. Approved indirect funds are awarded as part of the award amount, and no additional funds will be provided.

Generally, IDC rates for IHS grantees are negotiated with the Division of Cost Allocation at <https://rates.psc.gov/> or the Department of the Interior (Interior Business Center) at <https://ibc.doi.gov/ICS/tribal>. For questions regarding the indirect cost policy, please call the Grants Management Specialist listed under "Agency Contacts" or the main DGM office at (301) 443-5204.

3. Reporting Requirements

The grantee must submit required reports consistent with the applicable deadlines. Failure to submit required reports within the time allowed may result in suspension or termination of an active grant, withholding of additional awards for the project, or other enforcement actions such as withholding of payments or converting to the reimbursement method of payment. Continued failure to submit required reports may result in the imposition of special award provisions and/or the non-funding or non-award of other eligible projects or activities. This requirement applies whether the delinquency is attributable to the failure of the awardee organization or the individual responsible for preparation of the reports. Per DGM policy, all reports must be submitted electronically by attaching them as a "Grant Note" in *GrantSolutions*. Personnel responsible for submitting reports will be required to obtain a login and password for *GrantSolutions*. Please see the Agency Contacts list in Section VII for the systems contact information.

The reporting requirements for this program are noted below.

A. Progress Reports

Program progress reports are required annually. The progress reports are due within 30 days after the reporting period ends (specific dates will be listed in the NoA Terms and Conditions). Progress reports are required to be submitted via the IHS behavioral health online data portal and *GrantSolutions*. These reports must include a brief comparison of actual accomplishments to the goals established for the period, a summary of progress to date or, if applicable, provide sound justification for the lack of progress, in addition to other information requested by the DBH. A final report must be submitted within 90 days of expiration of the period of performance.

B. Financial Reports

Federal Cash Transaction Reports are due 30 days after the close of every calendar quarter to the Payment Management Services at <https://pms.psc.gov>. Failure to submit timely reports may result in adverse award actions blocking access to funds.

Federal Financial Reports are due 30 days after the end of each budget period, and a final report is due 90 days after the end of the period of performance.

Grantees are responsible and accountable for reporting accurate information on all required reports: The Progress Reports, the Federal Cash Transaction Report, and the Federal Financial Report.

C. Data Collection and Reporting

Program Evaluation will require grantee submission of annual progress reports through a web-based Behavioral Health Reporting portal system. Applicants are expected to collect data within their communities on prevalence rates of domestic violence, sexual assault, and child maltreatment. Progress reports will include the compilation of quantitative data (e.g., number served, screenings completed, etc.) and qualitative or narrative (text) data. Reporting elements may include data from local community-based and evidence-based programs pertaining to activities, processes, and outcomes, such as performance measures and other data relevant to evaluation outcomes including intended results (i.e., impact and outcomes).

In addition to the annual progress reports, the IHS will compile and provide aggregate program statistics including associated service unit GPRA health care facility data available in the National Data Warehouse. Each applicant should prioritize screening efforts as an effective tool in identifying women at risk of domestic violence so that these individuals can be referred for appropriate services. Therefore, the IHS will monitor and collect available service unit GPRA data reporting the proportion of AI/AN women ages 14–46 who have been screened for domestic violence/intimate partner violence for all health care facilities associated with the community awarded. For additional information regarding the IHS GPRA, see <https://www.ihs.gov/crs/gprareporting/>. Comprehensive information about CRS software and logic is available at <https://www.ihs.gov/crs/>.

D. Federal Sub-Award Reporting System (FSRS)

This award may be subject to the Transparency Act sub-award and

executive compensation reporting requirements of 2 CFR part 170.

The Transparency Act requires the OMB to establish a single searchable database, accessible to the public, with information on financial assistance awards made by Federal agencies. The Transparency Act also includes a requirement for recipients of Federal grants to report information about first-tier sub-awards and executive compensation under Federal assistance awards.

The IHS has implemented a Term of Award into all IHS Standard Terms and Conditions, NoAs, and funding announcements regarding the FSRS reporting requirement. This IHS Term of Award is applicable to all IHS grant and cooperative agreements issued on or after October 1, 2010, with a \$25,000 sub-award obligation threshold met for any specific reporting period.

For the full IHS award term implementing this requirement and additional award applicability information, visit the DGM Grants Management website at <https://www.ihs.gov/dgm/policytopics/>.

E. Compliance With Executive Order 13166 Implementation of Services Accessibility Provisions for All Grant Application Packages and Funding Opportunity Announcements

Should you successfully compete for an award, recipients of Federal financial assistance (FFA) from HHS must administer their programs in compliance with Federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex (including gender identity, sexual orientation, and pregnancy). This includes ensuring programs are accessible to persons with limited English proficiency and persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. Please see <https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html> and <https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html>.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting your legal obligation to take reasonable steps to ensure meaningful access to your programs or activities by limited English proficiency individuals, see <https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited->

[english-proficiency/fact-sheet-guidance/index.html](https://www.english-proficiency/fact-sheet-guidance/index.html) and <https://www.lep.gov>.

- For information on your specific legal obligations for serving qualified individuals with disabilities, including reasonable modifications and making services accessible to them, see <https://www.hhs.gov/ocr/civilrights/understanding/disability/index.html>.

- HHS funded health and education programs must be administered in an environment free of sexual harassment. See <https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html>.

- For guidance on administering your program in compliance with applicable Federal religious nondiscrimination laws and applicable Federal conscience protection and associated anti-discrimination laws, see <https://www.hhs.gov/conscience/conscience-protections/index.html> and <https://www.hhs.gov/conscience/religious-freedom/index.html>.

F. Federal Awardee Performance and Integrity Information System (FAPIIS)

The IHS is required to review and consider any information about the applicant that is in the FAPIIS at <https://www.fapiis.gov> before making any award in excess of the simplified acquisition threshold (currently \$250,000) over the period of performance. An applicant may review and comment on any information about itself that a Federal awarding agency previously entered. The IHS will consider any comments by the applicant, in addition to other information in FAPIIS, in making a judgment about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 45 CFR 75.205.

As required by 45 CFR part 75 Appendix XII of the Uniform Guidance, NFEs are required to disclose in FAPIIS any information about criminal, civil, and administrative proceedings, and/or affirm that there is no new information to provide. This applies to NFEs that receive Federal awards (currently active grants, cooperative agreements, and procurement contracts) greater than \$10,000,000 for any period of time during the period of performance of an award/project.

Mandatory Disclosure Requirements

As required by 2 CFR part 200 of the Uniform Guidance, and the HHS implementing regulations at 45 CFR part 75, the IHS must require an NFE or an applicant for a Federal award to disclose, in a timely manner, in writing

to the IHS or pass-through entity all violations of Federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the Federal award.

All applicants and recipients must disclose in writing, in a timely manner, to the IHS and to the HHS Office of Inspector General all information related to violations of Federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the Federal award. 45 CFR 75.113.

Disclosures must be sent in writing to: U.S. Department of Health and Human Services, Indian Health Service, Division of Grants Management, ATTN: Paul Gettys, Acting Director, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857 (Include "Mandatory Grant Disclosures" in subject line), Office: (301) 443-5204, Fax: (301) 594-0899, Email: Paul.Gettys@ihs.gov.

AND

U.S. Department of Health and Human Services, Office of Inspector General, ATTN: Mandatory Grant Disclosures, Intake Coordinator, 330 Independence Avenue SW, Cohen Building, Room 5527, Washington, DC 20201, URL: <https://oig.hhs.gov/fraud/report-fraud/> (Include "Mandatory Grant Disclosures" in subject line), Fax: (202) 205-0604, (Include "Mandatory Grant Disclosures" in subject line) or Email: MandatoryGranteeDisclosures@oig.hhs.gov.

Failure to make required disclosures can result in any of the remedies described in 45 CFR 75.371 Remedies for noncompliance, including suspension or debarment (see 2 CFR part 180 and 2 CFR part 376).

VII. Agency Contacts

1. Questions on the programmatic issues may be directed to: Audrey Solimon, Public Health Analyst, Indian Health Service, Division of Behavioral Health, 5600 Fishers Lane, Mail Stop: 08N34-A, Rockville, MD 20857, Phone: (301) 590-5421, Fax: (301) 594-6213, Email: Audrey.Solimon@ihs.gov.

2. Questions on grants management and fiscal matters may be directed to: Andrew Diggs, Grants Management Specialist, DGM, Indian Health Service, Division of Grants Management, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, Phone: (301) 443-2241, Email: Andrew.Diggs@ihs.gov.

3. Questions on systems matters may be directed to: Paul Gettys, Acting Director, DGM, Indian Health Service, Division of Grants Management, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, Phone: (301) 443-

2114; or the DGM main line (301) 443-5204, Email: Paul.Gettys@ihs.gov.

VIII. Other Information

The Public Health Service strongly encourages all grant, cooperative agreement, and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of the facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the HHS mission to protect and advance the physical and mental health of the American people.

Elizabeth A. Fowler,

Acting Director, Indian Health Service.

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BILLING CODE 4165-16-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Substance Abuse and Suicide Prevention Program: Substance Abuse Prevention, Treatment, and Aftercare

Announcement Type: New.

Funding Announcement Number:

HHS-2022-IHS-SAPTA-0001.

Assistance Listing (Catalog of Federal Domestic Assistance or CFDA) Number: 93.654.

Key Dates

Application Deadline Date: February 2, 2022.

Earliest Anticipated Start Date: March 21, 2022.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) is accepting applications for a component of the Substance Abuse and Suicide Prevention (SASP) Program: Substance Abuse Prevention, Treatment, and Aftercare (SAPTA). This program was first established by the Consolidated Appropriations Act of 2008, Public Law 110-161, 121 Stat. 1844, 2135 (then called the Methamphetamine and Suicide Prevention Initiative (MSPI)). This program is authorized under the Snyder Act, 25 U.S.C. 13; the Transfer Act, 42 U.S.C. 2001(a); and the Indian Health Care Improvement Act, 25 U.S.C. 1665a. This program is described in the Assistance Listings located at <https://sam.gov/content/home> (formerly known as the CFDA) under 93.654.

Background

The origin of this SASP SAPTA grant program began with the MSPI, conducted from September 2009–August 2015. In that nationally coordinated 6-year demonstration pilot project, the IHS funded 130 IHS, Tribal, and Urban Indian organizations (UIOs) and focused on providing methamphetamine and suicide prevention and intervention resources for Indian Country. The second phase of the funding cycle built on lessons learned from the MSPI pilot and was implemented from September 2015–September 2020 and funded 174 IHS, Tribal, and UIO projects. This phase of the SAPTA portion of the SASP Program will continue to build upon previous years' work, lessons learned and will continue to promote the use and development of evidence-based and practice-based models that represent culturally appropriate prevention and treatment approaches to substance use and suicide prevention from a community-driven context. For a complete listing of demonstration pilot and cohort one projects, please visit <https://www.ihs.gov/sasp/pilotprojects20092014/> and <https://www.ihs.gov/sasp/fundedprojects/>.

In previous years, awards were made from the same funding opportunity announcement with four distinct "purpose areas." In order to provide program clarity and tracking of outcomes, the IHS is offering funding through separate notice of funding opportunity announcements for fiscal year (FY) 2022. This funding opportunity is focused on Substance Abuse Prevention, Treatment, and Aftercare. There will not be separate "purpose areas" for this funding opportunity.

Purpose

The primary purpose of this program is to reduce the prevalence of substance abuse and decrease the overall use of addicting and illicit substances among American Indian and Alaska Native (AI/AN) populations. Tribes can accomplish these goals by:

1. Improving care coordination;
2. Expanding behavioral health care services through the use of culturally appropriate evidence-based and practice-based models to address these issues; and
3. In addition to any proposed activities for the adult population, develop, or expand on activities for the Generation Indigenous (Gen-I) Initiative by implementing early intervention strategies for AI/AN youth at risk for substance abuse behavior.

In alignment with the IHS 2019–2023 Strategic Plan Goal 1: To ensure that comprehensive, culturally appropriate personal and public health services are available and accessible to AI/AN people, the SASP program is designed to ensure access to comprehensive, culturally appropriate services and promote quality programming to address substance abuse for AI/AN community members. The IHS supports Tribal efforts that include addressing substance abuse prevention, treatment, and aftercare from a community-driven context. The IHS encourages applicants to develop and submit a plan that emphasizes cross-system collaboration, the inclusion of family, youth, and community resources, and culturally appropriate approaches.

Required Activities

The focus of this funding opportunity announcement is on the prevention, treatment, and aftercare for substance abuse among AI/AN populations.

The IHS is seeking applications that include the following required activities:

1. Foster coalitions and networks to improve care coordination:
 - a. Educate and train providers in the identification and care of substance abuse disorders with tools such as the Screening, Brief Intervention, and Referral to Treatment; the Alcohol, Smoking, and Substance Involvement Screening Test; the Addiction Severity Index; the Alcohol Use Disorders Identification Test; and trauma-informed care.
 - b. Educate and train community members to recognize the signs of substance abuse to prevent the spread of addictive and illicit substances.
 - c. Increase community awareness of local behavioral health services.
 - d. Develop community response plans related to substance abuse prevention and treatment services.
 - e. Establish local health system policies and protocols to integrate, coordinate, and/or provide access to substance abuse prevention and intervention services in schools, courts, corrections/detention systems, and law enforcement agencies.
2. Expand available behavioral health care treatment services:
 - a. Identify the target population to include, but not be limited to Tribal youth.
 - b. Develop a strategic plan to address the health system organizational needs for substance abuse disorders.
 - c. Integrate behavioral health into the primary care setting for substance abuse prevention and screening to include the

use, or expansion of telehealth and similar technologies.

d. Provide evidence-based substance abuse care for clients at risk for substance abuse disorders.

e. Provide access to culturally appropriate treatment services and resources.

f. Implement a trauma-informed approach and trauma-informed care treatment and services.

3. Improve the referral process:

a. Increase the capacity of community members and service providers (*i.e.*, primary care, schools, child welfare, criminal justice) to make appropriate referrals to behavioral health services and support systems related to substance abuse prevention, treatment, and aftercare.

b. Refer to cultural services and/or culturally appropriate substance abuse prevention, treatment, and aftercare services, including natural support systems.

4. In addition to any proposed activities for the adult population, develop, or expand on activities for the Gen-I Initiative by implementing culturally appropriate evidence-based and practice-based approaches to build resiliency, resistance, hardiness, empathy, promote positive development, and increase self-sufficiency behaviors among Native youth:

a. Implement evidence-based and practice-based interventions for substance abuse prevention for Native youth in the community.

b. Provide support services to Native youth and their families impacted by substance abuse.

c. Promote positive development and increase self-sufficiency of Native youth by providing culturally appropriate substance abuse prevention activities.

d. Promote family and community engagement in the planning and implementation of Native youth substance abuse prevention activities.

e. Provide school-based awareness/education about substance abuse prevention, treatment, and aftercare services.

f. Support the development of Native youth peer-to-peer support and education programs.

g. Promote/support the development of a Tribal Youth Council to provide guidance/feedback on community substance abuse prevention planning and strategic planning.

5. Develop a formal plan/process to ensure the sustainability of the project activities beyond the grant life-cycle. (Note: Tribes that have developed a Tribal Action Plan (TAP) under the Indian Alcohol and Substance Abuse

Prevention and Treatment Act of 1986, as amended by the Tribal Law and Order Act of 2010, may use SASP program funds to build on, or supplement their TAP work.)

a. Develop a strategic plan to address long-term substance abuse prevention, treatment, and aftercare needs of the community.

b. Assess community and workforce needs and assets via a community and organization needs assessment and community resource asset mapping.

II. Award Information

Funding Instrument—Grant

Estimated Funds Available

The total funding identified for FY 2022 is approximately \$14,000,000. Individual award amounts for the first budget year are anticipated to be between \$300,000 and \$400,000. The funding available for competing and subsequent continuation awards issued under this announcement is subject to the availability of appropriations and budgetary priorities of the Agency. The IHS is under no obligation to make awards that are selected for funding under this announcement.

Anticipated Number of Awards

Approximately 35 awards will be issued under this program announcement. Up to five awards will be set aside for eligible UIOs.

Period of Performance

The period of performance is for 5 years.

III. Eligibility Information

1. Eligibility

To be eligible for this new funding opportunity, applicants must be one of the following as defined by 25 U.S.C. 1603:

- A federally recognized Indian Tribe as defined by 25 U.S.C. 1603(14).

The term “Indian Tribe” means any Indian Tribe, band, nation, or other organized group or community, including any Alaska Native village or group, or regional or village corporation as defined in or established pursuant to the Alaska Native Claims Settlement Act (85 Stat. 688) [43 U.S.C. 1601 *et seq.*], which is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians.

- A Tribal organization as defined by 25 U.S.C. 1603(26). The term “Tribal organization” has the meaning given the term in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304(l)): “Tribal organization” means the

recognized governing body of any Indian Tribe; any legally established organization of Indians which is controlled, sanctioned, or chartered by such governing body or which is democratically elected by the adult members of the Indian community to be served by such organization and which includes the maximum participation of Indians in all phases of its activities: Provided that, in any case where a contract is let or grant made to an organization to perform services benefiting more than one Indian Tribe, the approval of each such Indian Tribe shall be a prerequisite to the letting or making of such contract or grant. Applicant shall submit letters of support and/or Tribal Resolutions from the Tribes to be served.

- An Urban Indian organization as defined by 25 U.S.C. 1603(29). The term “Urban Indian organization” means a nonprofit corporate body situated in an urban center, governed by an urban Indian controlled board of directors, and providing for the maximum participation of all interested Indian groups and individuals, which body is capable of legally cooperating with other public and private entities for the purpose of performing the activities described in 25 U.S.C. 1653(a).

Applicants must provide proof of nonprofit status with the application, e.g., 501(c)(3).

The program office will notify any applicants deemed ineligible.

Note: Please refer to Section IV.2 (Application and Submission Information/Subsection 2, Content and Form of Application Submission) for additional proof of applicant status documents required, such as Tribal Resolutions, proof of nonprofit status, etc.

2. Cost Sharing or Matching

The IHS does not require matching funds or cost sharing for grants or cooperative agreements.

3. Other Requirements

Applications with budget requests that exceed the highest dollar amount outlined under Section II Award Information, Estimated Funds Available, or exceed the period of performance outlined under Section II Award Information, Period of Performance, are considered not responsive and will not be reviewed. The Division of Grants Management (DGM) will notify the applicant.

Additional Required Documentation Tribal Resolution

The DGM must receive an official, signed Tribal Resolution prior to issuing

a Notice of Award (NoA) to any applicant selected for funding. An Indian Tribe or Tribal organization that is proposing a project affecting another Indian Tribe must include resolutions from all affected Tribes to be served. However, if an official, signed Tribal Resolution cannot be submitted with the application prior to the application deadline date, a draft Tribal Resolution must be submitted with the application by the deadline date in order for the application to be considered complete and eligible for review. The draft Tribal Resolution is not in lieu of the required signed resolution but is acceptable until a signed resolution is received. If an application without a signed Tribal Resolution is selected for funding, the applicant will be contacted by the Grants Management Specialist (GMS) listed in this funding announcement and given 90 days to submit an official, signed Tribal Resolution to the GMS. If the signed Tribal Resolution is not received within 90 days, the award will be forfeited.

Tribes organized with a governing structure other than a Tribal council may submit an equivalent document commensurate with their governing organization.

Proof of Nonprofit Status

Organizations claiming nonprofit status must submit a current copy of the 501(c)(3) Certificate with the application.

IV. Application and Submission Information

1. Obtaining Application Materials

The application package and detailed instructions for this announcement are available at <https://www.Grants.gov>.

Please direct questions regarding the application process to Mr. Paul Gettys at (301) 443–2114 or (301) 443–5204.

2. Content and Form Application Submission

Mandatory documents for all applicants include:

- Abstract (one page) summarizing the project.

- Application forms:

1. SF–424, Application for Federal Assistance.

2. SF–424A, Budget Information—Non-Construction Programs.

3. SF–424B, Assurances—Non-Construction Programs.

- Project Narrative (not to exceed 15 pages). See Section IV.2.A, Project Narrative for instructions.

1. Background information on the organization.

2. Proposed scope of work, objectives, and activities that provide a description

of what the applicant plans to accomplish.

- Timeline (one page).
- Budget Justification and Narrative (not to exceed four pages). See Section IV.2.B, Budget Narrative for instructions.

- Tribal Resolution or Tribal Letter of Support (only required for Tribes and Tribal organizations).

- Letter(s) of Commitment:
 1. Local Organizational Partners;
 2. Community Partners;
 3. For Tribal organizations: from the board of directors (or relevant equivalent);

- 4. For UIOs: From the board of directors (or relevant equivalent).

- 501(c)(3) Certificate (if applicable).
- Biographical sketches for all key personnel (e.g., project director, project coordinator, grants coordinator, etc.) (not to exceed one page each).

- Contractor/consultant qualifications and scope of work.

- Disclosure of Lobbying Activities (SF–LLL), if applicant conducts reportable lobbying.

- Certification Regarding Lobbying (GG–Lobbying Form).

- Copy of current Negotiated Indirect Cost rate (IDC) agreement (required in order to receive IDC).

- Documentation of current Office of Management and Budget (OMB) Financial Audit (if applicable).

Acceptable forms of documentation include:

1. Email confirmation from Federal Audit Clearinghouse (FAC) that audits were submitted; or

2. Face sheets from audit reports.

Applicants can find these on the FAC website at <https://harvester.census.gov/facdissem/Main.aspx>.

Public Policy Requirements

All Federal public policies apply to IHS grants and cooperative agreements. Pursuant to 45 CFR 80.3(d), an individual shall not be deemed subjected to discrimination by reason of their exclusion from benefits limited by Federal law to individuals eligible for benefits and services from the IHS. See <https://www.hhs.gov/grants/grants/grants-policies-regulations/index.html>.

Requirements for Project and Budget Narratives

A. Project Narrative

This narrative should be a separate document that is no more than 15 pages and must: (1) Have consecutively numbered pages; (2) use black font 12 points or larger; (3) be single-spaced; and (4) be formatted to fit standard letter paper (8½ x 11 inches).

Be sure to succinctly answer all questions listed under the evaluation criteria (refer to Section V.1, Evaluation Criteria) and place all responses and required information in the correct section noted below or they will not be considered or scored. If the narrative exceeds the page limit, the application will be considered not responsive and will not be reviewed. The 15-page limit for the narrative does not include the standard forms, Tribal Resolutions, budget, budget justification and narrative, and/or other items.

There are three parts to the narrative: Part 1—Program Planning; Part 2—Program Data Collection and Evaluation; and Part 3—Program Accomplishments Report. See below for additional details about what must be included in the narrative. The page limits below are for each narrative and budget submitted.

Part 1: Program Planning (Limit—10 Pages)

Describe the scope of work the Tribe, Tribal organization, or UIO by clearly and concisely outlining the following required components:

1. Goals and Objectives. Reference all required objectives.

2. Project Activities. Link your project activities to your outlined goals and objectives.

3. Organization Capacity and Staffing/Administration. State your organization's current capacity to implement and manage this award (i.e., current staffing, facilities, information systems, and experience with previous similar projects).

Part 2: Program Data Collection and Evaluation (Limit—3 Pages)

Based on the required objectives, describe how the Tribe, Tribal organization, or UIO plans to collect data for the proposed project and activities. Identify any type(s) of evaluation(s) that will be used and how you will collaborate with partners (i.e., Tribal Epidemiology Center (TEC)) to complete any evaluation efforts or data collection. Funded projects are encouraged to coordinate data collection efforts with their TEC or Urban Epidemiology Center (for urban awardees) and should describe their plan for coordination and collaboration with the TEC.

Part 3: Program Accomplishments Report (Limit—2 Pages)

Describe the Tribe, Tribal organization, or UIO's significant program activities and achievements/accomplishments over the past 5 years associated with substance abuse prevention, treatment, and aftercare

activities. Provide success stories, data, or other examples of how other funded projects/programs made an impact in your community to address substance abuse. If applicable, provide justification for lack of progress of previous efforts.

B. Budget Narrative (Limit—4 Pages)

Provide a budget narrative that explains the amounts requested for each line item of the budget from the SF–424A (Budget Information for Non-Construction Programs). The budget narrative can include a more detailed spreadsheet than is provided by the SF–424A. The budget narrative should specifically describe how each item will support the achievement of proposed objectives. Be very careful about showing how each item in the “Other” category is justified. For subsequent budget years (see Multi-Year Project Requirements in Section V.1, Application Review Information, Evaluation Criteria), the narrative should highlight the changes from the first year or clearly indicate that there are no substantive budget changes during the period of performance. Do NOT use the budget narrative to expand the project narrative.

The SASP program proposal template and associated templates for the timeline chart, biographical sketch, budget and budget narrative/justification, can be located and downloaded at the SASP program website at <https://www.ihs.gov/sasp/newsannouncements/>.

3. Submission Dates and Times

Applications must be submitted through *Grants.gov* by 11:59 p.m. Eastern Time on the Application Deadline Date. Any application received after the application deadline will not be accepted for review. *Grants.gov* will notify the applicant via email if the application is rejected.

If technical challenges arise and assistance is required with the application process, contact *Grants.gov* Customer Support (see contact information at <https://www.grants.gov>). If problems persist, contact Mr. Paul Gettys (Paul.Gettys@ihs.gov), Acting Director, DGM, by telephone at (301) 443–2114 or (301) 443–5204. Please be sure to contact Mr. Gettys at least ten days prior to the application deadline. Please do not contact the DGM until you have received a *Grants.gov* tracking number. In the event you are not able to obtain a tracking number, call the DGM as soon as possible.

The IHS will not acknowledge receipt of applications.

4. Intergovernmental Review

Executive Order 12372 requiring intergovernmental review is not applicable to this program.

5. Funding Restrictions

- Pre-award costs are allowable up to 90 days before the start date of the award provided the costs are otherwise allowable if awarded. Pre-award costs are incurred at the risk of the applicant.
- The available funds are inclusive of direct and indirect costs.
- Only one grant will be awarded per applicant.
- The purchase of food (*i.e.*, as supplies, for meetings or events, etc.) is not an allowable cost with this grant funding and should not be included in the budget/budget justification.

6. Electronic Submission Requirements

All applications must be submitted via *Grants.gov*. Please use the <https://www.Grants.gov> website to submit an application. Find the application by selecting the “Search Grants” link on the homepage. Follow the instructions for submitting an application under the Package tab. No other method of application submission is acceptable.

If the applicant cannot submit an application through *Grants.gov*, a waiver must be requested. Prior approval must be requested and obtained from Mr. Paul Gettys, Acting Director, DGM. A written waiver request must be sent to GrantsPolicy@ihs.gov with a copy to Paul.Gettys@ihs.gov. The waiver request must: (1) Be documented in writing (emails are acceptable) before submitting an application by some other method; and (2) include clear justification for the need to deviate from the required application submission process.

Once the waiver request has been approved, the applicant will receive a confirmation of approval email containing submission instructions. A copy of the written approval must be included with the application that is submitted to the DGM. Applications that are submitted without a copy of the signed waiver from the Acting Director of the DGM will not be reviewed. The Grants Management Officer of the DGM will notify the applicant via email of this decision. Applications submitted under waiver must be received by the DGM no later than 5:00 p.m. Eastern Time on the Application Deadline Date. Late applications will not be accepted for processing. Applicants that do not register for both the System for Award Management (SAM) and *Grants.gov* and/or fail to request timely assistance with technical issues will not be

considered for a waiver to submit an application via alternative method.

Please be aware of the following:

- Please search for the application package in <https://www.Grants.gov> by entering the Assistance Listing (CFDA) number or the Funding Opportunity Number. Both numbers are located in the header of this announcement.
- If you experience technical challenges while submitting your application, please contact *Grants.gov* Customer Support (see contact information at <https://www.grants.gov>).
- Upon contacting *Grants.gov*, obtain a tracking number as proof of contact. The tracking number is helpful if there are technical issues that cannot be resolved and a waiver from the agency must be obtained.
- Applicants are strongly encouraged not to wait until the deadline date to begin the application process through *Grants.gov* as the registration process for SAM and *Grants.gov* could take up to 20 working days.
- Please follow the instructions on *Grants.gov* to include additional documentation that may be requested by this funding announcement.
- Applicants must comply with any page limits described in this funding announcement.
- After submitting the application, the applicant will receive an automatic acknowledgment from *Grants.gov* that contains a *Grants.gov* tracking number. The IHS will not notify the applicant that the application has been received.

Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS)

Applicants and grantee organizations are required to obtain a DUNS number and maintain an active registration in the SAM database. The DUNS number is a unique 9-digit identification number provided by D&B that uniquely identifies each entity. The DUNS number is site specific; therefore, each distinct performance site may be assigned a DUNS number. Obtaining a DUNS number is easy, and there is no charge. To obtain a DUNS number, please access the request service through <https://fedgov.dnb.com/webform>, or call (866) 705-5711.

The Federal Funding Accountability and Transparency Act of 2006, as amended (“Transparency Act”), requires all HHS recipients to report information on sub-awards. Accordingly, all IHS grantees must notify potential first-tier sub-recipients that no entity may receive a first-tier sub-award unless the entity has provided its DUNS number to the prime grantee organization. This requirement ensures the use of a universal identifier

to enhance the quality of information available to the public pursuant to the Transparency Act.

System for Award Management (SAM)

Organizations that are not registered with SAM must have a DUNS number first, then access the SAM online registration through the SAM home page at <https://sam.gov> (U.S. organizations will also need to provide an Employer Identification Number from the Internal Revenue Service that may take an additional 2–5 weeks to become active). Please see SAM.gov for details on the registration process and timeline. Registration with the SAM is free of charge, but can take several weeks to process. Applicants may register online at <https://sam.gov>.

Additional information on implementing the Transparency Act, including the specific requirements for DUNS and SAM, are available on the DGM Grants Management, Policy Topics web page at <https://www.ihs.gov/dgm/policytopics/>.

V. Application Review Information

Possible points assigned to each section are noted in parentheses. The project narrative and budget narrative should include only the first year of activities; information for multi-year projects should be included as a separate document. See “Multi-year Project Requirements” at the end of this section for more information. The project narrative should be written in a manner that is clear to outside reviewers unfamiliar with prior related activities of the applicant. It should be well organized, succinct, and contain all information necessary for reviewers to fully understand the project. Attachments requested in the criteria do not count toward the page limit for the narratives. Points will be assigned to each evaluation criteria adding up to a total of 100 possible points. Points are assigned as follows:

1. Evaluation Criteria

A. Statement of Need (20 Points)

1. Describe the history and current situation in the applicant’s Tribal community (“community” means the applicant’s Tribe, village, Tribal organization, or consortium of Tribes or Tribal organizations). Provide facts and evidence that support the need for the project and establishes that the Tribe, Tribal organization, or UIO understands the problems and can reasonably address them.

2. Provide background information on the Tribe, Tribal organization, or UIO.

3. Identify the proposed catchment area and provide demographic

information on the population(s) to receive services through the targeted systems or agencies, e.g., race, ethnicity, federally recognized Tribe, language, age, socioeconomic status, sexual identity (sexual orientation, gender identity), and other relevant factors, such as literacy. Describe the stakeholders and resources in the catchment area that can help implement the needed infrastructure development.

4. Based on the information and/or data currently available, document the prevalence of substance abuse rates. Examples of data sources for the quantitative data are local epidemiologic data (e.g., TECs, IHS Area Offices), state data (e.g., from state needs assessments, state health reports), and/or national data (e.g., Substance Abuse and Mental Health Services Administration's (SAMHSA) National Survey on Drug Use and Health, Centers for Disease Control and Prevention National Center for Health Statistics reports, and U.S. Census). This list is not exhaustive; applicants may submit other valid data, as appropriate for the applicant's proposed project.

5. Based on the information and/or data currently available, document the need for an enhanced infrastructure to increase the capacity to implement, sustain, and improve effective behavioral health services in the proposed catchment area that is consistent with the purpose of this funding opportunity announcement. Based on available data, describe the service gaps and other problems related to the need for infrastructure development. Identify the source of the data. Documentation of need may come from a variety of qualitative and quantitative sources such as organizational quality improvement measures, internal audits of services and programs, or other previous program reviews and assessments.

6. Describe the existing behavioral health service gaps, barriers, and other systemic challenges related to the need for planning and infrastructure development and coordination of substance abuse prevention, treatment, and aftercare services.

7. Describe potential project partners and community resources in the catchment area that can participate in the planning process and infrastructure development.

8. Affirm the goals of the project are consistent with priorities of the Tribal government or board of directors and that the governing body is in support of this application.

B. Project Goals, Objectives, Activities, and Approach (35 Points)

Evidence-Based Practices, Practice-Based Evidence, Promising Practices, and Local Efforts: The IHS strongly emphasizes the use of data and evidence in policymaking and program development and implementation in developing and implementing Tribal and/or culturally appropriate substance abuse prevention, treatment, and aftercare, as well as early intervention strategies. Applicants are required to identify one or more evidence-based practice, practice-based evidence, best or promising practice, and/or local effort that they plan to implement in the project narrative section of their application. The SASP program website (<https://www.ihs.gov/sasp/>) is one resource that applicants may use to find information to build on the foundation of prior projects' substance abuse prevention and treatment efforts.

The IHS recognizes the limited range of formally evaluated evidence-based practices for substance abuse prevention, treatment, and aftercare efforts that have been developed specifically for the AI/AN population. In addition to formally evaluated practices, evidence for other practices allowed in this grant program may include unpublished studies, preliminary evaluation results, clinical (or other professional association) guidelines, findings from focus groups with community members, local community surveys, and so on. Each applicant is required to:

- Document the evidence that the practice(s) you have chosen is appropriate for the outcomes you want to achieve;
- Explain how the practice you have chosen meets the three goals stated in the Purpose section of this announcement;
- Describe any modifications/adaptations you will need to make to your proposed practice(s) to meet the goals of your project and why you believe the changes will improve the outcomes; and
- Discuss training needs or plans for training to successfully implement the proposed evidence-based practice(s).

1. Clearly and concisely describe the purpose of the proposed project, including goals and objectives and how they are linked. Describe how the achievement of goals will increase system capacity to support the goals and required activities identified in Section I.

2. Clearly and concisely describe how the proposed project activities are related to the proposed project's goals

and objectives. Describe how the project activities will increase the capacity of the identified community to plan, improve and sustain the coordination of a collaborative behavioral health and wellness service system to address substance abuse.

3. Discuss how the proposed approach addresses the local language, concepts, attitudes, norms, and values about substance abuse.

4. Describe how the proposed project will address issues of diversity within the population of focus including age, race, gender, ethnicity, culture/cultural identity, language, sexual orientation, disability, and literacy.

5. Describe how members of the community (including youth and families that may receive services) will be involved in the planning, implementation, data collection, and evaluation of the project.

6. Describe how the efforts of the proposed project will be coordinated with any other related Federal grants or programs funded through the IHS, SAMHSA, Bureau of Indian Affairs, or other Federal agencies.

7. Provide a timeline chart depicting a realistic timeline for the project period showing key activities, milestones, and responsible staff. These key activities should include the required activities identified in Section I.

8. Identify any other organization(s) that will participate in the proposed project. Describe their roles and responsibilities and demonstrate their commitment to the project.

C. Organizational Capabilities, Key Personnel, and Qualifications (15 Points)

1. Describe the management capability and experience of the applicant Tribe, Tribal organization, or UIO and other participating organizations in administering and sustaining results of similar grants and projects.

2. Describe significant program activities and achievements or accomplishments over the past 5 years associated with substance abuse prevention, treatment, and aftercare.

3. Describe the applicant Tribe, Tribal organization, or UIO experience and capacity to provide and sustain culturally appropriate/competent services to the community and specific populations of focus.

4. Describe the resources available for the proposed project (e.g., facilities, equipment, information technology systems, and financial management systems).

5. Describe how project continuity will be maintained if/when there is a

change in the operational environment (e.g., staff turnover, change in project leadership, change in elected officials) to ensure project stability and implementation of activities and goals over the life of the grant.

6. Provide a complete list of staff positions anticipated for the project, including the Project Director, Project Coordinator, and other key personnel, showing the role of each and their level of effort and qualifications.

7. For key staff currently on board, include a biographical sketch for the Project Director, Project Coordinator, or other key positions as attachments to the project proposal/application. Do not include any of the following in the biographical sketch:

- Personally Identifiable Information (i.e., SSN, home address, etc.);
- Resumes; or
- Curriculum Vitae.

D. Program Evaluation (Data Collection & Reporting) (20 Points)

1. Describe the applicant's plan for data collection and document the applicant's ability to ensure accurate data tracking and meeting required reporting requirements/deadlines.

2. Provide a clear, specific plan for how data related to project will be collected, managed, analyzed, and reported.

3. Describe any type(s) of evaluation(s) that will be used to assess the project during the grant life cycle.

4. Explain how you will collaborate with partners (i.e., TEC) to complete any evaluation efforts or data collection.

E. Budget and Budget Justification (10 Points)

1. The applicant is required to include a line item budget for all expenditures identifying reasonable and allowable costs necessary to accomplish the goals and objectives as outlined in the project narrative for project year one only. The budget expenditures should correlate with the scope of work described in the project narrative for the first project year expenses only.

2. The applicant must provide a narrative justification of the budget line items, as well as a description of existing resources and other support the applicant expects to receive for the proposed project. Other support is defined as funds or resources, whether Federal, non-Federal, or institutional, in direct support of activities through fellowships, gifts, prizes, in-kind contributions, or non-Federal means. (This should correspond to Item #18 on the applicant's SF-424, Estimated Funding, and SF-424A Budget

Information, Section C Non-Federal resources.)

3. Provide a narrative justification supporting the development or continued collaboration with other partners regarding the proposed activities to be implemented.

4. Depending on the availability of funds, the IHS may host annual meetings to provide in-depth training and technical assistance to awardees. In order to help establish critical mass of community and staff members who are informed and committed to implement the project, awardees should plan to send a minimum of three people (including the Project Director/Project Coordinator) to one meeting of all awardees in each year of the grant. At these meetings, awardees will receive training related to grant objectives, discuss success and challenges in implementation of the program, present the results of their projects, and receive other technical assistance from IHS staff and/or contractors. Each meeting may be up to 3 days. The locations will be determined at a later date, but applicants should estimate costs for Denver, Colorado as a potential site that is accessible to most of "Indian Country" and attendance is strongly encouraged. The Division of Behavioral Health (DBH) may determine that a virtual meeting(s) may be an option, if Federal government travel restrictions are in place, or if funding is not available to support an in-person meeting.

Multi-Year Project Requirements

Applications must include a brief project narrative and budget (one additional page per year) addressing the developmental plans for each additional year of the project. This attachment will not count as part of the project narrative or the budget narrative.

Additional documents can be uploaded as Other Attachments in *Grants.gov*.

These can include:

- Work plan, logic model, and/or timeline for proposed objectives.
- Position descriptions for key staff (i.e., Project Director, Project Coordinator).
- Consultant or contractor proposed scope of work and letter of commitment (if applicable).
- Current Indirect Cost Rate Agreement.
- Organizational chart.
- Map of area identifying project location(s).
- Additional documents to support narrative (i.e., data tables, key news articles, etc.).

- Advisory board(s) description (membership, roles and functions, and frequency of meetings).

2. Review and Selection

Each application will be prescreened for eligibility and completeness as outlined in the funding announcement. Applications that meet the eligibility criteria shall be reviewed for merit by the Objective Review Committee (ORC) based on evaluation criteria. Incomplete applications and applications that are not responsive to the administrative thresholds (budget limit, project period limit) will not be referred to the ORC and will not be funded. The applicant will be notified of this determination.

Applicants must address all program requirements and provide all required documentation.

3. Notifications of Disposition

All applicants will receive an Executive Summary Statement from the IHS DBH within 30 days of the conclusion of the ORC outlining the strengths and weaknesses of their application. The summary statement will be sent to the Authorizing Official identified on the face page (SF-424) of the application.

A. Award Notices for Funded Applications

The NoA is the authorizing document for which funds are dispersed to the approved entities and reflects the amount of Federal funds awarded, the purpose of the award, the terms and conditions of the award, the effective date of the award, and the budget/project period. Each entity approved for funding must have a user account in GrantSolutions in order to retrieve the NoA. Please see the Agency Contacts list in Section VII for the systems contact information.

B. Approved but Unfunded Applications

Approved applications not funded due to lack of available funds will be held for 1 year. If funding becomes available during the course of the year, the application may be reconsidered.

Note: Any correspondence, other than the official NoA executed by an IHS grants management official announcing to the project director that an award has been made to their organization, is not an authorization to implement their program on behalf of the IHS.

VI. Award Administration Information

1. Administrative Requirements

Awards issued under this announcement are subject to, and are

administered in accordance with, the following regulations and policies:

A. The Criteria as Outlined in This Program Announcement

B. Administrative Regulations for Grants

- Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards currently in effect or implemented during the period of award, other Department regulations and policies in effect at the time of award, and applicable statutory provisions. At the time of publication, this includes 45 CFR part 75, at <https://www.govinfo.gov/content/pkg/CFR-2020-title45-vol1/pdf/CFR-2020-title45-vol1-part75.pdf>.

- Please review all HHS regulatory provisions for Termination at 45 CFR 75.372, at https://www.ecfr.gov/cgi-bin/retrieveECFR?gp&SID=2970eec67399fab1413ede53d7895d99&mc=true&pt45.1.75&r=PART&ty=HTML&se45.1.75_1372#se45.1.75_1372.

C. Grants Policy

- HHS Grants Policy Statement, Revised January 2007, at <https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgrps107.pdf>.

D. Cost Principles

- Uniform Administrative Requirements for HHS Awards, “Cost Principles,” located at 45 CFR part 75 subpart E.

E. Audit Requirements

- Uniform Administrative Requirements for HHS Awards, “Audit Requirements,” located at 45 CFR part 75 subpart F.

F. As of August 13, 2020, 2 CFR 200 was updated to include a prohibition on certain telecommunications and video surveillance services or equipment. This prohibition is described in 2 CFR 200.216. This will also be described in the terms and conditions of every IHS grant and cooperative agreement awarded on or after August 13, 2020.

2. Indirect Costs

This section applies to all recipients that request reimbursement of indirect costs (IDC) in their application budget. In accordance with HHS Grants Policy Statement, Part II–27, the IHS requires applicants to obtain a current IDC rate agreement and submit it to the DGM prior to the DGM issuing an award. The rate agreement must be prepared in accordance with the applicable cost principles and guidance as provided by

the cognizant agency or office. A current rate covers the applicable grant activities under the current award’s budget period. If the current rate agreement is not on file with the DGM at the time of award, the IDC portion of the budget will be restricted. The restrictions remain in place until the current rate agreement is provided to the DGM.

Per 45 CFR 75.414(f) Indirect (F&A) costs, “any non-Federal entity (NFE) [i.e., applicant] that has never received a negotiated indirect cost rate, . . . may elect to charge a de minimis rate of 10 percent of modified total direct costs which may be used indefinitely. As described in Section 75.403, costs must be consistently charged as either indirect or direct costs, but may not be double charged or inconsistently charged as both. If chosen, this methodology once elected must be used consistently for all Federal awards until such time as the NFE chooses to negotiate for a rate, which the NFE may apply to do at any time.”

Electing to charge a de minimis rate of 10 percent only applies to applicants that have never received an approved negotiated indirect cost rate from HHS or another cognizant federal agency. Applicants awaiting approval of their indirect cost proposal may request the 10 percent de minimis rate. When the applicant chooses this method, costs included in the indirect cost pool must not be charged as direct costs to the grant.

Available funds are inclusive of direct and appropriate indirect costs. Approved indirect funds are awarded as part of the award amount, and no additional funds will be provided.

Generally, IDC rates for IHS grantees are negotiated with the Division of Cost Allocation at <https://rates.psc.gov/> or the Department of the Interior (Interior Business Center) at <https://ibc.doi.gov/ICS/tribal>. For questions regarding the indirect cost policy, please call the Grants Management Specialist listed under “Agency Contacts” or the main DGM office at (301) 443–5204.

3. Reporting Requirements

The grantee must submit required reports consistent with the applicable deadlines. Failure to submit required reports within the time allowed may result in suspension or termination of an active grant, withholding of additional awards for the project, or other enforcement actions such as withholding of payments or converting to the reimbursement method of payment. Continued failure to submit required reports may result in the imposition of special award provisions

and/or the non-funding or non-award of other eligible projects or activities. This requirement applies whether the delinquency is attributable to the failure of the awardee organization or the individual responsible for preparation of the reports. Per DGM policy, all reports must be submitted electronically by attaching them as a “Grant Note” in GrantSolutions. Personnel responsible for submitting reports will be required to obtain a login and password for GrantSolutions. Please see the Agency Contacts list in section VII for the systems contact information.

The reporting requirements for this program are noted below.

A. Progress Reports

Program progress reports are required annually. The progress reports are due within 30 days after the reporting period ends (specific dates will be listed in the NoA Terms and Conditions). These reports must include a brief comparison of actual accomplishments to the goals established for the period, a summary of progress to date or, if applicable, provide sound justification for the lack of progress, and other pertinent information as required. A final report must be submitted within 90 days of expiration of the period of performance and must provide a comprehensive summary of accomplishments and outcomes relative to each of the stated goals and objectives over the period of performance.

B. Financial Reports

Federal Cash Transaction Reports are due 30 days after the close of every calendar quarter to the Payment Management Services at <https://pms.psc.gov>. Failure to submit timely reports may result in adverse award actions blocking access to funds.

Federal Financial Reports are due 30 days after the end of each budget period, and a final report is due 90 days after the end of the Period of Performance. Grantees are responsible and accountable for reporting accurate information on all required reports: The Progress Reports, the Federal Cash Transaction Report, and the Federal Financial Report.

C. Data Collection and Reporting

All grantees will be required to collect and report data pertaining to activities, processes, and outcomes via the IHS Behavioral Health Reporting Portal (BHRP), within 30 days after the budget period ends for each project year (specific dates will be listed in the NoA Terms and Conditions). The BHRP will be open to project staff on a 24 hour per day/7 day per week basis for the

duration of each reporting period. Technical assistance for web-based data entry will be timely and readily available to awardees by assigned DBH staff. In addition to the annual progress reports, the IHS will compile and provide aggregate program statistics from data available in the National Data Warehouse (NDW). The IHS will use NDW data related to substance abuse prevention, treatment, and aftercare services, including associated community-level health care facility data as a method to monitor outcomes and impact of grant activities.

D. Federal Sub-Award Reporting System (FSRS)

This award may be subject to the Transparency Act sub-award and executive compensation reporting requirements of 2 CFR part 170.

The Transparency Act requires the OMB to establish a single searchable database, accessible to the public, with information on financial assistance awards made by Federal agencies. The Transparency Act also includes a requirement for recipients of Federal grants to report information about first-tier sub-awards and executive compensation under Federal assistance awards. The IHS has implemented a Term of Award into all IHS Standard Terms and Conditions, NoAs, and funding announcements regarding the FSRS reporting requirement. This IHS Term of Award is applicable to all IHS grant and cooperative agreements issued on or after October 1, 2010, with a \$25,000 sub-award obligation threshold met for any specific reporting period. For the full IHS award term implementing this requirement and additional award applicability information, visit the DGM Grants Management website at <https://www.ihs.gov/dgm/policytopics/>.

E. Compliance With Executive Order 13166 Implementation of Services Accessibility Provisions for All Grant Application Packages and Funding Opportunity Announcements

Should you successfully compete for an award, recipients of Federal financial assistance (FFA) from HHS must administer their programs in compliance with Federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex (including gender identity, sexual orientation, and pregnancy). This includes ensuring programs are accessible to persons with limited English proficiency and persons with disabilities. The HHS Office for Civil

Rights provides guidance on complying with civil rights laws enforced by HHS. Please see <https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html> and <https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html>.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting your legal obligation to take reasonable steps to ensure meaningful access to your programs or activities by limited English proficiency individuals, see <https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html> and <https://www.lep.gov>.

- For information on your specific legal obligations for serving qualified individuals with disabilities, including reasonable modifications and making services accessible to them, see <https://www.hhs.gov/ocr/civilrights/understanding/disability/index.html>.

- HHS funded health and education programs must be administered in an environment free of sexual harassment. See <https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html>.

- For guidance on administering your program in compliance with applicable Federal religious nondiscrimination laws and applicable Federal conscience protection and associated anti-discrimination laws, see <https://www.hhs.gov/conscience/conscience-protections/index.html> and <https://www.hhs.gov/conscience/religious-freedom/index.html>.

F. Federal Awardee Performance and Integrity Information System (FAPIIS)

The IHS is required to review and consider any information about the applicant that is in the FAPIIS at <https://www.fapiis.gov> before making any award in excess of the simplified acquisition threshold (currently \$250,000) over the period of performance. An applicant may review and comment on any information about itself that a Federal awarding agency previously entered. The IHS will consider any comments by the applicant, in addition to other information in FAPIIS, in making a judgment about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants, as described in 45 CFR 75.205.

As required by 45 CFR part 75 Appendix XII of the Uniform Guidance, NFEs are required to disclose in FAPIIS

any information about criminal, civil, and administrative proceedings, and/or affirm that there is no new information to provide. This applies to NFEs that receive Federal awards (currently active grants, cooperative agreements, and procurement contracts) greater than \$10,000,000 for any period of time during the period of performance of an award/project.

Mandatory Disclosure Requirements

As required by 2 CFR part 200 of the Uniform Guidance, and the HHS implementing regulations at 45 CFR part 75, the IHS must require an NFE or an applicant for a Federal award to disclose, in a timely manner, in writing to the IHS or pass-through entity all violations of Federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the Federal award.

All applicants and recipients must disclose, in a timely manner, in writing to the IHS and to the HHS Office of Inspector General all information related to violations of Federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the Federal award. 45 CFR 75.113.

Disclosures must be sent in writing to: U.S. Department of Health and Human Services, Indian Health Service, Division of Grants Management, ATTN: Paul Gettys, Acting Director, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857 (Include "Mandatory Grant Disclosures" in subject line), Office: (301) 443-5204, Fax: (301) 594-0899, Email: Paul.Gettys@ihs.gov.

AND

U.S. Department of Health and Human Services, Office of Inspector General, ATTN: Mandatory Grant Disclosures, Intake Coordinator, 330 Independence Avenue SW, Cohen Building, Room 5527, Washington, DC 20201, URL: <https://oig.hhs.gov/fraud/report-fraud/> (Include "Mandatory Grant Disclosures" in subject line), Fax: (202) 205-0604 (Include "Mandatory Grant Disclosures" in subject line) or Email: MandatoryGranteeDisclosures@oig.hhs.gov.

Failure to make required disclosures can result in any of the remedies described in 45 CFR 75.371 Remedies for noncompliance, including suspension or debarment (see 2 CFR part 180 and 2 CFR part 376).

VII. Agency Contacts

1. Questions on the programmatic issues may be directed to: Audrey Solimon, Public Health Analyst, Indian Health Service, Division of Behavioral

Health, 5600 Fishers Lane, Mail Stop: 08N34–A, Rockville, MD 20857, Phone: (301) 590–5421, Fax: (301) 594–6213, Email: Audrey.Solimon@ihs.gov.

2. Questions on grants management and fiscal matters may be directed to: Willis Grant, Grants Management Specialist, Indian Health Service, Division of Grants Management, Rockville, MD 20857, Phone: (301) 443–2214, Fax: (301) 594–0899, Email: Willis.Grant@ihs.gov.

3. Questions on systems matters may be directed to: Paul Gettys, Acting Director, Indian Health Service, Division of Grants Management, Rockville, MD 20857, Phone: (301) 443–2114; or the DGM main line (301) 443–5204, Fax: (301) 443–9602, Email: Paul.Gettys@ihs.gov.

VIII. Other Information

The Public Health Service strongly encourages all grant, cooperative agreement, and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of the facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the HHS mission to protect and advance the physical and mental health of the American people.

Elizabeth A. Fowler,

Acting Director, Indian Health Service.

[FR Doc. 2021–24020 Filed 11–3–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Substance Abuse and Suicide Prevention Program: Suicide Prevention, Intervention, and Postvention

Announcement Type: New.

Funding Announcement Number: HHS–2022–IHS–SPIP–0001.

Assistance Listing (Catalog of Federal Domestic Assistance or CFDA) Number: 93.654.

Key Dates

Application Deadline Date: February 2, 2022.

Earliest Anticipated Start Date: March 21, 2022.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) is accepting applications for a component of the Substance Abuse and Suicide Prevention (SASP) Program: Suicide Prevention, Intervention, and Postvention (SPIP). This program is authorized under the Snyder Act, 25 U.S.C. 13; the Transfer Act, 42 U.S.C. 2001(a); and the Indian Health Care Improvement Act, 25 U.S.C. 1601–1683. This program is described in the Assistance Listings located at <https://sam.gov/content/home> (formerly known as the CFDA) under 93.654.

Background

The origin of the SASP SPIP grant program began with the Methamphetamine and Suicide Prevention Initiative (MSPI), conducted from September 2009–August 2015. In that nationally coordinated 6-year demonstration pilot project, the IHS funded 130 IHS, Tribal, and Urban Indian organizations (UIOs) that focused on providing methamphetamine and suicide prevention and intervention resources for Indian Country.

The second phase of the funding cycle built on lessons learned from the MSPI pilot and was implemented from September 2015–September 2020 and funded 174 IHS, Tribal, and UIO projects. This phase of the SPIP portion of the SASP Program will build upon previous years' work and lessons learned, and will continue to promote the use and development of evidence-based and practice-based models that represent culturally appropriate prevention and treatment approaches to substance use and suicide prevention from a community-driven context. For a complete listing of demonstration pilot and cohort one projects, please visit <https://www.ihs.gov/sasp/pilotprojects20092014/> and <https://www.ihs.gov/sasp/fundedprojects/>.

In previous years, awards were made from the same funding opportunity announcement with four distinct “purpose areas.” In order to provide program clarity and tracking of outcomes, the IHS is offering funding through separate notice of funding opportunity announcements for fiscal year (FY) 2022. This funding opportunity is focused on Suicide Prevention, Intervention, and Postvention. There will not be separate “purpose areas” for this funding opportunity.

Purpose

The primary purpose of this program is to reduce the prevalence of suicide

among American Indian and Alaska Native (AI/AN) populations. Tribes can accomplish these goals by:

1. Improving care coordination;
2. Expanding behavioral health care services through the use of culturally appropriate evidence-based and practice-based models to address these issues; and
3. Developing or expanding on activities for the Generation Indigenous (Gen-I) Initiative by implementing early intervention strategies for AI/AN youth at risk for suicidal behavior, in addition to any proposed activities for the adult population.

In alignment with the IHS 2019–2023 Strategic Plan Goal 1: To ensure that comprehensive, culturally appropriate personal and public health services are available and accessible to AI/AN people, the SASP program is designed to ensure access to comprehensive, culturally appropriate services and promote quality programming to address suicide for AI/AN youth and adults. The IHS supports Tribal efforts that include addressing suicide prevention, intervention, and postvention from a community-driven context. The IHS encourages applicants to develop and submit a plan that emphasizes cross-system collaboration, the inclusion of family, youth, and community resources, and culturally appropriate approaches.

Required Activities

The focus of this funding opportunity announcement is on the prevention, intervention, and postvention of suicide ideations, suicide attempts, and suicides among AI/AN populations.

The IHS is seeking applications that include the following required activities:

1. Foster coalitions and networks to improve care coordination:
 - a. Educate and train providers on model practices for suicide screening (e.g., National Institute of Mental Health's Ask Suicide-Screening Questions); evidence-based suicide risk assessment (e.g., National Institute of Mental Health's Brief Suicide Safety Assessment); suicide care such as the Collaborative Assessment and Management of Suicidality (CAMS) model; Safety Planning (e.g., Suicide Prevention and Resource Center); Lethal Means Counseling (e.g., Counseling on Access to Lethal Means); and trauma informed care (e.g., Dialectical Behavioral Therapy, Cognitive Therapy for Suicide Prevention, Problem Solving Therapy, Mentalization-Based Treatment, Psychodynamic Interpersonal Therapy, and Cognitive

Behavioral Therapy for Suicide Prevention).

b. Educate and train community members to recognize and respond to the warning signs of suicide and prevent and intervene in suicides and suicide ideations (*e.g.*, Questions, Persuade and Refer, Applied Suicide Intervention Skills Training, and Mental Health First Aid).

c. Increase community awareness of local behavioral health resources.

d. Develop community suicide response teams.

e. Develop community suicide response plans.

f. Establish local health system policies/protocols to integrate suicide prevention and intervention services in schools, courts, corrections/detention systems, and law enforcement agencies.

2. Expand available behavioral health care treatment services:

a. Develop a strategic plan to address the health system organizational needs for suicide prevention, intervention, and postvention services including the use, or expansion, of telehealth and similar technologies.

b. Integrate behavioral health into the primary care setting for suicide care and screening to include the use or expansion of telehealth and similar technologies.

c. Provide evidence-based suicide care for clients at risk for suicide.

d. Provide access to culturally appropriate treatment services and resources.

e. Implement a trauma-informed approach and trauma-informed care treatment and services.

3. Improve the referral process:

a. Increase the capacity of community members and service providers (*i.e.*, primary care, schools, child welfare, and criminal justice) to make appropriate screening and referral to behavioral health services and supports related to suicide prevention, intervention, and postvention.

b. Refer to cultural services and/or culturally appropriate suicide prevention, intervention, or postvention services, including natural support systems.

4. In addition to any proposed activities for the adult population, develop or expand on activities for the Gen-I Initiative by implementing culturally appropriate evidence-based and practice-based approaches to build resiliency, resistance, hardiness, empathy, promote positive development, and increase self-sufficiency behaviors among Native youth:

a. Implement evidence-based and practice-based interventions in suicide

prevention for Native youth in the community.

b. Provide support services to Native youth and their families impacted by suicide.

c. Promote positive development and increase self-sufficiency of Native youth by providing culturally appropriate suicide prevention activities through use of traditional practices (*e.g.*, language rejuvenation, language immersion, song and storytelling teaching, and oral history rejuvenation).

d. Promote family and community engagement in the planning and implementation of Native youth suicide prevention activities (*e.g.*, Gathering of Native Americans).

e. Provide school-based awareness/education about suicide prevention, intervention, postvention, and aftercare (*e.g.*, Hope Squad).

f. Support the development of Native youth peer-to-peer support and education programs.

g. Promote/support the development of a Tribal Youth Council to provide guidance/feedback on community suicide prevention planning and strategic planning.

5. Development of a formal plan/process to ensure the sustainability of the project activities beyond the grant life-cycle:

a. Develop a community-based strategic plan to address the long-term suicide prevention, intervention, and postvention needs of the community.

b. Assess community and workforce needs and assets via a community and organization needs assessment and community resource asset mapping.

II. Award Information

Funding Instrument—Grant

Estimated Funds Available

The total funding identified for FY 2022 is approximately \$14,000,000. Individual award amounts for the first budget year are anticipated to be from \$300,000 to \$400,000. The funding available for competing and subsequent continuation awards issued under this announcement is subject to the availability of appropriations and budgetary priorities of the Agency. The IHS is under no obligation to make awards that are selected for funding under this announcement.

Anticipated Number of Awards

Approximately 35 awards will be issued under this program announcement. Up to five awards will be set aside for eligible Urban Indian organizations.

Period of Performance

The period of performance is for 5 years.

III. Eligibility Information

1. Eligibility

To be eligible for this new funding opportunity, applicants must be one of the following, as defined by 25 U.S.C. 1603:

- A federally recognized Indian Tribe as defined by 25 U.S.C. 1603(14). The term “Indian Tribe” means any Indian Tribe, band, nation, or other organized group or community, including any Alaska Native village or group, or regional or village corporation, as defined in or established pursuant to the Alaska Native Claims Settlement Act (85 Stat. 688) [43 U.S.C. 1601 *et seq.*], which is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians.

- A Tribal organization as defined by 25 U.S.C. 1603(26). The term “Tribal organization” has the meaning given the term in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304(l)): “Tribal organization” means the recognized governing body of any Indian Tribe; any legally established organization of Indians which is controlled, sanctioned, or chartered by such governing body or which is democratically elected by the adult members of the Indian community to be served by such organization and which includes the maximum participation of Indians in all phases of its activities: Provided that, in any case where a contract is let or grant made to an organization to perform services benefiting more than one Indian Tribe, the approval of each such Indian Tribe shall be a prerequisite to the letting or making of such contract or grant. Applicant shall submit letters of support and/or Tribal Resolutions from the Tribes to be served.

- An Urban Indian organization, as defined by 25 U.S.C. 1603(29). The term “Urban Indian organization” means a nonprofit corporate body situated in an urban center, governed by an urban Indian controlled board of directors, and providing for the maximum participation of all interested Indian groups and individuals, which body is capable of legally cooperating with other public and private entities for the purpose of performing the activities described in 25 U.S.C. 1653(a). Applicants must provide proof of nonprofit status with the application, *e.g.*, 501(c)(3).

The program office will notify any applicants deemed ineligible.

Note: Please refer to Section IV.2 (Application and Submission Information/ Subsection 2, Content and Form of Application Submission) for additional proof of applicant status documents required, such as Tribal Resolutions, proof of nonprofit status, etc.

2. Cost Sharing or Matching

The IHS does not require matching funds or cost sharing for grants or cooperative agreements.

3. Other Requirements

Applications with budget requests that exceed the highest dollar amount outlined under Section II Award Information, Estimated Funds Available, or exceed the period of performance outlined under Section II Award Information, Period of Performance, are considered not responsive and will not be reviewed. The Division of Grants Management (DGM) will notify the applicant.

Additional Required Documentation Tribal Resolution

The DGM must receive an official, signed Tribal Resolution prior to issuing a Notice of Award (NoA) to any applicant selected for funding. An Indian Tribe or Tribal organization that is proposing a project affecting another Indian Tribe must include resolutions from all affected Tribes to be served. However, if an official, signed Tribal Resolution cannot be submitted with the application prior to the application deadline date, a draft Tribal Resolution must be submitted with the application by the deadline date in order for the application to be considered complete and eligible for review. The draft Tribal Resolution is not in lieu of the required signed resolution but is acceptable until a signed resolution is received. If an application without a signed Tribal Resolution is selected for funding, the applicant will be contacted by the Grants Management Specialist (GMS) listed in this funding announcement and given 90 days to submit an official, signed Tribal Resolution to the GMS. If the signed Tribal Resolution is not received within 90 days, the award will be forfeited.

Tribes organized with a governing structure other than a Tribal council may submit an equivalent document commensurate with their governing organization.

Proof of Nonprofit Status

Organizations claiming nonprofit status must submit a current copy of the

501(c)(3) Certificate with the application.

IV. Application and Submission Information

1. Obtaining Application Materials

The application package and detailed instructions for this announcement are available at <https://www.Grants.gov>.

Please direct questions regarding the application process to Mr. Paul Gettys at (301) 443-2114 or (301) 443-5204.

2. Content and Form Application Submission

Mandatory documents for all applicants include:

- Abstract (one page) summarizing the project.
- Application forms:
 1. SF-424, Application for Federal Assistance.
 2. SF-424A, Budget Information—Non-Construction Programs.
 3. SF-424B, Assurances—Non-Construction Programs.
- Project Narrative (not to exceed 15 pages). See Section IV.2.A, Project Narrative for instructions.
 1. Background information on the organization.
 2. Proposed scope of work, objectives, and activities that provide a description of what the applicant plans to accomplish.
 - Timeline (one page).
 - Budget Justification and Narrative (not to exceed four pages). See Section IV.2.B, Budget Narrative for instructions.
 - Tribal Resolution or Tribal Letter of Support (only required for Tribes and Tribal organizations).
 - Letter(s) of Commitment:
 1. Local Organizational Partners;
 2. Community Partners;
 3. For Tribal organizations: from the board of directors (or relevant equivalent);
 4. For Urban Indian organizations: from the board of directors (or relevant equivalent).
 - 501(c)(3) Certificate (if applicable).
 - Biographical sketches for all key personnel (e.g., project director, project coordinator, grants coordinator, etc.) (not to exceed one page each).
 - Contractor/consultant qualifications and scope of work.
 - Disclosure of Lobbying Activities (SF-LLL), if applicant conducts reportable lobbying.
 - Certification Regarding Lobbying (GG-Lobbying Form).
 - Copy of current Negotiated Indirect Cost rate (IDC) agreement (required in order to receive IDC).
 - Documentation of current Office of Management and Budget (OMB) Financial Audit (if applicable).

Acceptable forms of documentation include:

1. Email confirmation from Federal Audit Clearinghouse (FAC) that audits were submitted; or
 2. Face sheets from audit reports.
- Applicants can find these on the FAC website at <https://harvester.census.gov/facdissem/Main.aspx>.

Public Policy Requirements

All Federal public policies apply to IHS grants and cooperative agreements. Pursuant to 45 CFR 80.3(d), an individual shall not be deemed subjected to discrimination by reason of their exclusion from benefits limited by Federal law to individuals eligible for benefits and services from the IHS. See <https://www.hhs.gov/grants/grants/grants-policies-regulations/index.html>.

Requirements for Project and Budget Narratives

A. Project Narrative

This narrative should be a separate document that is no more than 15 pages and must: (1) Have consecutively numbered pages; (2) use black font 12 points or larger; (3) be single-spaced; and (4) be formatted to fit standard letter paper (8½ x 11 inches).

Be sure to succinctly answer all questions listed under the evaluation criteria (refer to Section V.1, Evaluation Criteria) and place all responses and required information in the correct section noted below or they will not be considered or scored. If the narrative exceeds the page limit, the application will be considered not responsive and not be reviewed. The 15-page limit for the narrative does not include the standard forms, Tribal Resolutions, budget, budget justification and narrative, and/or other items.

There are three parts to the narrative: Part 1—Program Planning; Part 2—Program Data Collection and Evaluation; and Part 3—Program Accomplishments Report. See below for additional details about what must be included in the narrative. The page limits below are for each narrative and budget submitted.

Part 1: Program Planning (Limit—10 Pages)

Describe the scope of work the Tribe, Tribal organization, or UIO are planning by clearly and concisely outlining the following required components:

1. Goals and Objectives. Reference all required objectives.
2. Project Activities. Link your project activities to your outlined goals and objectives.
3. Organization Capacity and Staffing/ Administration. State your organization's current capacity to

implement and manage this award (*i.e.*, current staffing, facilities, information systems, and experience with previous similar projects).

Part 2: Program Data Collection and Evaluation (Limit—3 Pages)

Based on the required objectives, describe how the Tribe, Tribal organization, or UIO plans to collect data for the proposed project and activities. Identify any type(s) of evaluation(s) that will be used and how you will collaborate with partners (*i.e.*, Tribal Epidemiology Center (TEC)) to complete any evaluation efforts or data collection. Funded projects are encouraged to coordinate data collection efforts with their TEC or Urban Epidemiology Center (for urban awardees) and should describe their plan for coordination and collaboration with the TEC.

Part 3: Program Accomplishments Report (Limit—2 Pages)

Describe the Tribe, Tribal organization, or UIO's significant program activities and achievements/accomplishments over the past 5 years associated with suicide prevention, intervention, and postvention activities. Provide success stories, data, or other examples of how other funded projects/programs made an impact in your community to address suicide. If applicable, provide justification for lack of progress of previous efforts.

B. Budget Narrative (Limit—4 Pages)

Provide a budget narrative that explains the amounts requested for each line item of the budget from the SF-424A (Budget Information for Non-Construction Programs). The budget narrative can include a more detailed spreadsheet than is provided by the SF-424A. The budget narrative should specifically describe how each item will support the achievement of proposed objectives. Be very careful about showing how each item in the "Other" category is justified. For subsequent budget years (see Multi-Year Project Requirements in Section V.1, Application Review Information, Evaluation Criteria), the narrative should highlight the changes from year one or clearly indicate that there are no substantive budget changes during the period of performance. Do NOT use the budget narrative to expand the project narrative.

The SASP program proposal template and associated templates for the timeline chart, biographical sketch, budget and budget narrative/justification can be located and downloaded from the SASP program

website at <https://www.ihs.gov/sasp/newsannouncements/>.

3. Submission Dates and Times

Applications must be submitted through *Grants.gov* by 11:59 p.m. Eastern Time on the Application Deadline Date. Any application received after the application deadline will not be accepted for review. *Grants.gov* will notify the applicant via email if the application is rejected.

If technical challenges arise and assistance is required with the application process, contact *Grants.gov* Customer Support (see contact information at <https://www.grants.gov>). If problems persist, contact Mr. Paul Gettys (Paul.Gettys@ihs.gov), Acting Director, DGM, by telephone at (301) 443-2114 or (301) 443-5204. Please be sure to contact Mr. Gettys at least ten days prior to the application deadline. Please do not contact the DGM until you have received a *Grants.gov* tracking number. In the event you are not able to obtain a tracking number, call the DGM as soon as possible.

The IHS will not acknowledge receipt of applications.

4. Intergovernmental Review

Executive Order 12372 requiring intergovernmental review is not applicable to this program.

5. Funding Restrictions

- Pre-award costs are allowable up to 90 days before the start date of the award provided the costs are otherwise allowable if awarded. Pre-award costs are incurred at the risk of the applicant.
- The available funds are inclusive of direct and indirect costs.
- Only one grant will be awarded per applicant.
- The purchase of food (*i.e.*, as supplies, for meetings or events, etc.) is not an allowable cost with this grant funding and should not be included in the budget/budget justification.

6. Electronic Submission Requirements

All applications must be submitted via *Grants.gov*. Please use the <https://www.Grants.gov> website to submit an application. Find the application by selecting the "Search Grants" link on the homepage. Follow the instructions for submitting an application under the Package tab. No other method of application submission is acceptable.

If the applicant cannot submit an application through *Grants.gov*, a waiver must be requested. Prior approval must be requested and obtained from Mr. Paul Gettys, Acting Director, DGM. A written waiver request must be sent to GrantsPolicy@ihs.gov

with a copy to Paul.Gettys@ihs.gov. The waiver request must: (1) Be documented in writing (emails are acceptable) before submitting an application by some other method, and (2) include clear justification for the need to deviate from the required application submission process.

Once the waiver request has been approved, the applicant will receive a confirmation of approval email containing submission instructions. A copy of the written approval must be included with the application that is submitted to the DGM. Applications that are submitted without a copy of the signed waiver from the Acting Director of the DGM will not be reviewed. The Grants Management Officer of the DGM will notify the applicant via email of this decision.

Applications submitted under waiver must be received by the DGM no later than 5:00 p.m. Eastern Time on the Application Deadline Date. Late applications will not be accepted for processing. Applicants that do not register for both the System for Award Management (SAM) and *Grants.gov* and/or fail to request timely assistance with technical issues will not be considered for a waiver to submit an application via alternative method.

Please be aware of the following:

- Please search for the application package in <https://www.Grants.gov> by entering the Assistance Listing (CFDA) number or the Funding Opportunity Number. Both numbers are located in the header of this announcement.
- If you experience technical challenges while submitting your application, please contact *Grants.gov* Customer Support (see contact information at <https://www.Grants.gov/>).
- Upon contacting *Grants.gov*, obtain a tracking number as proof of contact. The tracking number is helpful if there are technical issues that cannot be resolved and a waiver from the agency must be obtained.

• Applicants are strongly encouraged not to wait until the deadline date to begin the application process through *Grants.gov* as the registration process for SAM and *Grants.gov* could take up to 20 working days.

• Please follow the instructions on *Grants.gov* to include additional documentation that may be requested by this funding announcement.

• Applicants must comply with any page limits described in this funding announcement.

• After submitting the application, the applicant will receive an automatic acknowledgment from *Grants.gov* that contains a *Grants.gov* tracking number.

The IHS will not notify the applicant that the application has been received.

Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS)

Applicants and grantee organizations are required to obtain a DUNS number and maintain an active registration in the SAM database. The DUNS number is a unique 9-digit identification number provided by D&B that uniquely identifies each entity. The DUNS number is site specific; therefore, each distinct performance site may be assigned a DUNS number. Obtaining a DUNS number is easy, and there is no charge. To obtain a DUNS number, please access the request service through <https://fedgov.dnb.com/webform>, or call (866) 705-5711.

The Federal Funding Accountability and Transparency Act of 2006, as amended ("Transparency Act"), requires all HHS recipients to report information on sub-awards. Accordingly, all IHS grantees must notify potential first-tier sub-recipients that no entity may receive a first-tier sub-award unless the entity has provided its DUNS number to the prime grantee organization. This requirement ensures the use of a universal identifier to enhance the quality of information available to the public pursuant to the Transparency Act.

System for Award Management (SAM)

Organizations that are not registered with SAM must have a DUNS number first, then access the SAM online registration through the SAM home page at <https://sam.gov> (U.S. organizations will also need to provide an Employer Identification Number from the Internal Revenue Service that may take an additional 2–5 weeks to become active). Please see *SAM.gov* for details on the registration process and timeline. Registration with the SAM is free of charge but can take several weeks to process. Applicants may register online at <https://sam.gov>.

Additional information on implementing the Transparency Act, including the specific requirements for DUNS and SAM, are available on the DGM Grants Management, Policy Topics web page: <https://www.ihs.gov/dgm/policytopics/>.

V. Application Review Information

Possible points assigned to each section are noted in parentheses. The project narrative and budget narrative should include only the first year of activities; information for multi-year projects should be included as a separate document. See "Multi-year Project Requirements" at the end of this

section for more information. The narrative section should be written in a manner that is clear to outside reviewers unfamiliar with prior related activities of the applicant. It should be well organized, succinct, and contain all information necessary for reviewers to fully understand the project. Attachments requested in the criteria do not count toward the page limit for the narratives. Points will be assigned to each evaluation criteria adding up to a total of 100 possible points. Points are assigned as follows:

1. Evaluation Criteria

A. Statement of Need (20 Points)

1. Describe the history and current situation in the applicant's Tribal community ("community" means the applicant's Tribe, village, Tribal organization, or consortium of Tribes or Tribal organizations). Provide facts and evidence that supports the need for the project and establish that the Tribe, Tribal organization, or UIO understands the problems and can reasonably address them.

2. Provide background information on the Tribe, Tribal organization, or UIO.

3. Identify the proposed catchment area and provide demographic information on the population(s) to receive services through the targeted systems or agencies (e.g., race, ethnicity, federally recognized Tribe, language, age, socioeconomic status, sexual identity (sexual orientation, gender identity), and other relevant factors, such as literacy). Describe the stakeholders and resources in the catchment area that can help implement the needed infrastructure development.

4. Based on the information and/or data currently available, document the prevalence of suicide ideations, attempts, and completions. Data sources may include, but is not limited to, local data sources, TECs, IHS Area Offices, County/State-level data, or National databases such as the Centers for Disease Control and Prevention (CDC) National Violent Death Reporting System at <https://www.cdc.gov/violenceprevention/datasources/nvdrs/index.html>, CDC State Profiles at <https://www.cdc.gov/violenceprevention/datasources/nvdrs/stateprofiles.html>, and/or the CDC Web-based Injury Statistics Query and Reporting System at <https://www.cdc.gov/injury/wisqars/index.html>.

5. Based on the information and/or data currently available, document the need for an enhanced infrastructure to increase the capacity to implement, sustain, and improve effective behavioral health services in the

proposed catchment area that is consistent with the purpose of this funding opportunity announcement. Based on available data, describe the service gaps and other problems related to the need for infrastructure development. Identify the source of the data. Documentation of need may come from a variety of qualitative and quantitative sources.

6. Describe the existing behavioral health service gaps, barriers, and other systemic challenges related to the need for planning and infrastructure development and coordination of suicide prevention services.

7. Describe potential project partners and community resources in the catchment area that can participate in the planning process and infrastructure development.

8. Affirm the goals of the project are consistent with priorities of the Tribal government or board of directors and that the governing body is in support of this application.

B. Project Goals, Objectives, Activities, and Approach (35 Points)

Evidence-Based Practices, Practice-Based Evidence, Promising Practices, and Local Efforts: The IHS strongly emphasizes the use of data and evidence in policymaking and program development and implementation in developing and implementing Tribal and/or culturally appropriate suicide prevention, intervention, and postvention, as well as early intervention strategies. Applicants are required to identify one or more evidence-based practice, practice-based evidence, best or promising practice, and/or local effort that they plan to implement in the Project Narrative section of their application. The SASP program website (<https://www.ihs.gov/sasp/>) is one resource that applicants may use to find information to build on the foundation of prior projects' suicide prevention and treatment efforts.

The IHS recognizes the limited range of formally evaluated evidence-based practices for suicide prevention, intervention, and postvention efforts that have been developed specifically for the AI/AN population. In addition to formally evaluated practices, evidence for other practices allowed in this grant program may include unpublished studies, preliminary evaluation results, clinical (or other professional association) guidelines, findings from focus groups with community members, local community surveys, etc. Each applicant is required to:

- Document the evidence that the practice(s) you have chosen is

appropriate for the outcomes you want to achieve;

- Explain how the practice you have chosen meets the goals for this announcement, as identified in Section I;

- Describe any modifications/adaptations you will need to make to your proposed practice(s) to meet the goals of your project and why you believe the changes will improve the outcomes; and

- Discuss training needs or plans for training to successfully implement the proposed evidence-based practice(s).

1. Clearly and concisely describe the purpose of the proposed project, including goals and objectives and how they are linked. Describe how the achievement of goals will increase system capacity to support the goals and required activities identified in Section I.

2. Clearly and concisely describe how the proposed project activities are related to the proposed project's goals and objectives. Describe how the project activities will increase the capacity of the identified community to plan, improve, and sustain the coordination of a collaborative behavioral health and wellness service system to prevent suicide.

3. Discuss how the proposed approach addresses the local language, concepts, attitudes, norms, and values about suicide.

4. Describe how the proposed project will address issues of diversity within the population of focus including age, race, gender, ethnicity, culture/cultural identity, language, sexual orientation, disability, and literacy.

5. Describe how members of the community (including youth and families that may receive services) will be involved in the planning, implementation, data collection, and evaluation of the project.

6. Describe how the efforts of the proposed project will be coordinated with any other related Federal grants or programs funded through the IHS, Substance Abuse and Mental Health Services Administration, the Bureau of Indian Affairs, or other Federal agencies.

7. Provide a timeline chart depicting a realistic timeline for the project period showing key activities, milestones, and responsible staff. These key activities should include the required activities outlined in Section I.

8. Identify any other organization(s) that will participate in the proposed project. Describe their roles and responsibilities and demonstrate their commitment to the project.

C. Organizational Capabilities, Key Personnel, and Qualifications (15 Points)

1. Describe the management capability and experience of the applicant Tribe, Tribal organization, or UIO and other participating organizations in administering and sustaining results of similar grants and projects.

2. Describe significant program activities and achievements or accomplishments over the past 5 years associated with suicide prevention.

3. Describe the applicant Tribe, Tribal organization, or UIO experience and capacity to provide and sustain culturally appropriate/competent services to the community and specific populations of focus.

4. Describe the resources available for the proposed project (*e.g.*, facilities, equipment, information technology systems, and financial management systems).

5. Describe how project continuity will be maintained when there is a change in the operational environment (*e.g.*, staff turnover, change in project leadership, and change in elected officials) to ensure project stability over the life of the grant.

6. Provide a complete list of staff positions anticipated for the project, including the Project Director, Project Coordinator, and other key personnel, showing the role of each and their level of effort and qualifications.

7. For key staff currently on board, include a biographical sketch for the Project Director, Project Coordinator, or other key positions as attachments to the project proposal/application. Do not include any of the following in the biographical sketch:

- Personally Identifiable Information (*i.e.*, SSN, home address, etc.);
- Resumes; or
- Curriculum Vitae.

D. Program Evaluation (Data Collection & Reporting) (20 Points)

1. Describe the applicant's plan for data collection and document the applicant's ability to ensure accurate data tracking and meeting required reporting requirements/deadlines.

2. Provide a clear, specific plan for how data related to the project will be collected, managed, analyzed, and reported.

3. Describe any type(s) of evaluation(s) that will be used to assess the project during the grant life cycle.

4. Explain how you will collaborate with partners (*i.e.*, Tribal Epidemiology Center) to complete any evaluation efforts or data collection.

E. Budget and Budget Justification (10 Points)

1. The applicant is required to include a line item budget for all expenditures identifying reasonable and allowable costs necessary to accomplish the goals and objectives, as outlined in the project narrative for Project Year one only. The budget expenditures should correlate with the scope of work described in the project narrative for the first project year expenses only.

2. The applicant must provide a narrative justification of the budget line items, as well as a description of existing resources and other support the applicant expects to receive for the proposed project. Other support is defined as funds or resources, whether Federal, non-Federal, or institutional, in direct support of activities through fellowships, gifts, prizes, in-kind contributions, or non-Federal means. (This should correspond to Item #18 on the applicant's SF-424, Estimated Funding, and SF-424A, Budget Information, Section C Non-Federal resources.)

3. Provide a narrative justification supporting the development or continued collaboration with other partners regarding the proposed activities to be implemented.

4. Depending on the availability of funds, the IHS may host annual meetings to provide in-depth training and technical assistance to awardees. In order to help establish critical mass of community and staff members who are informed and committed to implement the project, awardees should plan to send a minimum of three people (including the Project Director/Project Coordinator) to one meeting of all awardees in each year of the grant. At these meetings, awardees will receive training related to grant objectives, discuss success and challenges in implementation of the program, present the results of their projects, and receive other technical assistance from IHS staff and/or contractors. Each meeting may be up to 3 days. The locations will be determined at a later date, but applicants should estimate costs for Denver, Colorado as a potential site that is accessible to most of "Indian Country" and attendance is strongly encouraged. The Division of Behavioral Health (DBH) may determine that a virtual meeting(s) may be an option, if Federal government travel restrictions are in place, or if funding is not available to support an in-person meeting.

Multi-Year Project Requirements

Applications must include a brief project narrative and budget (one additional page per year) addressing the developmental plans for each additional year of the project. This attachment will not count as part of the project narrative or the budget narrative.

Additional documents can be uploaded as Other Attachments in *Grants.gov*. These can include:

- Work plan, logic model, and/or timeline for proposed objectives.
- Position descriptions for key staff (i.e., Project Director, Project Coordinator).
- Consultant or contractor proposed scope of work and letter of commitment (if applicable).
- Current Indirect Cost Rate Agreement.
- Organizational chart.
- Map of area identifying project location(s).
- Additional documents to support narrative (i.e., data tables, key news articles, etc.).
- Advisory board(s) description (membership, roles and functions, and frequency of meetings).

2. Review and Selection

Each application will be prescreened for eligibility and completeness as outlined in the funding announcement. Applications that meet the eligibility criteria shall be reviewed for merit by the Objective Review Committee (ORC) based on evaluation criteria. Incomplete applications and applications that are not responsive to the administrative thresholds (budget limit, project period limit) will not be referred to the ORC and will not be funded. The applicant will be notified of this determination.

Applicants must address all program requirements and provide all required documentation.

3. Notifications of Disposition

All applicants will receive an Executive Summary Statement from the IHS DBH within 30 days of the conclusion of the ORC outlining the strengths and weaknesses of their application. The summary statement will be sent to the Authorizing Official identified on the face page (SF-424) of the application.

A. Award Notices for Funded Applications

The NoA is the authorizing document for which funds are dispersed to the approved entities and reflects the amount of Federal funds awarded, the purpose of the award, the terms and conditions of the award, the effective date of the award, and the budget/

project period. Each entity approved for funding must have a user account in GrantSolutions in order to retrieve the NoA. Please see the Agency Contacts list in Section VII for the systems contact information.

B. Approved but Unfunded Applications

Approved applications not funded due to lack of available funds will be held for 1 year. If funding becomes available during the course of the year, the application may be reconsidered.

Note: Any correspondence, other than the official NoA executed by an IHS grants management official announcing to the project director that an award has been made to their organization, is not an authorization to implement their program on behalf of the IHS.

VI. Award Administration Information

1. Administrative Requirements

Awards issued under this announcement are subject to, and are administered in accordance with, the following regulations and policies:

A. The Criteria as Outlined in This Program Announcement

B. Administrative Regulations for Grants

- Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards currently in effect or implemented during the period of award, other Department regulations and policies in effect at the time of award, and applicable statutory provisions. At the time of publication, this includes 45 CFR part 75, at <https://www.govinfo.gov/content/pkg/CFR-2020-title45-vol1/pdf/CFR-2020-title45-vol1-part75.pdf>.

- Please review all HHS regulatory provisions for Termination at 45 CFR 75.372, at https://www.ecfr.gov/cgi-bin/retrieveECFR?gp&SID=2970eec67399fab1413ede53d7895d99&mc=true&n=pt45.1.75&r=PART&ty=HTML&se45.1.75_1372#se45.1.75_1372.

C. Grants Policy

- HHS Grants Policy Statement, Revised January 2007, at <https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf>.

D. Cost Principles

- Uniform Administrative Requirements for HHS Awards, “Cost Principles,” located at 45 CFR part 75 subpart E.

E. Audit Requirements

- Uniform Administrative Requirements for HHS Awards, “Audit Requirements,” located at 45 CFR part 75 subpart F.

F. As of August 13, 2020, 2 CFR 200 was updated to include a prohibition on certain telecommunications and video surveillance services or equipment. This prohibition is described in 2 CFR 200.216. This will also be described in the terms and conditions of every IHS grant and cooperative agreement awarded on or after August 13, 2020.

2. Indirect Costs

This section applies to all recipients that request reimbursement of indirect costs (IDC) in their application budget. In accordance with HHS Grants Policy Statement, Part II-27, the IHS requires applicants to obtain a current IDC rate agreement and submit it to the DGM prior to the DGM issuing an award. The rate agreement must be prepared in accordance with the applicable cost principles and guidance as provided by the cognizant agency or office. A current rate covers the applicable grant activities under the current award's budget period. If the current rate agreement is not on file with the DGM at the time of award, the IDC portion of the budget will be restricted. The restrictions remain in place until the current rate agreement is provided to the DGM.

Per 45 CFR 75.414(f) Indirect (F&A) costs, “any non-Federal entity (NFE) [i.e., applicant] that has never received a negotiated indirect cost rate, . . . may elect to charge a de minimis rate of 10 percent of modified total direct costs which may be used indefinitely. As described in Section 75.403, costs must be consistently charged as either indirect or direct costs, but may not be double charged or inconsistently charged as both. If chosen, this methodology once elected must be used consistently for all Federal awards until such time as the NFE chooses to negotiate for a rate, which the NFE may apply to do at any time.”

Electing to charge a de minimis rate of 10 percent only applies to applicants that have never received an approved negotiated indirect cost rate from HHS or another cognizant federal agency. Applicants awaiting approval of their indirect cost proposal may request the 10 percent de minimis rate. When the applicant chooses this method, costs included in the indirect cost pool must not be charged as direct costs to the grant.

Available funds are inclusive of direct and appropriate indirect costs.

Approved indirect funds are awarded as part of the award amount, and no additional funds will be provided.

Generally, IDC rates for IHS grantees are negotiated with the Division of Cost Allocation at <https://rates.psc.gov/> or the Department of the Interior (Interior Business Center) at <https://ibc.doi.gov/ICS/tribal>. For questions regarding the indirect cost policy, please call the Grants Management Specialist listed under "Agency Contacts" or the main DGM office at (301) 443-5204.

3. Reporting Requirements

The grantee must submit required reports consistent with the applicable deadlines. Failure to submit required reports within the time allowed may result in suspension or termination of an active grant, withholding of additional awards for the project, or other enforcement actions such as withholding of payments or converting to the reimbursement method of payment. Continued failure to submit required reports may result in the imposition of special award provisions and/or the non-funding or non-award of other eligible projects or activities. This requirement applies whether the delinquency is attributable to the failure of the awardee organization or the individual responsible for preparation of the reports. Per DGM policy, all reports must be submitted electronically by attaching them as a "Grant Note" in GrantSolutions. Personnel responsible for submitting reports will be required to obtain a login and password for GrantSolutions. Please see the Agency Contacts list in Section VII for the systems contact information.

The reporting requirements for this program are noted below.

A. Progress Reports

Program progress reports are required annually. The progress reports are due within 30 days after the reporting period ends (specific dates will be listed in the NoA Terms and Conditions). These reports must include a brief comparison of actual accomplishments to the goals established for the period, a summary of progress to date or, if applicable, provide sound justification for the lack of progress, and other pertinent information as required. A final report must be submitted within 90 days of expiration of the period of performance and must provide a comprehensive summary of accomplishments and outcomes relative to each of the stated goals and objectives over the period of the grant.

B. Financial Reports

Federal Cash Transaction Reports are due 30 days after the close of every calendar quarter to the Payment Management Services at <https://pms.psc.gov>. Failure to submit timely reports may result in adverse award actions blocking access to funds.

Federal Financial Reports are due 30 days after the end of each budget period, and a final report is due 90 days after the end of the Period of Performance.

Grantees are responsible and accountable for reporting accurate information on all required reports: The Progress Reports, the Federal Cash Transaction Report, and the Federal Financial Report.

C. Data Collection and Reporting

All grantees will be required to collect and report data pertaining to activities, processes, and outcomes via the IHS Behavioral Health Reporting Portal (BHRP) within 30 days after the budget period ends for each project year (specific dates will be listed in the NoA Terms and Conditions). The BHRP will be open to project staff on a 24 hour per day/7 day per week basis for the duration of each reporting period. Technical assistance for web-based data entry will be timely and readily available to awardees by assigned DBH staff.

In addition to the annual progress reports, the IHS will compile and provide aggregate program statistics from data available in the National Data Warehouse (NDW). The IHS will use NDW data related to suicide prevention, intervention, and postvention, including associated community-level health care facility data, as a method to monitor outcomes and impact of grant activities.

D. Federal Sub-Award Reporting System (FSRS)

This award may be subject to the Transparency Act sub-award and executive compensation reporting requirements of 2 CFR part 170.

The Transparency Act requires the OMB to establish a single searchable database, accessible to the public, with information on financial assistance awards made by Federal agencies. The Transparency Act also includes a requirement for recipients of Federal grants to report information about first-tier sub-awards and executive compensation under Federal assistance awards.

The IHS has implemented a Term of Award into all IHS Standard Terms and Conditions, NoAs, and funding announcements regarding the FSRS reporting requirement. This IHS Term of

Award is applicable to all IHS grant and cooperative agreements issued on or after October 1, 2010, with a \$25,000 sub-award obligation threshold met for any specific reporting period.

For the full IHS award term implementing this requirement and additional award applicability information, visit the DGM Grants Management website at <https://www.ihs.gov/dgm/policytopics/>.

E. Compliance With Executive Order 13166 Implementation of Services Accessibility Provisions for All Grant Application Packages and Funding Opportunity Announcements

Should you successfully compete for an award, recipients of Federal financial assistance (FFA) from HHS must administer their programs in compliance with Federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex (including gender identity, sexual orientation, and pregnancy). This includes ensuring programs are accessible to persons with limited English proficiency and persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. Please see <https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html> and <https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html>.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting your legal obligation to take reasonable steps to ensure meaningful access to your programs or activities by limited English proficiency individuals, see <https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html> and <https://www.lep.gov>.

- For information on your specific legal obligations for serving qualified individuals with disabilities, including reasonable modifications and making services accessible to them, see <https://www.hhs.gov/ocr/civilrights/understanding/disability/index.html>.

- HHS funded health and education programs must be administered in an environment free of sexual harassment. See <https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html>.

- For guidance on administering your program in compliance with applicable Federal religious nondiscrimination laws and applicable Federal conscience

protection and associated anti-discrimination laws, see <https://www.hhs.gov/conscience/conscience-protections/index.html> and <https://www.hhs.gov/conscience/religious-freedom/index.html>.

F. Federal Awardee Performance and Integrity Information System (FAPIS)

The IHS is required to review and consider any information about the applicant that is in the FAPIS at <https://www.fapis.gov> before making any award in excess of the simplified acquisition threshold (currently \$250,000) over the period of performance. An applicant may review and comment on any information about itself that a Federal awarding agency previously entered. The IHS will consider any comments by the applicant, in addition to other information in FAPIS, in making a judgment about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants, as described in 45 CFR 75.205.

As required by 45 CFR part 75 Appendix XII of the Uniform Guidance, NFEs are required to disclose in FAPIS any information about criminal, civil, and administrative proceedings, and/or affirm that there is no new information to provide. This applies to NFEs that receive Federal awards (currently active grants, cooperative agreements, and procurement contracts) greater than \$10,000,000 for any period of time during the period of performance of an award/project.

Mandatory Disclosure Requirements

As required by 2 CFR part 200 of the Uniform Guidance, and the HHS implementing regulations at 45 CFR part 75, the IHS must require an NFE or an applicant for a Federal award to disclose, in a timely manner, in writing to the IHS or pass-through entity all violations of Federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the Federal award.

All applicants and recipients must disclose, in a timely manner, in writing to the IHS and to the HHS Office of Inspector General of all information related to violations of Federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the Federal award. 45 CFR 75.113.

Disclosures must be sent in writing to: U.S. Department of Health and Human Services, Indian Health Service, Division of Grants Management, ATTN: Paul Gettys, Acting Director, 5600 Fishers Lane, Mail Stop: 09E70,

Rockville, MD 20857 (Include "Mandatory Grant Disclosures" in subject line), Office: (301) 443-5204, Fax: (301) 594-0899, Email: Paul.Gettys@ihs.gov.

AND

U.S. Department of Health and Human Services, Office of Inspector General, ATTN: Mandatory Grant Disclosures, Intake Coordinator, 330 Independence Avenue SW, Cohen Building, Room 5527, Washington, DC 20201, URL: <https://oig.hhs.gov/fraud/report-fraud/> (Include "Mandatory Grant Disclosures" in subject line), Fax: (202) 205-0604 (Include "Mandatory Grant Disclosures" in subject line) or Email: MandatoryGranteeDisclosures@oig.hhs.gov.

Failure to make required disclosures can result in any of the remedies described in 45 CFR 75.371 Remedies for noncompliance, including suspension or debarment (see 2 CFR part 180 and 2 CFR part 376).

VII. Agency Contacts

1. *Questions on the programmatic issues may be directed to:* Audrey Solimon, Public Health Analyst, Indian Health Service, Division of Behavioral Health, 5600 Fishers Lane, Mail Stop: 08N34-A, Rockville, MD 20857, Phone: (301) 590-5421, Fax: (301) 594-6213, Email: Audrey.Solimon@ihs.gov.

2. *Questions on grants management and fiscal matters may be directed to:* Donald Gooding, Grants Management Specialist, Indian Health Service, Division of Grants Management, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, Phone: (301) 443-2298, Fax: (301) 594-0899, Email: Donald.Gooding@ihs.gov.

3. *Questions on systems matters may be directed to:* Paul Gettys, Acting Director, Indian Health Service, Division of Grants Management, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, Phone: (301) 443-2114; or the DGM main line (301) 443-5204, Fax: (301) 443-9602, Email: Paul.Gettys@ihs.gov.

VIII. Other Information

The Public Health Service strongly encourages all grant, cooperative agreement, and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of the facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This

is consistent with the HHS mission to protect and advance the physical and mental health of the American people.

Elizabeth A. Fowler,

Acting Director, Indian Health Service.

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BILLING CODE 4165-16-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Behavioral Health Integration Initiative

Announcement Type: New.

Funding Announcement Number:

HHS-2022-IHS-BH2I-0001.

Assistance Listing (Catalog of Federal Domestic Assistance or CFDA) Number: 93.654.

Key Dates

Application Deadline Date: February 2, 2022.

Earliest Anticipated Start Date: March 21, 2022.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) is accepting applications for grants for the Behavioral Health Integration Initiative (BH2I) to plan, develop, implement, and evaluate behavioral health integration with primary care, community-based settings, and/or integrating primary care, nutrition, diabetes care, and chronic disease management with behavioral health. This program is authorized under the Snyder Act, 25 U.S.C. 13; the Transfer Act, 42 U.S.C. 2001(a); and the Indian Health Care Improvement Act, Subchapter V-A (Behavioral Health Programs), 25 U.S.C. 1665 *et seq.* This program is described in the Assistance Listings located at <https://sam.gov/content/home> (formerly known as the CFDA) under 93.654.

Background

The IHS supports changing the paradigm of mental health and substance use disorder to the patient-centered home model from the episodic, fragmented, specialty, and/or disease focused former models. Research has shown that more than 70 percent of primary care visits stem from behavioral health issues. Depression is the most common type of mental illness, currently affecting more than a quarter of the United States (U.S.) adult population. With major depression currently the second leading cause of disability, it is clear that primary care settings have become an important access point for addressing both

physical and behavioral health care needs. In addition, American Indian and Alaska Native (AI/AN) communities experience alarming rates of suicide, alcohol and drug-related deaths, domestic and sexual violence, and homicide. Describing the burden of trauma within any population is difficult; however, indicators measuring socially destructive behaviors are often used to illustrate impacts of trauma through lifespan accumulation and chronic stress. Studies now indicate that trauma can be passed from one generation to the next, resulting in intergenerational and historical trauma. While mental health needs can often go untreated and even unnoticed, the lasting effects of childhood trauma into adulthood are often evident in physical manifestations leading to negative health consequences. These extreme disparities highlight an urgent need for improving access to mental health services in primary care for children and families through the integration of behavioral health services, including trauma-informed care, within primary care settings. The majority of people with behavioral health disorders treated within an integrated primary care setting have improved outcomes because behavioral and physical health problems are interwoven, and the delivery of behavioral health services in primary care settings reduces stigma and discrimination often associated with seeking help for behavioral health disorders.

Purpose

The purpose of the BH2I program is to improve the physical and mental health status of people with behavioral health issues by developing an integrated and coordinated system of care. This effort supports the IHS mission to raise the physical, mental, social, and spiritual health of AI/AN individuals to the highest level. Increasing capacity among Tribal and Urban Indian Organization (UIO) health facilities to implement an integrative approach in the delivery of behavioral health services, including trauma-informed care, nutrition, exercise, social, spiritual, cultural, and primary care services, will improve morbidity and mortality outcomes among the AI/AN population. In addition, this effort will support activities to improve the quality of life for individuals suffering from mental illness, substance use disorders, and adverse childhood experiences. Other outcomes related to this effort include improved behavioral health services to increase access to integrated health and social well-being services and the early identification and

intervention of mental health, substance use, and serious physical health issues, including chronic disease. This work will also identify and assess various models addressing unique integrative needs and the challenges, barriers, and successes in AI/AN health systems. Finally, an improvement in the overall health of patients participating in integrative programs is expected.

For this grant, the full spectrum of behavioral health services are strongly encouraged and are defined as screening for mental and substance use disorders, including serious mental illness; alcohol, substance, and opioid use disorders; suicidality and trauma (e.g., interpersonal violence, physical abuse, adverse childhood experiences) assessment, including risk assessment and diagnosis; patient-centered treatment planning, evidence-based outpatient mental and substance use disorder treatment services (including pharmacological and psychosocial services); crisis services; peer support services; and care coordination.

Models of Care

The IHS understands unique challenges and circumstances exist across Tribal communities and sites. In fact, integrative models of care vary according to needs and capabilities but all strive to enhance clinical processes and workflow across multi-disciplinary teams. This program will support sites that have identified gaps in services and established efforts to link critical policy and service-level connections, including new and innovative ways of conducting business between differing management and operations of Federal and Tribal health services and programs. In addition, participants can expect to use technologies that facilitate behavioral health integration including technology that increases the site's ability to create a patient registry; document current procedural terminology (CPT) codes; and track behavioral health assessment scores with the capacity to provide care coordination between the behavioral health and primary care team.

Additional Required Activity

Grantees must plan to send a minimum of two people (including the project director) to at least one joint grantee meeting in every other year of the period of performance. For this grant cohort, grantee meetings will likely be held in years one, three, and five of the period of performance. You must include a detailed budget and narrative for this travel in your budget. At these meetings, grantees will present the results of their projects and Federal staff will provide technical assistance. Each

meeting will be up to three days. These meetings are usually held in the Washington, DC, area and attendance is mandatory. The IHS reserves the right to hold these grantee meetings through virtual/remote teleconference if the IHS budget or travel restrictions are prohibitive for holding an in-person meeting.

II. Award Information

Type of Award—Grant

Estimated Funds Available

The total funding identified for fiscal year (FY) 2022 is approximately \$6,000,000. Individual award amounts for the first budget year are anticipated to be between \$300,000 and \$400,000. The funding available for competing and subsequent continuation awards issued under this announcement is subject to the availability of appropriations and budgetary priorities of the agency. The IHS is under no obligation to make awards that are selected for funding under this announcement.

Anticipated Number of Awards

Approximately 15 awards will be issued under this program announcement, with a set aside of up to two awards issued to eligible UIOs.

Period of Performance

The period of performance is for 5 years.

III. Eligibility Information

1. Eligibility

To be eligible for this funding opportunity an applicant must be one of the following as defined by 25 U.S.C. 1603:

- A federally recognized Indian Tribe as defined by 25 U.S.C. 1603(14). The term "Indian Tribe" means any Indian Tribe, band, nation, or other organized group or community, including any Alaska Native village or group, or regional or village corporation as defined in or established pursuant to the Alaska Native Claims Settlement Act (85 Stat. 688) [43 U.S.C. 1601 *et seq.*], which is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians.

- A Tribal organization as defined by 25 U.S.C. 1603(26). The term "Tribal organization" has the meaning given the term in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304(l)): "Tribal organization" means the recognized governing body of any Indian Tribe; any legally established organization of Indians which is

controlled, sanctioned, or chartered by such governing body or which is democratically elected by the adult members of the Indian community to be served by such organization and which includes the maximum participation of Indians in all phases of its activities: Provided that, in any case where a contract is let or grant made to an organization to perform services benefiting more than one Indian Tribe, the approval of each such Indian Tribe shall be a prerequisite to the letting or making of such contract or grant. Applicant shall submit letters of support and/or Tribal Resolutions from the Tribes to be served.

- An Urban Indian organization, as defined by 25 U.S.C. 1603(29). The term "Urban Indian organization" means a nonprofit corporate body situated in an urban center, governed by an urban Indian controlled board of directors, and providing for the maximum participation of all interested Indian groups and individuals, which body is capable of legally cooperating with other public and private entities for the purpose of performing the activities described in 25 U.S.C. 1653(a). Applicants must provide proof of nonprofit status with the application, e.g., 501(c)(3).

The program office will notify any applicants deemed ineligible.

Note: Please refer to Section IV.2 (Application and Submission Information/ Subsection 2, Content and Form of Application Submission) for additional proof of applicant status documents required, such as Tribal Resolutions, proof of nonprofit status, etc.

2. Cost Sharing or Matching

The IHS does not require matching funds or cost sharing for grants or cooperative agreements.

3. Other Requirements

Applications with budget requests that exceed the highest dollar amount outlined under Section II Award Information, Estimated Funds Available, or exceed the period of performance outlined under Section II Award Information, Period of Performance, are considered not responsive and will not be reviewed. The Division of Grants Management (DGM) will notify the applicant.

Additional Required Documentation

Tribal Resolution

The DGM must receive an official, signed Tribal Resolution prior to issuing a Notice of Award (NoA) to any applicant selected for funding. An Indian Tribe or Tribal organization that

is proposing a project affecting another Indian Tribe must include resolutions from all affected Tribes to be served. However, if an official, signed Tribal Resolution cannot be submitted with the application prior to the application deadline date, a draft Tribal Resolution must be submitted with the application by the deadline date in order for the application to be considered complete and eligible for review. The draft Tribal Resolution is not in lieu of the required signed resolution but is acceptable until a signed resolution is received. If an application without a signed Tribal Resolution is selected for funding, the applicant will be contacted by the Grants Management Specialist (GMS) listed in this funding announcement and given 90 days to submit an official, signed Tribal Resolution to the GMS. If the signed Tribal Resolution is not received within 90 days, the award will be forfeited.

Tribes organized with a governing structure other than a Tribal council may submit an equivalent document commensurate with their governing organization.

Proof of Nonprofit Status

Organizations claiming nonprofit status must submit a current copy of the 501(c)(3) Certificate with the application.

IV. Application and Submission Information

1. Obtaining Application Materials

The application package and detailed instructions for this announcement are available at <https://www.Grants.gov>.

Please direct questions regarding the application process to Mr. Paul Gettys at (301) 443-2114 or (301) 443-5204.

2. Content and Form Application Submission

Mandatory documents for all applicants include:

- Abstract (one page) summarizing the project.
- Application forms:
 1. SF-424, Application for Federal Assistance.
 2. SF-424A, Budget Information—Non-Construction Programs.
 3. SF-424B, Assurances—Non-Construction Programs.
- Project Narrative (not to exceed 17 pages). See Section IV.2.A, Project Narrative for instructions.

1. Background information on the organization.
2. Proposed scope of work, objectives, and activities that provide a description of what the applicant plans to accomplish.

- Budget Justification and Narrative (not to exceed four pages). See Section IV.2.B, Budget Narrative for instructions.

- Tribal Resolution(s).
- Letter(s) of Support:
 1. For all applicants: From local organizational partners;
 2. For all applicants: From community partners;
 3. For Tribal organizations and UIOs: From the board of directors (or relevant equivalent).
- 501(c)(3) Certificate (if applicable).
- Biographical sketches for all Key Personnel.
- Contractor/Consultant resumes or qualifications and scope of work.
- Disclosure of Lobbying Activities (SF-LLL), if applicant conducts reportable lobbying.
- Certification Regarding Lobbying (GG-Lobbying Form).
- Copy of current Negotiated Indirect Cost rate (IDC) agreement (required in order to receive IDC).
- Organizational Chart (optional).
- Documentation of current Office of Management and Budget (OMB) Financial Audit (if applicable).

Acceptable forms of documentation include:

1. Email confirmation from Federal Audit Clearinghouse (FAC) that audits were submitted; or
 2. Face sheets from audit reports.
- Applicants can find these on the FAC website at <https://harvester.census.gov/facdissem/Main.aspx>.

Public Policy Requirements

All Federal public policies apply to IHS grants and cooperative agreements. Pursuant to 45 CFR 80.3(d), an individual shall not be deemed subjected to discrimination by reason of their exclusion from benefits limited by Federal law to individuals eligible for benefits and services from the IHS. See <https://www.hhs.gov/grants/grants/grants-policies-regulations/index.html>.

Requirements for Project and Budget Narratives

A. Project Narrative

This narrative should be a separate document that is no more than 17 pages and must: (1) Have consecutively numbered pages; (2) use black font 12 points or larger; (3) be single-spaced; and (4) be formatted to fit standard letter paper (8½ x 11 inches).

Be sure to succinctly answer all questions listed under the evaluation criteria (refer to Section V.1, Evaluation Criteria) and place all responses and required information in the correct section noted below or they will not be

considered or scored. If the narrative exceeds the page limit, the application will be considered not responsive and will not be reviewed. The 17-page limit for the narrative does not include the work plan, standard forms, Tribal Resolutions, budget, budget justifications, narratives, and/or other items.

There are five parts to the project narrative:

Part A—Statement of Need;

Part B—Program Planning and

Implementation Approach;

Part C—Staff and Organization Capacity;

Part D—Performance Assessment and Data; and

Part E—Evaluation Plan.

See below for additional details about what must be included in the narrative.

Part A: Statement of Need (Limit—2 Pages)

Describe the current situation in the applicant's Tribal community ("community" means the applicant's Tribe, village, Tribal organization, or consortium of Tribes or Tribal organizations). Provide the facts and evidence that support the need for the project, and that establish the Tribe, Tribal organization, or UIO understands the problems and can reasonably address them.

Part B: Program Planning and Implementation Approach (Limit—9 Pages)

- State the purpose, goals, and objectives of your proposed project.
- Describe evidence-based programs, services, or practices you propose to implement, or to continue to implement through support of this grant opportunity.
- Describe your plan to formally integrate behavioral health through your health care system.

Part C: Staff and Organization Capacity (Limit—2 Pages)

This section should describe the applicant's organization and structure and the capabilities possessed to complete proposed activities. This program will focus on the applicant's ability to implement a formalized integration plan focused on enhancing the clinical processes for patient care among the IHS service areas.

- Identify a program director who will implement proposed grant activities and administer the grant, including progress and financial reports or provide salary costs for the addition of full-time equivalent (FTE) licensed behavioral health provider(s).

Part D: Performance Assessment and Data (Limit—2 Pages)

This section of the application should describe efforts to collect and report project data that will support and demonstrate BH2I activities. BH2I grantees will be required to collect and report data pertaining to activities, processes, and outcomes. Data collection activities should capture and document actions conducted throughout awarded years, including those that will contribute relevant project impact.

Part E: Evaluation Plan (Limit—2 Pages)

The evaluation section should describe applicant's plan to evaluate program activities. The evaluation plan should describe expected results and any identified metrics to support program effectiveness. Evaluation plans should incorporate questions related to outcomes and processes including documentation of lessons learned.

- Describe efforts to monitor improvements through the evaluation of the following:
 1. Implementation team.
 2. Partnerships to achieve goals.
 3. Sustainability.
 4. Level of integration.
 5. Measurement-based screening tools.
 6. Patient tracking system.

B. Budget Narrative (Limit—4 Pages)

Provide a budget narrative that explains the amounts requested for each line item of the budget from the SF-424A (Budget Information for Non-Construction Programs). The budget narrative can include a more detailed spreadsheet than is provided by the SF-424A. The budget narrative should specifically describe how each item will support the achievement of proposed objectives. Be very careful about showing how each item in the "Other" category is justified. For subsequent budget years (see Multi-Year Project Requirements in Section V.1, Application Review Information, Evaluation Criteria), the narrative should highlight the changes from year one or clearly indicate that there are no substantive budget changes during the period of performance. Do NOT use the budget narrative to expand the project narrative.

3. Submission Dates and Times

Applications must be submitted through *Grants.gov* by 11:59 p.m. Eastern Time on the Application Deadline Date. Any application received after the application deadline will not be accepted for review. *Grants.gov* will notify the applicant via email if the application is rejected.

If technical challenges arise and assistance is required with the application process, contact *Grants.gov* Customer Support (see contact information at <https://www.grants.gov>). If problems persist, contact Mr. Paul Gettys (Paul.Gettys@ihs.gov), Acting Director, DGM, by telephone at (301) 443-2114 or (301) 443-5204. Please be sure to contact Mr. Gettys at least ten days prior to the application deadline. Please do not contact the DGM until you have received a *Grants.gov* tracking number. In the event you are not able to obtain a tracking number, call the DGM as soon as possible.

The IHS will not acknowledge receipt of applications.

4. Intergovernmental Review

Executive Order 12372 requiring intergovernmental review is not applicable to this program.

5. Funding Restrictions

- Pre-award costs are allowable up to 90 days before the start date of the award provided the costs are otherwise allowable if awarded. Pre-award costs are incurred at the risk of the applicant.
- The available funds are inclusive of direct and indirect costs.
- Only one grant will be awarded per applicant.

6. Electronic Submission Requirements

All applications must be submitted via *Grants.gov*. Please use the <https://www.Grants.gov> website to submit an application. Find the application by selecting the "Search Grants" link on the homepage. Follow the instructions for submitting an application under the Package tab. No other method of application submission is acceptable.

If the applicant cannot submit an application through *Grants.gov*, a waiver must be requested. Prior approval must be requested and obtained from Mr. Paul Gettys, Acting Director, DGM. A written waiver request must be sent to GrantsPolicy@ihs.gov with a copy to Paul.Gettys@ihs.gov. The waiver request must: (1) Be documented in writing (emails are acceptable) before submitting an application by some other method; and (2) include clear justification for the need to deviate from the required application submission process.

Once the waiver request has been approved, the applicant will receive a confirmation of approval email containing submission instructions. A copy of the written approval must be included with the application that is submitted to the DGM. Applications that are submitted without a copy of the signed waiver from the Acting Director

of the DGM will not be reviewed. The Grants Management Officer of the DGM will notify the applicant via email of this decision. Applications submitted under waiver must be received by the DGM no later than 5:00 p.m. Eastern Time on the Application Deadline Date. Late applications will not be accepted for processing. Applicants that do not register for both the System for Award Management (SAM) and *Grants.gov* and/or fail to request timely assistance with technical issues will not be considered for a waiver to submit an application via alternative method.

Please be aware of the following:

- Please search for the application package in <https://www.Grants.gov> by entering the Assistance Listing (CFDA) number or the Funding Opportunity Number. Both numbers are located in the header of this announcement.
- If you experience technical challenges while submitting your application, please contact *Grants.gov* Customer Support (see contact information at <https://www.grants.gov>).
- Upon contacting *Grants.gov*, obtain a tracking number as proof of contact. The tracking number is helpful if there are technical issues that cannot be resolved and a waiver from the agency must be obtained.
- Applicants are strongly encouraged not to wait until the deadline date to begin the application process through *Grants.gov* as the registration process for SAM and *Grants.gov* could take up to 20 working days.
- Please follow the instructions on *Grants.gov* to include additional documentation that may be requested by this funding announcement.
- Applicants must comply with any page limits described in this funding announcement.
- After submitting the application, the applicant will receive an automatic acknowledgment from *Grants.gov* that contains a *Grants.gov* tracking number. The IHS will not notify the applicant that the application has been received.

Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS)

Applicants and grantee organizations are required to obtain a DUNS number and maintain an active registration in the SAM database. The DUNS number is a unique 9-digit identification number provided by D&B that uniquely identifies each entity. The DUNS number is site specific; therefore, each distinct performance site may be assigned a DUNS number. Obtaining a DUNS number is easy, and there is no charge. To obtain a DUNS number, please access the request service

through <https://fedgov.dnb.com/webform>, or call (866) 705-5711.

The Federal Funding Accountability and Transparency Act of 2006, as amended (“Transparency Act”), requires all HHS recipients to report information on sub-awards. Accordingly, all IHS grantees must notify potential first-tier sub-recipients that no entity may receive a first-tier sub-award unless the entity has provided its DUNS number to the prime grantee organization. This requirement ensures the use of a universal identifier to enhance the quality of information available to the public pursuant to the Transparency Act.

System for Award Management (SAM)

Organizations that are not registered with SAM must have a DUNS number first, then access the SAM online registration through the SAM home page at <https://sam.gov> (U.S. organizations will also need to provide an Employer Identification Number from the Internal Revenue Service that may take an additional 2–5 weeks to become active). Please see *SAM.gov* for details on the registration process and timeline. Registration with the SAM is free of charge but can take several weeks to process. Applicants may register online at <https://sam.gov>.

Additional information on implementing the Transparency Act, including the specific requirements for DUNS and SAM, are available on the DGM Grants Management, Policy Topics web page at <https://www.ihs.gov/dgm/policytopics/>.

V. Application Review Information

Possible points assigned to each section are noted in parentheses. The project narrative and budget narrative should include only the first year of activities; information for multi-year projects should be included as a separate document. See “Multi-year Project Requirements” at the end of this section for more information. The project narrative should be written in a manner that is clear to outside reviewers unfamiliar with prior related activities of the applicant. It should be well organized, succinct, and contain all information necessary for reviewers to fully understand the project. Attachments requested in the criteria do not count toward the page limit for the narratives. Points will be assigned to each evaluation criteria adding up to a total of 100 possible points. Points are assigned as follows:

1. Evaluation Criteria

Applications will be reviewed and scored according to the quality of

responses to the required application components in Sections A–F outlined below. In developing the required sections of this application, use the instructions provided for each section, which have been tailored to this program. The application must use the six sections (Sections A–F) in developing the application. The applicant must place the required information in the correct section or it will not be considered for review. The number of points after each section heading is the maximum number of points the review committee may assign to that section. Although scoring weights are not assigned to individual bullets, each bullet is assessed deriving the overall section score.

A. Statement of Need (25 Points)

- Describe the service area/target population demonstrating the need for new/increased integrated primary health care/behavioral health services.
- Describe the needs in your service area and/or among your target population for new/increased integrated primary health care/behavioral health services.
- Describe the unique characteristics of the service area and population that impact access to or utilization of behavioral health care.
- Describe existing behavioral health care providers in the service area, including identified gaps in behavioral health care services the applicant can address via BH2I funds.

B. Program Planning and Implementation Approach (25 Points)

- Describe the purpose, goals, and objectives of the proposed project to address the mental and physical health needs through an integrated approach between primary health care/behavioral health services.
- Describe the evidence-based practices, practice-based evidence, promising practices, and intervention efforts, including culturally appropriate services and interventions, to produce meaningful and relevant results including additional details to support evidence of effectiveness to support the proposed project.
- Describe the current level of behavioral health integration (using the SAMHSA–HRSA Center for Integrated Health Solutions framework at https://www.integration.samhsa.gov/integrated-care-models/CIHS_Framework_Final_charts.pdf) and forecast how they will progress to higher levels of health integration.
- Describe the plan to formally integrate behavioral health through:

1. Improving workflow in the assessment of behavioral health in primary care such as screenings, referral, and policy development;

2. Improving or changing health information technology in ways that facilitate behavioral health integration;

3. Improving physical environment barriers in the delivery of integrated health care;

4. Cross training of staff, including psycho-education training for staff within primary care settings and basic medical education for behavioral health staff;

5. Establishing formal and informal channels of communication to facilitate behavioral health integration.

C. Staff and Organizational Capacity (20 Points)

- Describe the organization's current system of providing at least one service of primary care and/or behavioral health, including screening, assessment, and care management. Describe the delivery, operation, and/or management of at least one portion of direct primary care or behavioral health treatment services.

- Describe how you will identify qualified professionals who will implement proposed grant activities, administer the grant, including completion and submission of progress and financial reports, and how project continuity will be maintained if/when there is a change in the operational environment (e.g., staff turnover, change in project leadership) to ensure project stability over the life of the grant.

- Describe the organization's plan to hire full-time equivalent (FTE) licensed behavioral health provider(s).

- Include a biographical sketch for individuals identified and currently on staff in the project director, project coordinator, and other key positions as attachments to the project proposal/application. Each biographical sketch should not exceed one page. Do not include any of the following:

- Personally Identifiable Information;
- Resumes; or
- Curriculum Vitae.

D. Performance Assessment & Data (10 Points)

- Describe plans for data collection, management, analysis, and reporting for integration activities.

- Describe your process for data collection that will be required as part of the evidence-based practice, or proposed evidence-based projects.

- Explain the proposed efforts to utilize health information technology including accessibility, collection, and monitoring of relevant data for proposed BH2I project.

- Discuss the proposed evaluation methods (including expertise and tools) to assess impacts and outcomes.

E. Evaluation Plan (10 Points)

- Describe proposed methods, including quantitative and qualitative tools and resources, techniques to measure outcomes, and any partners who will conduct evaluation if separate from the primary applicant.

- Describe performance measures and other data relevant to evaluation outcomes, including intended results (i.e., impact and outcomes).

- Discuss how expected results will be measured (define indicators or tools used to monitor and measure progress).

- Describe a plan to monitor improvements through the evaluation of increased coordinated care, co-located care, and integrated care using the SAMHSA–HRSA Center for Integrated Health Solutions six-level framework at https://www.integration.samhsa.gov/integrated-care-models/A_Standard_Framework_for_Levels_of_Integrated_Healthcare.pdf.

F. Categorical Budget and Budget Justification (10 Points)

This narrative must include a line item budget with a narrative justification for all expenditures identifying reasonable allowable, allocable costs necessary to accomplish the goals and objectives as outlined in the project narrative. Budget should match the scope of work described in the project narrative and include anticipated travel to the grantee meeting in the first year. Anticipated travel in subsequent years should be included in the multi-year project narrative and budget. The budget and budget narrative should not exceed four pages.

Multi-Year Project Requirements

Applications must include a brief project narrative and budget (one additional page per year) addressing the developmental plans for each additional year of the project. This attachment will not count as part of the project narrative or the budget narrative.

Additional documents can be uploaded as Other Attachments in *Grants.gov*. These can include:

- Work plan, logic model, and/or timeline for proposed objectives.
- Position descriptions for key staff.
- Resumes of key staff to reflect current duties.
- Consultant or contractor proposed scope of work and letter of commitment (if applicable).
- Current Indirect Cost Agreement.
- Organizational chart.
- Map of area identifying project location(s).

- Additional documents to support narrative (i.e., data tables, key news articles, etc.).

2. Review and Selection

Each application will be prescreened for eligibility and completeness as outlined in the funding announcement. Applications that meet the eligibility criteria shall be reviewed for merit by the Objective Review Committee (ORC) based on evaluation criteria. Incomplete applications and applications that are not responsive to the administrative thresholds (budget limit, project period limit) will not be referred to the ORC and will not be funded. The applicant will be notified of this determination.

Applicants must address all program requirements and provide all required documentation.

3. Notifications of Disposition

All applicants will receive an Executive Summary Statement from the IHS Division of Behavioral Health within 30 days of the conclusion of the ORC outlining the strengths and weaknesses of their application. The summary statement will be sent to the Authorizing Official identified on the face page (SF–424) of the application.

A. Award Notices for Funded Applications

The NoA is the authorizing document for which funds are dispersed to the approved entities and reflects the amount of Federal funds awarded, the purpose of the award, the terms and conditions of the award, the effective date of the award, and the budget/project period. Each entity approved for funding must have a user account in GrantSolutions in order to retrieve the NoA. Please see the Agency Contacts list in Section VII for the systems contact information.

B. Approved But Unfunded Applications

Approved applications not funded due to lack of available funds will be held for 1 year. If funding becomes available during the course of the year, the application may be reconsidered.

Note: Any correspondence, other than the official NoA executed by an IHS grants management official announcing to the project director that an award has been made to their organization, is not an authorization to implement their program on behalf of the IHS.

VI. Award Administration Information

1. Administrative Requirements

Awards issued under this announcement are subject to, and are

administered in accordance with, the following regulations and policies:

A. The criteria as outlined in this program announcement.

B. Administrative Regulations for Grants:

- Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards currently in effect or implemented during the period of award, other Department regulations and policies in effect at the time of award, and applicable statutory provisions. At the time of publication, this includes 45 CFR part 75, at <https://www.govinfo.gov/content/pkg/CFR-2020-title45-vol1/pdf/CFR-2020-title45-vol1-part75.pdf>.

- Please review all HHS regulatory provisions for Termination at 45 CFR 75.372, at https://www.ecfr.gov/cgi-bin/retrieveECFR?gp&SID=2970eec67399fab1413ede53d7895d99&mc=true&n=pt45.1.75&r=PART&ty=HTML&se45.1.75_1372#se45.1.75_1372.

C. Grants Policy:

- HHS Grants Policy Statement, Revised January 2007, at <https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf>.

D. Cost Principles:

- Uniform Administrative Requirements for HHS Awards, “Cost Principles,” at 45 CFR part 75 subpart E.

E. Audit Requirements:

- Uniform Administrative Requirements for HHS Awards, “Audit Requirements,” at 45 CFR part 75 subpart F.

F. As of August 13, 2020, 2 CFR 200 was updated to include a prohibition on certain telecommunications and video surveillance services or equipment. This prohibition is described in 2 CFR 200.216. This will also be described in the terms and conditions of every IHS grant and cooperative agreement awarded on or after August 13, 2020.

2. Indirect Costs

This section applies to all recipients that request reimbursement of indirect costs (IDC) in their grant application. In accordance with HHS Grants Policy Statement, Part II–27, IHS requires applicants to obtain a current IDC rate agreement and submit it to the DGM prior to the DGM issuing an award. The rate agreement must be prepared in accordance with the applicable cost principles and guidance as provided by the cognizant agency or office. A current rate covers the applicable grant activities under the current award’s budget period. If the current rate agreement is not on file with the DGM

at the time of award, the IDC portion of the budget will be restricted. The restrictions remain in place until the current rate is provided to the DGM.

Per 45 CFR 75.414(f) Indirect (F&A) costs, “any non-Federal entity (NFE) [i.e., applicant] that has never received a negotiated indirect cost rate, . . . may elect to charge a de minimis rate of 10 percent of modified total direct costs which may be used indefinitely. As described in Section 75.403, costs must be consistently charged as either indirect or direct costs, but may not be double charged or inconsistently charged as both. If chosen, this methodology once elected must be used consistently for all Federal awards until such time as the NFE chooses to negotiate for a rate, which the NFE may apply to do at any time.”

Electing to charge a de minimis rate of 10 percent only applies to applicants that have never received an approved negotiated indirect cost rate from HHS or another cognizant Federal agency. Applicants awaiting approval of their indirect cost proposal may request the 10 percent de minimis rate. When the applicant chooses this method, costs included in the indirect cost pool must not be charged as direct costs to the grant.

Available funds are inclusive of direct and appropriate indirect costs. Approved indirect funds are awarded as part of the award amount, and no additional funds will be provided.

Generally, IDC rates for IHS grantees are negotiated with the Division of Cost Allocation at <https://rates.psc.gov/> or the Department of the Interior (Interior Business Center) at <https://ibc.doi.gov/ICS/tribal>. For questions regarding the indirect cost policy, please call the Grants Management Specialist listed under “Agency Contacts” or the main DGM office at (301) 443–5204.

3. Reporting Requirements

The grantee must submit required reports consistent with the applicable deadlines. Failure to submit required reports within the time allowed may result in suspension or termination of an active grant, withholding of additional awards for the project, or other enforcement actions such as withholding of payments or converting to the reimbursement method of payment. Continued failure to submit required reports may result in the imposition of special award provisions and/or the non-funding or non-award of other eligible projects or activities. This requirement applies whether the delinquency is attributable to the failure of the awardee organization or the individual responsible for preparation

of the reports. Per DGM policy, all reports must be submitted electronically by attaching them as a “Grant Note” in GrantSolutions. Personnel responsible for submitting reports will be required to obtain a login and password for GrantSolutions. Please see the Agency Contacts list in Section VII for the systems contact information.

The reporting requirements for this program are noted below.

A. Progress Reports

Program progress reports are required annually. The progress reports are due within 30 days after the reporting period ends (specific dates will be listed in the NoA Terms and Conditions). These reports will include a set of standard questions that will be provided to each grantee. Additional information for reporting and associated requirements will be in the “Programmatic Terms and Conditions” in the official NoA, if funded. A final report must be submitted within 90 days of expiration of the period of performance.

B. Financial Reports

Federal Cash Transaction Reports are due 30 days after the close of every calendar quarter to the Payment Management Services at <https://pms.psc.gov>. Failure to submit timely reports may result in adverse award actions blocking access to funds.

Federal Financial Reports are due 30 days after the end of each budget period, and a final report is due 90 days after the end of the Period of Performance.

Grantees are responsible and accountable for reporting accurate information on all required reports: The Progress Reports, the Federal Cash Transaction Report, and the Federal Financial Report.

C. Data Collection and Reporting

All grantees will be required to collect and report data pertaining to activities, processes, and outcomes via the IHS Behavioral Health Portal, within 30 days after the budget period ends for each project year (specific dates will be listed in the NoA Terms and Conditions). The behavioral health online data portal will be open to project staff on a 24 hour/7 day per week basis for the duration of each reporting period. Technical assistance for web-based data entry will be timely and readily available to awardees by assigned IHS staff.

The annual data reports will include compilation of quantitative data (e.g., number served, screenings completed, etc.) and qualitative or narrative (text) data. Reporting elements should be specific to activities/programs, processes, and outcomes, such as

performance measures and other data relevant to evaluation outcomes including intended results (*i.e.*, impact and outcomes).

For program purposes, the IHS will compile and provide aggregate program statistics, including associated community-level health care facility data available in the National Data Warehouse related to suicide risk screenings. For the Behavioral Health Integration program, the IHS may monitor and collect data related to behavioral health integration services and outcomes for all health care facilities associated with the organizations awarded.

D. Federal Sub-Award Reporting System (FSRS)

This award may be subject to the Transparency Act sub-award and executive compensation reporting requirements of 2 CFR part 170.

The Transparency Act requires the OMB to establish a single searchable database, accessible to the public, with information on financial assistance awards made by Federal agencies. The Transparency Act also includes a requirement for recipients of Federal grants to report information about first-tier sub-awards and executive compensation under Federal assistance awards.

The IHS has implemented a Term of Award into all IHS Standard Terms and Conditions, NoAs, and funding announcements regarding the FSRS reporting requirement. This IHS Term of Award is applicable to all IHS grant and cooperative agreements issued on or after October 1, 2010, with a \$25,000 sub-award obligation threshold met for any specific reporting period.

For the full IHS award term implementing this requirement and additional award applicability information, visit the DGM Grants Management website at <https://www.ihs.gov/dgm/policytopics/>.

E. Compliance With Executive Order 13166 Implementation of Services Accessibility Provisions for All Grant Application Packages and Funding Opportunity Announcements

Should you successfully compete for an award, recipients of Federal financial assistance (FFA) from HHS must administer their programs in compliance with Federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex (including gender identity, sexual orientation, and pregnancy). This includes ensuring programs are

accessible to persons with limited English proficiency and persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. Please see <https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html> and <https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html>.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting your legal obligation to take reasonable steps to ensure meaningful access to your programs or activities by limited English proficiency individuals, see <https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html> and <https://www.lep.gov>.

- For information on your specific legal obligations for serving qualified individuals with disabilities, including reasonable modifications and making services accessible to them, see <https://www.hhs.gov/ocr/civilrights/understanding/disability/index.html>.

- HHS funded health and education programs must be administered in an environment free of sexual harassment. See <https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html>.

- For guidance on administering your program in compliance with applicable Federal religious nondiscrimination laws and applicable Federal conscience protection and associated anti-discrimination laws, see <https://www.hhs.gov/conscience/conscience-protections/index.html> and <https://www.hhs.gov/conscience/religious-freedom/index.html>.

F. Federal Awardee Performance and Integrity Information System (FAPIIS)

The IHS is required to review and consider any information about the applicant that is in the FAPIIS at <https://www.fapiis.gov>, before making any award in excess of the simplified acquisition threshold (currently \$250,000) over the period of performance. An applicant may review and comment on any information about itself that a Federal awarding agency previously entered. The IHS will consider any comments by the applicant, in addition to other information in FAPIIS, in making a judgment about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as, described in 45 CFR 75.205.

As required by 45 CFR part 75 Appendix XII, of the Uniform Guidance, NFEs are required to disclose in FAPIIS any information about criminal, civil, and administrative proceedings, and/or affirm that there is no new information to provide. This applies to NFEs that receive Federal awards (currently active grants, cooperative agreements, and procurement contracts) greater than \$10,000,000 for any period of time during the period of performance of an award/project.

Mandatory Disclosure Requirements

As required by 2 CFR part 200 of the Uniform Guidance, and the HHS implementing regulations at 45 CFR part 75, the IHS must require an NFE or an applicant for a Federal award to disclose, in a timely manner, in writing to the IHS or pass-through entity all violations of Federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the Federal award.

All applicants and recipients must disclose in writing, in a timely manner, to the IHS and to the HHS Office of Inspector General of all information related to violations of Federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the Federal award. 45 CFR 75.113.

Disclosures must be sent in writing to: U.S. Department of Health and Human Services, Indian Health Service, Division of Grants Management, ATTN: Paul Gettys, Acting Director, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857 (Include "Mandatory Grant Disclosures" in subject line), Office: (301) 443-5204, Fax: (301) 594-0899, Email: Paul.Gettys@ihs.gov;

AND

U.S. Department of Health and Human Services, Office of Inspector General, ATTN: Mandatory Grant Disclosures, Intake Coordinator, 330 Independence Avenue SW, Cohen Building, Room 5527, Washington, DC 20201, URL: <https://oig.hhs.gov/fraud/report-fraud/> (Include "Mandatory Grant Disclosures" in subject line), Fax: (202) 205-0604 (Include "Mandatory Grant Disclosures" in subject line) or Email: MandatoryGranteeDisclosures@oig.hhs.gov.

Failure to make required disclosures can result in any of the remedies described in 45 CFR 75.371 Remedies for noncompliance, including suspension or debarment (see 2 CFR part 180 and 2 CFR part 376).

VII. Agency Contacts

1. *Questions on the programmatic issues may be directed to:* Steven Whitehorn, Public Health Advisor, Indian Health Service, Division of Behavioral Health, 5600 Fishers Lane, Mail Stop 08N34A, Rockville, MD 20857, Phone: (301) 443-6581, Fax: (301) 594-6213, Email: Steven.Whitehorn@ihs.gov.

2. *Questions on grants management and fiscal matters may be directed to:* Willis Grant, Senior Grants Management Specialist, Indian Health Service, Division of Grants Management, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, Phone: (301) 443-5204, Fax: (301) 594-0899, Email: Willis.Grant@ihs.gov.

3. *Questions on systems matters may be directed to:* Paul Gettys, Acting Director, Indian Health Service, Division of Grants Management, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, Phone: (301) 443-2114; or the DGM main line (301) 443-5204, Fax: (301) 594-0899, Email: Paul.Gettys@ihs.gov.

VIII. Other Information

The Public Health Service strongly encourages all grant, cooperative agreement, and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of the facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the HHS mission to protect and advance the physical and mental health of the American people.

Elizabeth A. Fowler,

Acting Director, Indian Health Service.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Domestic Violence Prevention Program

Announcement Type: New.

Funding Announcement Number: HHS-2022-IHS-DVP-0001.

Assistance Listing (Catalog of Federal Domestic Assistance or CFDA) Number: 93.653.

Key Dates

Application Deadline Date: February 2, 2022.

Earliest Anticipated Start Date: March 21, 2022.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) is accepting applications for grants for the Domestic Violence Prevention (DVP) program, formerly known as the Domestic Violence Prevention Initiative (DVPI). This program was first established by the Omnibus Appropriations Act of 2009, Public Law 111-8, 123 Stat. 524, 735, and continued in the annual appropriations acts since that time. It is authorized under the Snyder Act, 25 U.S.C. 13; the Transfer Act, 42 U.S.C. 2001(a); and the Indian Health Care Improvement Act, 25 U.S.C. 1665a, 1665m. This program is described in the Assistance Listings located at <https://sam.gov/content/home> (formerly known as Catalog of Federal Domestic Assistance) under 93.653.

Background

The Division of Behavioral Health (DBH) serves as the primary source of national advocacy, policy development, management, and administration of behavioral health, alcohol and substance abuse, and family violence prevention programs. Domestic and sexual violence including child maltreatment are a public health concern among the American Indian/Alaska Native (AI/AN) population. American Indians and Alaska Natives experience high rates of sexual violence according to a 2016 publication from the Department of Justice. The National Crime Information Center reports that, in 2016, there were 5,712 reports of missing AI/AN women and girls. In addition, data published January 1, 2020, from the US National Institute of Justice's missing persons' database, National Missing and Unidentified Persons System (NamUs), logged 435 missing persons cases with 37 percent female and 63 percent male. The Centers for Disease Control and Prevention has reported that murder is the third-leading cause of death among AI/AN women and that rates of violence on reservations can be up to ten times higher than the national average.

In previous funding cycles, grant awards focused on community-based domestic violence prevention were funded under Purpose Area 1 of the DVPI. This activity is now announced as a distinct funding opportunity. This grant program will address issues related to the high rates of domestic and

sexual violence among AI/AN people. The DVP program promotes the development of evidence-based and practice-based models that represent culturally appropriate prevention and treatment approaches to domestic and sexual violence from a community-driven context. This program focuses on community-based prevention efforts that address domestic and sexual violence and are aligned with the national DVP goals, <https://www.ihs.gov/dvpi/aboutdvp/>.

Purpose

The purpose of this IHS grant is to support the development and/or expansion of a DVP program by incorporating prevention efforts addressing social, spiritual, physical, and emotional well-being of victims through the integration of culturally appropriate practices and trauma-informed services for Tribes, Tribal organizations, and Urban Indian organizations (UIO) serving the AI/AN population. This IHS program aims to promote prevention efforts that address domestic and sexual violence, including sexual exploitation/human trafficking, Missing and Murdered AI/AN people, and child maltreatment. To create an effective DVP program, cross-system collaboration with other community sectors to address violence is key—especially with law enforcement, emergency departments, social services, legal services, education, domestic violence coalitions, health care providers, behavioral health, shelters, and advocacy groups. An effective program includes raising awareness of and mitigating the negative health effects and social burden of domestic violence, sexual abuse and assault, child maltreatment (physical, sexual, and psychological/emotional abuse, neglect), sexual exploitation/human trafficking, and Missing and Murdered AI/AN people; providing victims advocacy services; integrating evidence-based practice or traditional and/or faith-based services; collecting and communicating data about prevalence, incidence, and risk factors; and establishing a plan to ensure the sustainability of the program beyond the life of this grant.

II. Award Information

Funding Instrument—Grant

Estimated Funds Available

The total funding identified for fiscal year (FY) 2022 is approximately \$7,890,000. Individual award amounts for the first budget year are anticipated to be between \$100,000 and \$200,000. The funding available for competing and subsequent continuation awards

issued under this announcement is subject to the availability of appropriations and budgetary priorities of the Agency. The IHS is under no obligation to make awards that are selected for funding under this announcement.

Anticipated Number of Awards

Approximately 39 awards will be issued under this program announcement. At least one award will be made in each IHS Area from which applications are received, and a set aside of up to five awards will be made to eligible Urban Indian organizations.

Period of Performance

The period of performance is for 5 years.

III. Eligibility Information

1. Eligibility

To be eligible for this new FY 2022 funding opportunity, applicants must be one of the following as defined by 25 U.S.C. 1603:

- A federally recognized Indian Tribe as defined by 25 U.S.C. 1603(14). The term “Indian Tribe” means any Indian Tribe, band, nation, or other organized group or community, including any Alaska Native village or group, or regional or village corporation as defined in or established pursuant to the Alaska Native Claims Settlement Act (85 Stat. 688) [43 U.S.C. 1601 *et seq.*], which is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians.

- A Tribal organization as defined by 25 U.S.C. 1603(26). The term “Tribal organization” has the meaning given the term in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304(l)): “Tribal organization” means the recognized governing body of any Indian Tribe; any legally established organization of Indians which is controlled, sanctioned, or chartered by such governing body or which is democratically elected by the adult members of the Indian community to be served by such organization and which includes the maximum participation of Indians in all phases of its activities: Provided that, in any case where a contract is let or grant made to an organization to perform services benefiting more than one Indian Tribe, the approval of each such Indian Tribe shall be a prerequisite to the letting or making of such contract or grant. Applicant shall submit letters of support and/or Tribal Resolutions from the Tribes to be served.

- An Urban Indian organization as defined by 25 U.S.C. 1603(29). The term “Urban Indian organization” means a nonprofit corporate body situated in an urban center, governed by an urban Indian controlled board of directors, and providing for the maximum participation of all interested Indian groups and individuals, which body is capable of legally cooperating with other public and private entities for the purpose of performing the activities described in 25 U.S.C. 1653(a). Applicants must provide proof of nonprofit status with the application, e.g., 501(c)(3).

The program office will notify any applicants deemed ineligible.

Note: Please refer to Section IV.2 (Application and Submission Information/ Subsection 2, Content and Form of Application Submission) for additional proof of applicant status documents required, such as Tribal Resolutions, proof of nonprofit status, etc.

2. Cost Sharing or Matching

The IHS does not require matching funds or cost sharing for grants or cooperative agreements.

3. Other Requirements

Applications with budget requests that exceed the highest dollar amount outlined under Section II Award Information, Estimated Funds Available, or exceed the period of performance outlined under Section II Award Information, Period of Performance, are considered not responsive and will not be reviewed. The Division of Grants Management (DGM) will notify the applicant.

Additional Required Documentation Tribal Resolution

The DGM must receive an official, signed Tribal Resolution prior to issuing a Notice of Award (NoA) to any applicant selected for funding. An Indian Tribe or Tribal organization that is proposing a project affecting another Indian Tribe must include resolutions from all affected Tribes to be served. However, if an official, signed Tribal Resolution cannot be submitted with the application prior to the application deadline date, a draft Tribal Resolution must be submitted with the application by the deadline date in order for the application to be considered complete and eligible for review. The draft Tribal Resolution is not in lieu of the required signed resolution but is acceptable until a signed resolution is received. If an application without a signed Tribal Resolution is selected for funding, the applicant will be contacted by the

Grants Management Specialist (GMS) listed in this funding announcement and given 90 days to submit an official, signed Tribal Resolution to the GMS. If the signed Tribal Resolution is not received within 90 days, the award will be forfeited.

Tribes organized with a governing structure other than a Tribal council may submit an equivalent document commensurate with their governing organization.

Proof of Nonprofit Status

Organizations claiming nonprofit status must submit a current copy of the 501(c)(3) Certificate with the application.

IV. Application and Submission Information

1. Obtaining Application Materials

The application package and detailed instructions for this announcement are available at <https://www.Grants.gov>.

Please direct questions regarding the application process to Mr. Paul Gettys at (301) 443-2114 or (301) 443-5204.

2. Content and Form Application Submission

Mandatory documents for all applicants include:

- Abstract (one page) summarizing the project.
- Application forms:
 1. SF-424, Application for Federal Assistance.
 2. SF-424A, Budget Information—Non-Construction Programs.
 3. SF-424B, Assurances—Non-Construction Programs.
- Project Narrative (not to exceed 15 pages). See Section IV.2.A, Project Narrative, for additional instructions.
 1. Background information on the organization.
 2. Proposed scope of work, objectives, and activities that provide a description of what the applicant plans to accomplish.
- Budget Justification and Narrative (not to exceed four pages). See Section IV.2.B, Budget Narrative for instructions.
- Work plan with a timeline, limit one page.
- Tribal Resolution(s) or Tribal Letter of Support (only required for Tribes and Tribal organizations).
- Letters of Commitment:
 1. For all applicants: From local organizational partners;
 2. For all applicants: From community partners;
 3. For Tribal organizations: From the board of directors (or relevant equivalent);

4. For Urban Indian organizations: From the board of directors (or relevant equivalent).

- 501(c)(3) Certificate where applicable.
- Biographical sketches for all Key Personnel.
- Contractor/Consultant resumes or qualifications and scope of work.
- Disclosure of Lobbying Activities (SF–LLL), if applicant conducts reportable lobbying.
- Certification Regarding Lobbying (GG–Lobbying Form).
- Copy of current Negotiated Indirect Cost rate (IDC) agreement (required in order to receive IDC).
- Organizational Chart (optional).
- Documentation of current Office of Management and Budget (OMB) Financial Audit.

Acceptable forms of documentation include:

1. Email confirmation from Federal Audit Clearinghouse (FAC) that audits were submitted; or
 2. Face sheets from audit reports.
- Applicants can find these on the FAC website at <https://harvester.census.gov/facdissem/Main.aspx>.

Public Policy Requirements

All Federal public policies apply to IHS grants and cooperative agreements. Pursuant to 45 CFR 80.3(d), an individual shall not be deemed subjected to discrimination by reason of their exclusion from benefits limited by Federal law to individuals eligible for benefits and services from the IHS. See <https://www.hhs.gov/grants/grants/grants-policies-regulations/index.html>.

Requirements for Project and Budget Narratives

A. Project Narrative

This narrative should be a separate document that is no more than 15 pages and must: (1) Have consecutively numbered pages; (2) use black font 12 points or larger; (3) be single-spaced; and (4) be formatted to fit standard letter paper (8½ x 11 inches).

Be sure to succinctly answer all questions listed under the evaluation criteria (refer to Section V.1, Evaluation Criteria) and place all responses and required information in the correct section noted below or they will not be considered or scored. If the narrative exceeds the page limit, the application will be considered not responsive and not be reviewed. The 15-page limit for the narrative does not include the work plan with timeline, standard forms, Tribal Resolutions, budget, budget justifications, narratives, and/or other items or requested attachments. There are four parts to the Project Narrative:

Part 1—Statement of Need
Part 2—Program Plan
Part 3—Organizational Capacity
Part 4—Program Evaluation

Part 1: Statement of Need (Limit—2 Pages)

The project narrative must include the statement of need that addresses the nature and scope of the problem (e.g., domestic and sexual violence, child maltreatment, and sexual exploitation/human trafficking). For more information, refer to Section V.1.A, Evaluation Criteria—Statement of Need details.

Part 2: Program Plan (Limit—9 Pages)

Describe the proposed program plan, an outline of goal(s), proposed implementation of the required six objectives and activities. Refer to Section V.1.B, Evaluation Criteria—Program Plan for details.

Part 3: Organizational Capacity (Limit—2 Pages)

Describe the applicant's management capability and experience in administering grants. Refer to Section V.1.C, Evaluation Criteria—Organizational Capacity for more information.

Part 4: Program Evaluation (Limit—2 Pages)

Describe how you plan to collect data for the proposed project activities and identify what type of evaluation method will be used. Applicants are encouraged to partner with their Tribal Epidemiology Center (TEC) or Urban Epidemiology Center (for urban applicant) and should describe their plan for coordination and collaboration with the TEC. Refer to Section V.1.D, Evaluation Criteria—Program Evaluation for more information.

B. Budget Narrative (Limit—4 Pages)

Provide a budget narrative that explains the amounts requested for each line item of the budget from the SF–424A (Budget Information for Non-Construction Programs). The budget narrative can include a more detailed spreadsheet than is provided by the SF–424A. The budget narrative should specifically describe how each item will support the achievement of proposed objectives. Be very careful about showing how each item in the “Other” category is justified. For subsequent budget years (see Multi-Year Project Requirements in Section V.1, Application Review Information, Evaluation Criteria), the narrative should highlight the changes from the first year or clearly indicate that there

are no substantive budget changes during the period of performance. Do NOT use the budget narrative to expand the project narrative.

Applicants are invited to propose a project with an annual budget within the range stated under Section II, Award Information, Estimated Funds Available. Applications with a budget higher than the upper limit will be deemed ineligible.

3. Submission Dates and Times

Applications must be submitted through *Grants.gov* by 11:59 p.m. Eastern Time on the Application Deadline Date. Any application received after the application deadline will not be accepted for review. *Grants.gov* will notify the applicant via email if the application is rejected.

If technical challenges arise and assistance is required with the application process, contact *Grants.gov* Customer Support (see contact information at <https://www.grants.gov>). If problems persist, contact Mr. Paul Gettys (Paul.Gettys@ihs.gov), Acting Director, DGM, by telephone at (301) 443–2114 or (301) 443–5204. Please be sure to contact Mr. Gettys at least ten days prior to the application deadline. Please do not contact the DGM until you have received a *Grants.gov* tracking number. In the event you are not able to obtain a tracking number, call the DGM as soon as possible.

The IHS will not acknowledge receipt of applications.

4. Intergovernmental Review

Executive Order 12372 requiring intergovernmental review is not applicable to this program.

5. Funding Restrictions

- Pre-award costs are allowable up to 90 days before the start date of the award provided the costs are otherwise allowable if awarded. Pre-award costs are incurred at the risk of the applicant.
- The available funds are inclusive of direct and indirect costs.
- Only one grant will be awarded per applicant.

6. Electronic Submission Requirements

All applications must be submitted via *Grants.gov*. Please use the <https://www.Grants.gov> website to submit an application. Find the application by selecting the “Search Grants” link on the homepage. Follow the instructions for submitting an application under the Package tab. No other method of application submission is acceptable.

If the applicant cannot submit an application through *Grants.gov*, a waiver must be requested. Prior

approval must be requested and obtained from Mr. Paul Gettys, Acting Director, DGM. A written waiver request must be sent to GrantsPolicy@ihs.gov with a copy to Paul.Gettys@ihs.gov. The waiver request must: (1) Be documented in writing (emails are acceptable) before submitting an application by some other method, and (2) include clear justification for the need to deviate from the required application submission process.

Once the waiver request has been approved, the applicant will receive a confirmation of approval email containing submission instructions. A copy of the written approval must be included with the application that is submitted to the DGM. Applications that are submitted without a copy of the signed waiver from the Acting Director of the DGM will not be reviewed. The Grants Management Officer of the DGM will notify the applicant via email of this decision. Applications submitted under waiver must be received by the DGM no later than 5:00 p.m. Eastern Time on the Application Deadline Date. Late applications will not be accepted for processing. Applicants that do not register for both the System for Award Management (SAM) and *Grants.gov* and/or fail to request timely assistance with technical issues will not be considered for a waiver to submit an application via alternative method.

Please be aware of the following:

- Please search for the application package in <https://www.Grants.gov> by entering the Assistance Listing (CFDA) number or the Funding Opportunity Number. Both numbers are located in the header of this announcement.
- If you experience technical challenges while submitting your application, please contact *Grants.gov* Customer Support (see contact information at <https://www.Grants.gov>).
- Upon contacting *Grants.gov*, obtain a tracking number as proof of contact. The tracking number is helpful if there are technical issues that cannot be resolved and a waiver from the agency must be obtained.
- Applicants are strongly encouraged not to wait until the deadline date to begin the application process through *Grants.gov* as the registration process for SAM and *Grants.gov* could take up to 20 working days.
- Please follow the instructions on *Grants.gov* to include additional documentation that may be requested by this funding announcement.
- Applicants must comply with any page limits described in this funding announcement.
- After submitting the application, the applicant will receive an automatic

acknowledgment from *Grants.gov* that contains a *Grants.gov* tracking number. The IHS will not notify the applicant that the application has been received.

Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS)

Applicants and grantee organizations are required to obtain a DUNS number and maintain an active registration in the SAM database. The DUNS number is a unique 9-digit identification number provided by D&B that uniquely identifies each entity. The DUNS number is site specific; therefore, each distinct performance site may be assigned a DUNS number. Obtaining a DUNS number is easy, and there is no charge. To obtain a DUNS number, please access the request service through <https://fedgov.dnb.com/webform>, or call (866) 705-5711.

The Federal Funding Accountability and Transparency Act of 2006, as amended (“Transparency Act”), requires all HHS recipients to report information on sub-awards. Accordingly, all IHS grantees must notify potential first-tier sub-recipients that no entity may receive a first-tier sub-award unless the entity has provided its DUNS number to the prime grantee organization. This requirement ensures the use of a universal identifier to enhance the quality of information available to the public pursuant to the Transparency Act.

System for Award Management (SAM)

Organizations that are not registered with SAM must have a DUNS number first, then access the SAM online registration through the SAM home page at <https://sam.gov> (U.S. organizations will also need to provide an Employer Identification Number from the Internal Revenue Service that may take an additional 2–5 weeks to become active). Please see *SAM.gov* for details on the registration process and timeline. Registration with the SAM is free of charge, but can take several weeks to process. Applicants may register online at <https://sam.gov>.

Additional information on implementing the Transparency Act, including the specific requirements for DUNS and SAM, are available on the DGM Grants Management, Policy Topics web page: <https://www.ihs.gov/dgm/policytopics/>.

V. Application Review Information

Possible points assigned to each section are noted in parentheses. The project narrative and budget narrative should include only the first year of activities; information for multi-year projects should be included as a

separate document. See “Multi-year Project Requirements” at the end of this section for more information. The narrative section should be written in a manner that is clear to outside reviewers unfamiliar with prior related activities of the applicant. It should be well organized, succinct, and contain all information necessary for reviewers to fully understand the project. Attachments requested in the criteria do not count toward the page limit for the project narrative. Points will be assigned to each evaluation criteria adding up to a total of 100 possible points.

1. Evaluation Criteria

A. Statement of Need (20 points)

The project narrative must include the statement of need that describes the background knowledge and context on the issue of domestic and sexual violence, child maltreatment, and sexual exploitation/human trafficking in the community. The applicant should use data to provide evidence that the problem exists, describe the size of the problem, and the effects of the problem on the population of focus and the community at large. The data documentation of need may come from a variety of qualitative and quantitative sources. Examples of data sources to be included are local epidemiologic data from Trends in Indian Health and State data; national data from My Tribal Area by the U.S Census Bureau; Centers for Disease Control and Prevention reports; Department of Justice; and Substance Abuse and Mental Health Services Administration, National Survey on Drug Use and Health.

1. Describe your plan to meet the needs and conditions of your priority population.

2. Describe your plan to support the development of and/or expansion of a DVP program.

3. Provide your demographics of the community (e.g., race, ethnicity, Federally-recognized Tribe, language, age, socioeconomic status, and other relevant factors, such as literacy.)

4. Provide your incidence and prevalence rates about domestic and sexual violence and child maltreatment in your community or region.

5. Describe your plan to address existing service gaps, barriers, and other systemic challenges related to the need for program planning and capacity building.

B. Program Plan (35 Points)

Using the six objectives, you should describe the purpose of the proposed program plan in the narrative, a work plan, and timeline that clearly outlines the goal(s), objectives, and activities.

Objective 1: Establish a community coordinated response (CCR) system to address violence.

1. Describe your plan to foster cross-system collaboration to establish a community CCR system.

2. Describe your plan in using a CCR to establish a cross-system collaboration and shared resources with shelters, law enforcement, the legal system, health care facilities, child protective services, transitional housing, food banks, social services, behavioral health, local coalitions, substance abuse treatment program, and religious institutions.

3. Describe your plan to collaborate with local, state and Federal agencies to improve response time for domestic and sexual violence, child maltreatment, and suspected sexual exploitation/human trafficking.

4. Describe your plan to develop policies, protocols, and procedures that improve local interagency coordination leading to more uniform responses to domestic and sexual violence, child maltreatment, and suspected sexual exploitation/human trafficking.

Objective 2: Increase educational awareness about the negative health effects and social burden on domestic and sexual violence, child maltreatment, and sexual exploitation/human trafficking in community settings and health.

1. Recommended topics for training in community settings:

- a. Domestic Violence 101.
- b. Trauma Informed Care.
- c. Healthy Relationship Behaviors and Warning Signs of Abuse.
- d. Coping and problem solving skills.
- e. Parental use of reasoning to resolve conflict.
- f. Empowerment.
- g. Consent, Reproductive Coercion.
- h. Child Maltreatment.
- i. SOAR for Native Communities.
- j. Sexual exploitation/human trafficking in Indian Country.
- k. Educational Awareness addressing Missing and Murdered AI/AN people, including community-based trainings that highlight at-risk groups and protection and prevention activities with a focus on ambiguous and traumatic loss.

2. Recommended topics for training in health care and interagency settings:

- a. Domestic Violence 101.
 - b. Trauma Informed Care.
 - c. SOAR for Native Communities.
 - d. Sexual Exploitation/Human Trafficking.
 - e. Child Maltreatment.
3. Recommended types of public health messages:
- a. Prevention Awareness Events.
 - b. Educational Brochures.

c. Radio/TV/billboards announcements, advertisement, and social media.

Objective 3: Develop or expand victim advocacy services.

1. Describe your plans for how victim advocacy services will be developed or expanded for victims and their families.

a. Types of services to be included in the work plan.

(1) Describe your plan about crisis intervention that includes conducting culturally-sensitive screenings and trauma informed interviews.

(2) Describe your plan to address family support throughout resolution process of crisis.

(3) Describe your plan for promoting victim and family safety, which may include safety planning, advocating for Protection Orders, and other assistance during legal investigation and prosecution phases.

(4) Describe your plan for case management services.

(5) Describe your plan to provide emotional and health connectedness support using culture and resilience.

(6) Describe your plan to develop a peer-to-peer support system for victims and their families.

(7) Describe your plan for referrals that includes medical, social services, counseling, housing, employment and cultural services.

(8) Describe project plan to identify and disseminate relevant local and responsive resources and information to be shared with victims and/or local partners seeking support services that require immediate attention (e.g., care coordination services that increase access to timely forensic examination services, including follow-up visits, and access to HIV, STD, pregnancy prophylaxis, and aftercare services).

Objective 4: Integrate at least one program/intervention that is an evidence-based practice, or known as a promising practice, to facilitate the social and emotional well-being of victims and their families.

1. Describe your chosen practice that is appropriate to achieve the desired outcomes.

2. Describe your plan to modify/adapt your proposed practice to meet the goal(s) and objectives of the project and why changes will improve the outcomes.

3. Describe your training needs or plans to successfully implement the proposed practice.

Objective 5: Integrate community-based culturally appropriate practices and/or faith-based services to facilitate the social and emotional well-being of victims and their children.

1. Describe your plan on integrating culturally appropriate practices and/or

faith-based services to facilitate the social and emotional well-being of victims and their children.

Objective 6: Develop a formal plan to ensure the sustainability of these objectives and activities beyond the life of this grant.

1. Describe your plan for sustainability of these objectives and activities beyond the life of the grant.

C. Organizational Capacity (15 Points)

1. Describe your management's capability and experience in administering grants and projects and identify your department/division that will administer this project.

2. Describe your experience and capacity to provide culturally relevant services to the community.

3. Describe the resources available for your proposed project (e.g., facilities, equipment, information technology systems, and financial management systems).

4. Describe your organizational experience in implementing a cross-system collaboration in combatting domestic and sexual violence, child maltreatment, and sexual exploitation/human trafficking.

5. Describe your plan to include an advisory body, including membership, roles and functions, and frequency of meetings. This group may function as the cross-system collaboration work group.

6. Describe how your project continuity will be maintained if/when there is a change in the operational environment (e.g., staff turnover, change in project leadership, change in elected officials) to ensure project stability over the life of the grant.

7. Describe the staff positions showing the role and level of effort (percent) committed. In addition to any direct service staff, a full-time project lead/project coordinator is recommended to serve as the primary point of contact, manage implementation of project objectives, and establish local programmatic activities and policy focused on partnership and sustainability. For individuals in key positions that are identified and currently on staff, include a biographical sketch. Each biographical sketch should not exceed one page and should be submitted as Other Attachments in *Grants.gov*. Do not include any of the following in the biographical sketch:

- Personally Identifiable Information (i.e., SSN, home address, etc.);
- Resumes; or
- Curriculum Vitae.

D. Program Evaluation (20 Points)

Program Evaluation will require grantee submission of annual progress reports through a web-based Behavioral Health Reporting portal system. Applicants are expected to collect data within their communities on prevalence rates of domestic violence, sexual assault, sexual exploitation/human trafficking, and child maltreatment. Progress reports will include the compilation of quantitative data (e.g., number served; screenings completed, etc.) and qualitative or narrative (text) data. Reporting elements may include data from local community-based and evidence-based programs pertaining to activities, processes, and outcomes, such as performance measures and other data relevant to evaluation outcomes, including intended results (i.e., impact and outcomes).

In addition to the annual progress reports, the IHS will compile and provide aggregate program statistics, including associated community-level Government Performance Results Act (GPRA) health care facility data available in the National Data Warehouse. Each applicant should prioritize screening efforts as an effective tool in identifying women at risk of domestic violence so that these individuals can be referred for appropriate services. Therefore, the IHS will monitor and collect the proportion of AI/AN women ages 14–46 who have been screened for domestic violence/intimate partner violence for all health care facilities associated with the I/T/U awarded. For additional information regarding IHS GPRA, see <https://www.ihs.gov/crs/gprareporting/>. Comprehensive information about CRS software and logic is at <https://www.ihs.gov/crs/>.

1. Describe your plan on gathering data, including data related to evidence-based programs and interventions proposed, how variables will be measured, what method will be used, and how the data will be used for quality improvement and sustainability of program.

2. Describe your plan on collaborating with your regional TEC to complete evaluation efforts.

3. Describe how you will prioritize screening efforts as a tool in identifying AI/AN women ages 14–46 who are at risk for intimate partner violence/domestic violence (IPV/DV) so that these individuals can be referred for appropriate services and data can be collected for GPRA measures related to IPV/DV.

4. Describe how you will prioritize screening efforts as a tool in identifying

AI/AN people who are at risk for sexual exploitation/human trafficking so that these individuals can be referred for appropriate services and how data will be collected.

5. Describe your plan to establish necessary data-sharing agreements that will be used in support of these activities.

E. Budget and Budget Narrative (10 Points)

The budget must match the program and work plan described in the program narrative for the first budget year expenses only.

1. Create a budget narrative and a line item budget that are aligned with your goal(s), objectives, and activities listed in the program and work plan described in the project narrative for the first year.

2. Include travel funds for your project director and coordinator to attend an annual grantee meeting.

Multi-Year Project Requirements

Applications must include a brief project narrative and budget (one additional page per year) addressing the developmental plans for each additional year of the project. This attachment will not count as part of the project narrative or the budget narrative.

Additional documents can be uploaded as Other Attachments in *Grants.gov*. These can include:

- Work plan, timeline, and logic model for the program plan.
- Position descriptions for key staff.
- Consultant or contractor proposed scope of work and letter of commitment (if applicable).
- Current Indirect Cost Rate Agreement.
- Organizational chart.
- Abstract.
- Map of area identifying project location(s).

2. Review and Selection

Each application will be prescreened for eligibility and completeness as outlined in the funding announcement. Applications that meet the eligibility criteria shall be reviewed for merit by the Objective Review Committee (ORC) based on evaluation criteria. Incomplete applications and applications that are not responsive to the administrative thresholds (budget limit, project period limit) will not be referred to the ORC and will not be funded. The applicant will be notified of this determination.

Applicants must address all program requirements and provide all required documentation.

3. Notifications of Disposition

All applicants will receive an Executive Summary Statement from the

IHS Division of Behavioral Health within 30 days of the conclusion of the ORC outlining the strengths and weaknesses of their application. The summary statement will be sent to the Authorizing Official identified on the face page (SF–424) of the application.

A. Award Notices for Funded Applications

The NoA is the authorizing document for which funds are dispersed to the approved entities and reflects the amount of Federal funds awarded, the purpose of the award, the terms and conditions of the award, the effective date of the award, and the budget/project period. Each entity approved for funding must have a user account in GrantSolutions in order to retrieve the NoA. Please see the Agency Contacts list in Section VII for the systems contact information.

B. Approved but Unfunded Applications

Approved applications not funded due to lack of available funds will be held for 1 year. If funding becomes available during the course of the year, the application may be reconsidered.

Note: Any correspondence other than the official NoA executed by an IHS grants management official announcing to the project director that an award has been made to their organization is not an authorization to implement their program on behalf of the IHS.

VI. Award Administration Information**1. Administrative Requirements**

Awards issued under this announcement are subject to, and are administered in accordance with, the following regulations and policies:

A. The criteria as outlined in this program announcement.

B. Administrative Regulations for Grants:

- Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards currently in effect or implemented during the period of award, other Department regulations and policies in effect at the time of award, and applicable statutory provisions. At the time of publication, this includes 45 CFR part 75, at <https://www.govinfo.gov/content/pkg/CFR-2020-title45-vol1/pdf/CFR-2020-title45-vol1-part75.pdf>.

• Please review all HHS regulatory provisions for Termination at 45 CFR 75.372, at https://www.ecfr.gov/cgi-bin/retrieveECFR?gp&SID=2970eec67399fab1413ede53d7895d99&mc=true&n=pt45.1.75&r=PART&ty=HTML&se45.1.75_1372#se45.1.75_1372.

C. Grants Policy:

• HHS Grants Policy Statement, Revised January 2007, at <http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf>.

D. Cost Principles:

- Uniform Administrative

Requirements for HHS Awards, “Cost Principles,” located at 45 CFR part 75 subpart E.

E. Audit Requirements:

- Uniform Administrative

Requirements for HHS Awards, “Audit Requirements,” located at 45 CFR part 75 subpart F.

F. As of August 13, 2020, 2 CFR 200 was updated to include a prohibition on certain telecommunications and video surveillance services or equipment. This prohibition is described in 2 CFR 200.216. This will also be described in the terms and conditions of every IHS grant and cooperative agreement awarded on or after August 13, 2020.

2. Indirect Costs

This section applies to all recipients that request reimbursement of indirect costs (IDC) in their application budget. In accordance with HHS Grants Policy Statement, Part II–27, IHS requires applicants to obtain a current IDC rate agreement and submit it to the DGM prior to the DGM issuing an award. The rate agreement must be prepared in accordance with the applicable cost principles and guidance as provided by the cognizant agency or office. A current rate covers the applicable grant activities under the current award’s budget period. If the current rate agreement is not on file with the DGM at the time of award, the IDC portion of the budget will be restricted. The restrictions remain in place until the current rate agreement is provided to the DGM.

Per 45 CFR 75.414(f) Indirect (F&A) costs, “any non-Federal entity (NFE) [i.e., applicant] that has never received a negotiated indirect cost rate, . . . may elect to charge a de minimis rate of 10 percent of modified total direct costs which may be used indefinitely. As described in Section 75.403, costs must be consistently charged as either indirect or direct costs, but may not be double charged or inconsistently charged as both. If chosen, this methodology once elected must be used consistently for all Federal awards until such time as the NFE chooses to negotiate for a rate, which the NFE may apply to do at any time.”

Electing to charge a de minimis rate of 10 percent only applies to applicants that have never received an approved negotiated indirect cost rate from HHS

or another cognizant federal agency.

Applicants awaiting approval of their indirect cost proposal may request the 10 percent de minimis rate. When the applicant chooses this method, costs included in the indirect cost pool must not be charged as direct costs to the grant.

Available funds are inclusive of direct and appropriate indirect costs.

Approved indirect funds are awarded as part of the award amount, and no additional funds will be provided.

Generally, IDC rates for IHS grantees are negotiated with the Division of Cost Allocation at <https://rates.psc.gov/> or the Department of the Interior (Interior Business Center) at <https://ibc.doi.gov/ICS/tribal>. For questions regarding the indirect cost policy, please call the Grants Management Specialist listed under “Agency Contacts” or the main DGM office at (301) 443–5204.

3. Reporting Requirements

The grantee must submit required reports consistent with the applicable deadlines. Failure to submit required reports within the time allowed may result in suspension or termination of an active grant, withholding of additional awards for the project, or other enforcement actions such as withholding of payments or converting to the reimbursement method of payment. Continued failure to submit required reports may result in the imposition of special award provisions and/or the non-funding or non-award of other eligible projects or activities. This requirement applies whether the delinquency is attributable to the failure of the awardee organization or the individual responsible for preparation of the reports. Per DGM policy, all reports must be submitted electronically by attaching them as a “Grant Note” in GrantSolutions. Personnel responsible for submitting reports will be required to obtain a login and password for GrantSolutions. Please see the Agency Contacts list in Section VII for the systems contact information. The reporting requirements for this program are noted below.

A. Progress Reports

Program progress reports are required annually. The progress reports are due within 30 days after the reporting period ends (specific dates will be listed in the NoA Terms and Conditions). Progress reports are required to be submitted via the IHS behavioral health online data portal and GrantSolutions. These reports must include a brief comparison of actual accomplishments to the goals established for the period, a summary of progress to date or, if applicable,

provide sound justification for the lack of progress, in addition to other information requested by the Division of Behavioral Health. A final report must be submitted within 90 days of expiration of the period of performance.

B. Financial Reports

Federal Cash Transaction Reports are due 30 days after the close of every calendar quarter to the Payment Management Services at <https://pms.psc.gov>. Failure to submit timely reports may result in adverse award actions blocking access to funds.

Federal Financial Reports are due 30 days after the end of each budget period, and a final report is due 90 days after the end of the Period of Performance.

Grantees are responsible and accountable for reporting accurate information on all required reports: the Progress Reports, the Federal Cash Transaction Report, and the Federal Financial Report.

C. Data Collection and Reporting

Program Evaluation will require grantee submission of annual progress reports through a web-based Behavioral Health Reporting portal system. Applicants are expected to collect data within their communities on prevalence rates on domestic violence, sexual assault, child maltreatment, and evidence of human trafficking and/or Missing and Murdered AI/AN people. Progress reports will include the compilation of quantitative data (e.g., number served, screenings completed, etc.) and qualitative or narrative (text) data. Reporting elements may include data from local community-based and evidence-based programs pertaining to activities, processes, and outcomes such as performance measures and other data relevant to evaluation outcomes including intended results (i.e., impact and outcomes).

In addition to the annual progress reports, the IHS will compile and provide aggregate program statistics, including associated community-level GPRA health care facility data available in the National Data Warehouse. Each applicant should prioritize screening efforts as an effective tool in identifying women at risk of domestic violence so that these individuals can be referred for appropriate services. Therefore, the IHS will monitor and collect the proportion of AI/AN women ages 14–46 who have been screened for domestic violence/intimate partner violence for all health care facilities associated with the I/T/U awarded. For additional information regarding the IHS GPRA, see <https://www.ihs.gov/crs/gprareporting/>. Comprehensive information about CRS

software and logic is at <https://www.ihs.gov/crs/>.

D. Federal Sub-Award Reporting System (FSRS)

This award may be subject to the Transparency Act sub-award and executive compensation reporting requirements of 2 CFR part 170.

The Transparency Act requires the OMB to establish a single searchable database, accessible to the public, with information on financial assistance awards made by Federal agencies. The Transparency Act also includes a requirement for recipients of Federal grants to report information about first-tier sub-awards and executive compensation under Federal assistance awards.

The IHS has implemented a Term of Award into all IHS Standard Terms and Conditions, NoAs, and funding announcements regarding the FSRS reporting requirement. This IHS Term of Award is applicable to all the IHS grant and cooperative agreements issued on or after October 1, 2010, with a \$25,000 sub-award obligation threshold met for any specific reporting period.

For the full IHS award term implementing this requirement and additional award applicability information, visit the DGM Grants Management website at <https://www.ihs.gov/dgm/policytopics/>.

E. Compliance With Executive Order 13166 Implementation of Services Accessibility Provisions for All Grant Application Packages and Funding Opportunity Announcements

Should you successfully compete for an award, recipients of Federal financial assistance (FFA) from HHS must administer their programs in compliance with Federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex (including gender identity, sexual orientation, and pregnancy). This includes ensuring programs are accessible to persons with limited English proficiency and persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. Please see <https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html> and <https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html>.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting your legal

obligation to take reasonable steps to ensure meaningful access to your programs or activities by limited English proficiency individual, see <https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html> and <https://www.lep.gov>.

- For information on your specific legal obligations for serving qualified individuals with disabilities, including reasonable modifications and making services accessible to them, see <https://www.hhs.gov/ocr/civilrights/understanding/disability/index.html>.

- HHS funded health and education programs must be administered in an environment free of sexual harassment. See <https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html>.

- For guidance on administering your program in compliance with applicable Federal religious nondiscrimination laws and applicable Federal conscience protection and associated anti-discrimination laws, see <https://www.hhs.gov/conscience/conscience-protections/index.html> and <https://www.hhs.gov/conscience/religious-freedom/index.html>.

F. Federal Awardee Performance and Integrity Information System (FAPIIS)

The IHS is required to review and consider any information about the applicant that is in the FAPIIS at <https://www.fapiis.gov>, before making any award in excess of the simplified acquisition threshold (currently \$250,000) over the period of performance. An applicant may review and comment on any information about itself that a Federal awarding agency previously entered. The IHS will consider any comments by the applicant, in addition to other information in FAPIIS in making a judgment about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 45 CFR 75.205.

As required by 45 CFR part 75 Appendix XII of the Uniform Guidance, NFEs are required to disclose in FAPIIS any information about criminal, civil, and administrative proceedings, and/or affirm that there is no new information to provide. This applies to NFEs that receive Federal awards (currently active grants, cooperative agreements, and procurement contracts) greater than \$10,000,000 for any period of time during the period of performance of an award/project.

Mandatory Disclosure Requirements

As required by 2 CFR part 200 of the Uniform Guidance, and the HHS implementing regulations at 45 CFR part 75, the IHS must require an NFE or an applicant for a Federal award to disclose, in a timely manner, in writing to the IHS or pass-through entity all violations of Federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the Federal award.

All applicants and recipients must disclose, in a timely manner, in writing to the IHS and to the HHS Office of Inspector General all information related to violations of Federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the Federal award. 45 CFR 75.113.

Disclosures must be sent in writing to: U.S. Department of Health and Human Services, Indian Health Service, Division of Grants Management, ATTN: Paul Gettys, Acting Director, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857 (Include "Mandatory Grant Disclosures" in subject line), Office: (301) 443-5204, Fax: (301) 594-0899, Email: Paul.Gettys@ihs.gov;

AND

U.S. Department of Health and Human Services, Office of Inspector General, ATTN: Mandatory Grant Disclosures, Intake Coordinator, 330 Independence Avenue SW, Cohen Building, Room 5527, Washington, DC 20201, URL: <https://oig.hhs.gov/fraud/report-fraud/> (Include "Mandatory Grant Disclosures" in subject line), Fax: (202) 205-0604 (Include "Mandatory Grant Disclosures" in subject line) or Email: MandatoryGranteeDisclosures@oig.hhs.gov.

Failure to make required disclosures can result in any of the remedies described in 45 CFR 75.371 Remedies for noncompliance, including suspension or debarment (see 2 CFR part 180 and 2 CFR part 376).

VII. Agency Contacts

- Questions on the programmatic issues may be directed to: Audrey Solimon, Public Health Analyst, Indian Health Service, Division of Behavioral Health, 5600 Fisher Lane, Mail Stop: 08N34-A, Rockville, MD 20857, Phone: (301) 590-5421, Fax: (301) 594-6213, Email: Audrey.Solimon@ihs.gov.

- Questions on grants management and fiscal matters may be directed to: Andrew Diggs, Grants Management Specialist, DGM, Indian Health Service, Division of Grants Management, 5600 Fishers Lane, Mail Stop: 09E70,

Rockville, MD 20857, Phone: (301) 443-2241, Fax: (301) 594-0899, Email: Andrew.Diggs@ihs.gov.

3. Questions on systems matters may be directed to: Paul Gettys, Acting Director, DGM, Indian Health Service, Division of Grants Management, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, Phone: (301) 443-2114; or the DGM main line (301) 443-5204, Fax: (301) 594-0899, email: Paul.Gettys@ihs.gov.

VIII. Other Information

The Public Health Service strongly encourages all grant, cooperative agreement, and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of the facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the HHS mission to protect and advance the physical and mental health of the American people.

Elizabeth A. Fowler,
Acting Director, Indian Health Service.
[FR Doc. 2021-24023 Filed 11-3-21; 8:45 am]

BILLING CODE 4165-16-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Zero Suicide Initiative

Announcement Type: New.
Funding Announcement Number: HHS-2022-IHS-ZSI-0001.
Assistance Listing (Catalog of Federal Domestic Assistance or CFDA) Number: 93.654.

Key Dates

Application Deadline Date: February 2, 2022.
Earliest Anticipated Start Date: March 21, 2022.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) is accepting applications for a cooperative agreement for the Zero Suicide Initiative (ZSI). This program is authorized under the Snyder Act, 25 U.S.C. 13; the Transfer Act, 42 U.S.C. 2001(a); and the Indian Health Care Improvement Act, 25 U.S.C. 1665 *et seq.* This program is described in the Assistance Listings located at <https://sam.gov/content/home>

(formerly known as Catalog of Federal Domestic Assistance) under 93.654.

Background

Since 1999, suicide rates within the United States have been steadily increasing.¹ On March 2, 2018, the Centers for Disease Control and Prevention's Morbidity and Mortality Weekly report released a data report, "Suicides Among American Indian/Alaska Natives—National Violent Death Reporting System, 18 States, 2003 to 2014," which highlights American Indian/Alaska Natives having the highest rates of suicide of any racial/ethnic group in the United States. The suicide rate for American Indian/Alaska Native (AI/AN) adolescents and young adult ages 15 to 34 (19.1/100,000) was 1.3 times that of the national average for that age group (14/100,000).² In June 2019, the National Center for Health Statistics, Health E-Stat reported in "Suicide Rates for Females and Males by Race and Ethnicity: United States, 1999 and 2017," suicide rates increased for all race and ethnicity groups but the largest increase occurred for non-Hispanic AI/AN females (139% from 4.6 to 11.0 per 100,000). Suicide is the 8th leading cause of death among all AI/AN people across all ages and may be underestimated.

The 'Zero Suicide' model is a key component of the National Strategy for Suicide Prevention (NSSP) and is a priority of the National Action Alliance for Suicide Prevention (<https://theactionalliance.org/>). The 'Zero Suicide' model focuses on developing a system-wide approach to improving care for individuals at risk of suicide who are currently using health and behavioral health systems. This award will support implementation of the 'Zero Suicide' model within Tribal and Urban Indian health care facilities and systems that provide direct care services to AI/AN individuals in order to raise awareness of suicide, establish integrated systems of care, and improve outcomes for such individuals. Applicants are encouraged to visit <https://www.hhs.gov/surgeon-general/reports-and-publications/suicide-prevention/index.html> to access a copy of the 2012 National Strategy.

Purpose

The purpose of this program is to improve the system of care for those at

¹ Curtin SC, Hedegaard H. Suicide rates for females and males by race and ethnicity: United States, 1999 and 2017. NCHS Health E-Stat. 2019.

² Leavitt RA, Ertle AE, Sheats K, Petrosky E, Ivey-Stephenson A, Fowler KA (2018) Suicides Among American Indian/Alaska Natives—National Violent Death Reporting System, 18 States, 2003 to 2014. MMWR Morb Mortal Wkly Rep 2018;67: 37-240.

risk for suicide by implementing a comprehensive, culturally informed, multi-setting approach to suicide prevention in Indian health systems. This award represents a continuation of the IHS effort to implement the Zero Suicide approach in Indian Country. The intent of this announcement is to initiate a new, or build upon the previous, Zero Suicide Initiative efforts. Existing efforts have focused on foundational learning of the key concepts of the Zero Suicide framework, technical assistance, and consultation for several AI/AN Zero Suicide communities. As a result of these efforts, both the unique opportunities and challenges of implementing Zero Suicide in Indian Country have been identified. To best capitalize on opportunities and surmount such challenges, this program focuses on the core Seven Elements of the Zero Suicide model as developed by the Suicide Prevention Resource Center (SPRC) at <https://zerosuicide.edc.org/toolkit/zero-suicide-toolkit>:

1. Lead—Create and sustain a leadership-driven, safety-oriented culture committed to dramatically reducing suicide among people under care. Include survivors of suicide attempts and suicide loss in leadership and planning roles;
2. Train—Develop a competent, confident, and caring workforce;
3. Identify—Systematically identify and assess suicide risk among people receiving care;
4. Engage—Ensure every individual has a pathway to care that is both timely and adequate to meet his or her needs. Include collaborative safety planning and restriction of lethal means;
5. Treat—Use effective, evidence-based treatments that directly target suicidal thoughts and behaviors;
6. Transition—Provide continuous contact and support, especially after acute care; and,
7. Improve—Apply a data-driven, quality improvement approach to inform system changes that will lead to improved patient outcomes and better care for those at risk.

Required, Optional, and Allowable Activities

Each applicant must describe how they plan to implement the following core elements of this program in their project narrative and incorporate culture within the approach to each of the seven elements.

1. Lead

- a. Establish a leadership-driven strategic plan which includes session planning (see link <https://>

zerosuicide.edc.org/resources/resource-database/zero-suicide-work-plan-template) to transform the delivery of suicide care within the health care system.

b. Describe the organizational steps to broaden the responsibility for suicide care across the entire health care system.

c. Detail the specific role of leadership to ensure system transformation is achieved. Examples of leadership commitment can include, but are not limited to: Tribal Resolutions, Tribal codes, formal suicide care policies, and formation of Zero Suicide Initiative advisory boards.

2. Train

a. Evaluate training needs and develop a formal training plan for suicide prevention gatekeeper training (examples include, but are not limited to, Question Persuade Refer, Applied Suicide Intervention Skills Training, and Mental Health First Aid). In addition, the training plan should include training in treating suicide risk (examples include, but are not limited to, Dialectical Behavioral Therapy, Cognitive Processing Therapy for Suicide Prevention, and Cognitive Therapy for Suicidal Patients).

b. The formal training plan for staff should focus across the health care system to strengthen and advance the skills of health care staff and providers at all levels.

c. Training must target increasing competence in the delivery of culturally informed, evidence-based suicide care in all health care settings. Survey at <https://zerosuicide.edc.org/sites/default/files/ZS%20Workforce%20Survey%20July%202020.pdf> will be completed and reported on at the initiation of the period of performance.

d. Train new or existing staff with an emphasis in these functions (see link <https://zerosuicide.edc.org/resources/resource-database/suicide-care-training-options>).

e. Project/program oversight.

f. Case management/coordination to ensure continuity of care across and between various departments, health care systems, and or levels of care (e.g., transfer from high risk to low risk, discharge from inpatient mental health care).

g. Data collection support and access for Electronic Health Record (EHR), clinical application, project coordinator support, and other data related activities. Adopt and/or enhance computer systems, including management information system, EHRs, and other systems/software, to better document and manage patient needs,

the care process, integration with related support services, and track outcomes.

3. Identify

a. Implement system-wide policies and procedures for comprehensive suicide care standards to include, at a minimum:

i. Universal screening of all patients ages 10 and above for suicide risk using validated instruments (see link <https://zerosuicide.edc.org/resources/resource-database/ask-suicide-screening-questions-asq-toolkit>).

ii. Full suicide risk assessment of all patients with positive suicide risk screen (including risk level formulation), using (see link https://www.jointcommission.org/-/media/tjc/documents/resources/patient-safety-topics/suicide-prevention/pages-from-suicide-prevention-compendium_5_11_20_updated-july2020_ep3_4.pdf).

iii. Individual Safety Plan for all patients with positive suicide risk screen to include counseling patients on reduction to access of lethal means and means restriction (see link <https://www.sprc.org/resources-programs/patient-safety-plan-template>).

iv. Procedure and protocol for tracking patients at increased risk for suicide by placing patients on a suicide care management plan/pathway. This must also address how patients are monitored while on the plan/pathway, how often patients are re-evaluated to assess risk level, when it is appropriate to remove patient from plan/pathway, follow-up protocols after patients are removed from plan/pathway, etc. (see link https://www.jointcommission.org/seq_issue_56/).

b. Develop protocols for every individual identified as at risk of suicide to continuously monitor the individual's progress through their EHR or other data management system to include the following:

i. Rapid follow-up of adults who have attempted suicide or experienced a suicidal crisis after being discharged from a treatment facility, e.g., local emergency departments, inpatient psychiatric facilities, including direct linkage with appropriate health care agencies to ensure coordinated care services and protocols are in place to ensure patient safety, especially among high-risk adults with serious mental illness. This must include outreach telephone contact within 24 to 48 hours after discharge and securing an appointment within 1 week of discharge (see link <https://www.jointcommission.org/resources/patient-safety-topics/suicide-prevention/>).

ii. Establish health system leadership including outside service providers (i.e., local suicide prevention crisis lines to help with follow-up contacts, etc.), and develop teams to guide the implementation of the Zero Suicide model within their agencies.

4. Engage

a. Develop a Suicide Care Management Plan for every patient identified as high risk of suicide (see link <https://zerosuicide.edc.org/resources/resource-database/zero-suicide-work-plan-template>). Implement a process for continuous monitoring of those patients' progress through their EHR or other data management system, and adjust treatment as necessary.

5. Treat

a. Develop a strategy and specific plan (see link <https://zerosuicide.edc.org/resources/resource-database/zero-suicide-data-elements-worksheet>) to collect, analyze, and disseminate data related to suicide care across the health care system.

b. Use a data-informed approach for quality improvement at the levels of policy, process, and practice. Wherever possible, this approach should include a unified EHR, or memorandum of understanding/memorandum of agreement (MOU/MOA) to establish a process to share data between and across systems of care for all patients in a suicide risk clinical pathway. For example, a data report that indicates a high percentage of patients being discharged from inpatient stays failed to receive follow-up appointments may result in implementing a plan to reduce that number by changing staffing patterns and processes to focus on scheduling follow-up care.

c. Apply the use of evidence-based practices to screen, assess, and treat individuals at risk for suicide in a way that incorporates culturally informed practices and activities. Clearly describe how cultural best practices and/or traditional approaches are offered, utilized, and/or incorporated within the health care system to complement/augment into the evidence-based protocols with those at risk for suicide.

d. Evidence-based practices, where appropriate, may include:

i. Suicide risk screening—Ask Suicide-Screening Questions (see link <https://www.nimh.nih.gov/research/research-conducted-at-nimh/asq-toolkit-materials/index.shtml>).

ii. Columbia Suicide Severity Rating Scale (see link <https://cssrs.columbia.edu/the-columbia-scale-cssrs/cssrs-for-communities-and-healthcare/#filter=.general-use.english>).

iii. Suicide Risk Assessment—Brief Suicide Safety Assessment (see link <https://www.nimh.nih.gov/research/research-conducted-at-nimh/asq-toolkit-materials/youth-outpatient/youth-outpatient-brief-suicide-safety-assessment-worksheet.shtml>).

iv. Columbia Suicide Severity Rating Scale (see link <https://cssrs.columbia.edu/the-columbia-scale-c-srs/cssrs-for-communities-and-healthcare/#filter=.general-use.english>).

v. Suicide treatment—Dialectical Behavioral Therapy (see link <https://www.sprc.org/resources-programs/dialectical-behavior-therapy>).

vi. Cognitive Therapy for Suicidal Patients (see link <https://www.sprc.org/resources-programs/cognitive-therapy-suicide-prevention>).

vii. Cultural best practices and/or traditional approaches—Language immersion, traditional healers, and traditional ceremonies (see link <https://zerosuicide.edc.org/toolkit/toolkit-adaptations/indian-country>).

6. Transition

a. The Suicide Care Management Plan must include the following (see link <https://zerosuicide.edc.org/resources/resource-database/best-practices-care-transitions-individuals-suicide-risk-inpatient-care>):

i. Protocols for safety planning and reducing access to lethal means in a point-to-point transition of care within a system;

ii. Rapid follow-up of adults who have attempted suicide or experienced a suicidal crisis after being discharged from a treatment facility (e.g., local emergency departments, inpatient psychiatric facilities), including direct linkage with appropriate health care agencies to ensure coordinated care services are in place;

iii. Protocols to ensure patient safety, especially among high-risk adults in health care systems who have attempted suicide, experienced a suicidal crisis, and/or have a serious mental illness. This must include outreach telephone contact within 24 to 48 hours after discharge and securing an appointment within 1 week of discharge (see link <https://zerosuicide.edc.org/toolkit/transition> and/or <https://theactionalliance.org/healthcare/caretransitions>).

7. Improve

a. Describe the quality improvement activities that will be used to track progress towards your process and outcome measure and how these data will be used to inform the ongoing implementation of the project and beyond (see link <https://zerosuicide.edc.org/resources/resource-database/zero-suicide-work-plan-template>).

database/zero-suicide-work-plan-template).

In addition to the seven elements listed above, the following activities are also required:

1. Seek the IHS's approval for key positions to be filled. Key positions include, but are not limited to, the Project Director, Project Coordinator, and Evaluator.

2. Consult and accept guidance from IHS staff on performance of programmatic and data collection activities to achieve the goals of the cooperative agreement.

3. Maintain ongoing communication with the IHS including a minimum of one call per month, keeping Federal program staff informed of emerging issues, developments, and problems as appropriate.

4. Invite the IHS Program Official to observe and provide feedback to policy, steering, advisory, or other task forces.

5. Maintain ongoing collaboration with the IHS ZSI Technical Assistance Coordinating Center, the Suicide Prevention Resource Center, and the National Suicide Prevention Lifeline.

6. Provide required documentation for monthly and annual reporting and data surveillance around suicidal behavior in selected health and behavioral health care systems.

Practice-Based Evidence, Promising Practices, and Local Efforts

The IHS encourages the implementation of Tribal and/or culturally appropriate suicide prevention and intervention strategies but recognizes the limited range of formally evaluated evidence-based practices for suicide and substance abuse that have been developed specifically for the American Indians/Alaska Natives population. In addition to formally evaluated practices, which exist in the research and practice literature, evidence for other practices are allowed in this grant program. Evidence of other practices may include unpublished studies, preliminary evaluation results, clinical (or other professional association) guidelines, findings from focus groups with community members, local community surveys, etc.

• Document the evidence that the practice(s) you have chosen is appropriate for the outcomes you want to achieve.

• Explain how the practice you have chosen meets the goals for this program.

• Describe any modifications/adaptations you will need to make to your proposed practice(s) to meet the goals of your project and why you

believe the changes will improve the outcomes.

• Discuss training needs or plans for training to successfully implement the proposed evidence-based practice(s).

II. Award Information

Funding Instrument—Cooperative Agreement

Estimated Funds Available

The total funding identified for fiscal year (FY) 2022 is approximately \$2,000,000. Individual award amounts for the first budget year are anticipated to be between \$200,000 and \$300,000. The funding available for competing and subsequent continuation awards issued under this announcement is subject to the availability of appropriations and budgetary priorities of the Agency. The IHS is under no obligation to make awards that are selected for funding under this announcement.

Anticipated Number of Awards

Approximately 8–10 awards will be issued under this program announcement, with a set aside of up to two awards issued to eligible UIOs.

Period of Performance

The period of performance is for 5 years.

Cooperative Agreement

Cooperative agreements awarded by the Department of Health and Human Services (HHS) are administered under the same policies as grants. However, the funding agency, IHS, is anticipated to have substantial programmatic involvement in the project during the entire period of performance. Below is a detailed description of the level of involvement required of the IHS.

Substantial Agency Involvement Description for Cooperative Agreement

1. Approve all proposed key positions/personnel.

2. Facilitate linkages to other IHS/Federal government resources and help grantees access appropriate technical assistance.

3. Assure that the grantee's project activities are aligned with the mission, strategic goals and objectives of the IHS, and with the goals of the Zero Suicide Initiative.

4. Coordinate cross-site evaluation participation in grantee and staff required monitoring conference calls.

5. Promote collaboration with other IHS and Federal health and behavioral health initiatives, including the Substance Abuse Mental Health Services Administration (SAMHSA), the

National Action Alliance for Suicide Prevention, the National Suicide Prevention Lifeline, the SPRC, and the Zero Suicide Institute.

6. Provide technical assistance on all aspects of the ZSI program implementation and sustainability.

7. Share aggregate data related to suicide behavior and clinical care necessary to determine that the project has met expected and identified goals, objectives, and outcomes. Describe the process of continuous involvement based on results and analysis of the same.

III. Eligibility Information

1. Eligibility

To be eligible for this funding opportunity the applicant must be one of the following as defined by 25 U.S.C. 1603:

- A federally recognized Indian Tribe as defined by 25 U.S.C. 1603(14). The term “Indian Tribe” means any Indian Tribe, band, nation, or other organized group or community, including any Alaska Native village or group or regional or village corporation, as defined in or established pursuant to the Alaska Native Claims Settlement Act (85 Stat. 688) [43 U.S.C. 1601 *et seq.*], which is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians.

- A Tribal organization as defined by 25 U.S.C. 1603(26). The term “Tribal organization” has the meaning given the term in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304(1)): “Tribal organization” means the recognized governing body of any Indian Tribe; any legally established organization of Indians which is controlled, sanctioned, or chartered by such governing body or which is democratically elected by the adult members of the Indian community to be served by such organization and which includes the maximum participation of Indians in all phases of its activities: Provided that, in any case where a contract is let or grant made to an organization to perform services benefiting more than one Indian Tribe, the approval of each such Indian Tribe shall be a prerequisite to the letting or making of such contract or grant. Applicant shall submit letters of support and/or Tribal Resolutions from the Tribes to be served.

- An Urban Indian organization as defined by 25 U.S.C. 1603(29). The term “Urban Indian organization” means a nonprofit corporate body situated in an urban center, governed by an urban

Indian controlled board of directors, and providing for the maximum participation of all interested Indian groups and individuals, which body is capable of legally cooperating with other public and private entities for the purpose of performing the activities described in 25 U.S.C. 1653(a). Applicants must provide proof of nonprofit status with the application, *e.g.*, 501(c)(3).

The program office will notify any applicants deemed ineligible.

Note: Please refer to Section IV.2 (Application and Submission Information/Subsection 2, Content and Form of Application Submission) for additional proof of applicant status documents required, such as Tribal Resolutions, proof of nonprofit status, etc.

2. Cost Sharing or Matching

The IHS does not require matching funds or cost sharing for grants or cooperative agreements.

3. Other Requirements

Applications with budget requests that exceed the highest dollar amount outlined under Section II Award Information, Estimated Funds Available, or exceed the period of performance outlined under Section II Award Information, Period of Performance, are considered not responsive and will not be reviewed. The Division of Grants Management (DGM) will notify the applicant.

Additional Required Documentation Tribal Resolution

The DGM must receive an official, signed Tribal Resolution prior to issuing a Notice of Award (NoA) to any applicant selected for funding. An Indian Tribe or Tribal organization that is proposing a project affecting another Indian Tribe must include resolutions from all affected Tribes to be served. However, if an official, signed Tribal Resolution cannot be submitted with the application prior to the application deadline date, a draft Tribal Resolution must be submitted with the application by the deadline date in order for the application to be considered complete and eligible for review. The draft Tribal Resolution is not in lieu of the required signed resolution but is acceptable until a signed resolution is received. If an application without a signed Tribal Resolution is selected for funding, the applicant will be contacted by the Grants Management Specialist (GMS) listed in this funding announcement and given 90 days to submit an official, signed Tribal Resolution to the GMS. If the signed Tribal Resolution is not

received within 90 days, the award will be forfeited.

Tribes organized with a governing structure other than a Tribal council may submit an equivalent document commensurate with their governing organization.

Proof of Nonprofit Status

Organizations claiming nonprofit status must submit a current copy of the 501(c)(3) Certificate with the application.

IV. Application and Submission Information

1. Obtaining Application Materials

The application package and detailed instructions for this announcement are available at <https://www.Grants.gov>.

Please direct questions regarding the application process to Mr. Paul Gettys at (301) 443–2114 or (301) 443–5204.

2. Content and Form Application Submission

Mandatory documents for all applicants include:

- Abstract (one page) summarizing the project.

- Application forms:

1. SF–424, Application for Federal Assistance.

2. SF–424A, Budget Information—Non-Construction Programs.

3. SF–424B, Assurances—Non-Construction Programs.

- Project Narrative (not to exceed 30 pages). See IV.2.A, Project Narrative for instructions.

1. Background information on the organization.

2. Proposed scope of work, objectives, and activities that provide a description of what the applicant plans to accomplish.

- Budget Justification and Narrative (not to exceed four pages). See IV.2.B, Budget Narrative for instructions.

- One-page Timeline Chart.

- Tribal Resolution(s). A Tribal Resolution expressing a bona fide commitment to a Zero Suicide model within the health and behavioral health care system must be provided.

- Letters of Support from organization’s Board of Directors (if applicable).

- 501(c)(3) Certificate (if applicable).

- Biographical sketches for all Key Personnel.

- Contractor/Consultant resumes or qualifications and scope of work.

- Disclosure of Lobbying Activities (SF–LLL), if applicant conducts reportable lobbying.

- Certification Regarding Lobbying (GG—Lobbying Form).

- Copy of current Negotiated Indirect Cost rate (IDC) agreement (required in order to receive IDC).

- Organizational Chart (optional).
- Documentation of current Office of Management and Budget (OMB) Financial Audit (if applicable).

Acceptable forms of documentation include:

1. Email confirmation from Federal Audit Clearinghouse (FAC) that audits were submitted; or

2. Face sheets from audit reports.

Applicants can find these on the FAC website at <https://harvester.census.gov/facdissem/Main.aspx>.

Public Policy Requirements

All Federal public policies apply to IHS grants and cooperative agreements. Pursuant to 45 CFR 80.3(d), an individual shall not be deemed subjected to discrimination by reason of their exclusion from benefits limited by Federal law to individuals eligible for benefits and services from the IHS. See <https://www.hhs.gov/grants/grants/grants-policies-regulations/index.html>.

Requirements for Project and Budget Narratives

A. Project Narrative: This narrative should be a separate document that is no more than 30 pages and must: (1) Have consecutively numbered pages; (2) use black font 12 points or larger; (3) be single-spaced; and (4) be formatted to fit standard letter paper (8½ x 11 inches).

Be sure to succinctly answer all questions listed under the evaluation criteria (refer to Section V.1, Evaluation Criteria) and place all responses and required information in the correct section noted below or they will not be considered or scored. If the narrative exceeds the page limit, the application will be considered not responsive and will not be reviewed. The 30-page limit for the narrative does not include the work plan, standard forms, Tribal Resolutions, budget, budget justifications, narratives, and/or other items.

There are four parts to the project narrative:

Part 1—Statement of Need;

Part 2—Implementation Approach and Work Plan;

Part 3—Organizational Capacity;

Part 4—Data Collection and Reporting.

Below are additional details about what must be included in the project narrative.

The intent of this announcement is to initiate or build upon Zero Suicide Initiative efforts. Applicants previously funded by IHS for ZSI implementation must report on the status of their goals/

milestones. If goals/milestone were not achieved by those applicants, they are expected to provide clear explanation of the barriers that prevented the achievement of previous goal/milestones in the application to this funding announcement.

Part 1: Statement of Need (Limit—6 Pages)

The statement of need describes the scope and scale of suicide behavior within the community served and within the health and/or behavioral health system. This section must identify gaps in suicide care delivery and those gaps and any other barriers in providing comprehensive, culturally informed care to those at risk for suicide. The statement of need provides the facts and evidence that support the need for the project and establishes that the Tribe, Tribal organization, or UIO understands the problems and can reasonably address them. Applicant's data may include the following metrics outlined below.

Identify

- Describe the proposed catchment area and demographic information on the population(s) to receive services through the targeted systems or agencies, e.g., race, ethnicity, federally recognized Tribe, language, age, socioeconomic status, sex, and other relevant factors, such as literacy.

Improve

- Provide evidence of the prevalence of suicidal behavior within the population(s) of focus, including any current limitations of data collection in the health system. In addition, discuss how the proposed project will address disparities in access, service use, and outcomes for the population(s) of focus (see link <https://zerosuicide.edc.org/toolkit/indian-country/improve-indian-country>).

1. Number of screenings performed.

2. Number of those above screening cut off who receive a full suicide risk assessment.

3. Numbers of those receiving a full risk assessment who have a collaboratively developed safety plan.

4. Number of those with a collaboratively developed safety plan who have been counseled on reduction of access to lethal means.

5. Percentage of all behavioral health clinicians who use evidence-based practices to directly treat those at risk for suicide.

6. Percentage of follow up on those who may be at risk for suicide to ensure safe transitions through care.

7. Percentage of documentation on every loss by suicide.

- Documentation of the need for an enhanced infrastructure (system/process improvements) to increase the capacity to implement, sustain, and improve comprehensive, integrated, culturally informed, evidence-based suicide care within the identified health care system that is consistent with the purpose of the program as stated in this announcement (see link <https://zerosuicide.edc.org/resources/zero-suicide-workforce-survey-resources>). This may also include a clear description of any service gaps, staff/provider training deficits, service delivery fragmentations, and other barriers that could impact comprehensive suicide care for patients seen in the health system.

- Applicants are encouraged to review the Zero Suicide strategies and tools to help prepare for application to this announcement. Please see <http://zerosuicide.sprc.org/sites/zerosuicide.actionallianceforsuicideprevention.org/files/Zero%20Suicide%20Workplan%20Template%2012.6.17.pdf>.

Part 2: Implementation Approach & Work Plan (Limit—9 Pages)

Applicant should develop a viable plan to address each of the 7 Elements (see link <http://zerosuicide.edc.org/toolkit>) in a systematic, measureable, and interrelated manner. Evidence of plan to the identification, use, and measurement of the use of culturally informed practices and activities (see link <https://zerosuicide.edc.org/resources/populations/native-american-and-alaska-native>).

Please include a Project Timeline in the application.

Lead

- A clear description of strategies to engage the highest levels of leadership and a broad cross section of the hospital system in order to develop organizational commitment, participation and sustainability (Letters of Commitment should be included as attachments). If the program is to be managed by a consortium or Tribal organization, identify how the project office relates to the member community/communities.

Transition

- A contingency plan that addresses short-term maintenance and long-term sustainability. How will continuity be maintained if/when there is a change in the operational environment (e.g., health care system leadership, staff turnover, change in project leadership, change in elected officials, etc.) to

ensure project stability over the period of performance. Additionally, describe long-term plan for sustainability of the ZSI model beyond the period of performance.

- Include how your project plans to involve survivors of suicide attempts and suicide loss in assessing, planning, and implementing your project.

Part 3: Organizational Capacity (Limit—8 Pages)

This section focuses on how the organization may capitalize on existing resources, processes, human capital, quality initiatives, collaborative agreements, and surveillance capabilities as a means of overcoming barriers to a comprehensive, culturally informed system of suicide care.

Lead

- Describe any experience (successes and/or challenges) with the Zero Suicide model (e.g., attended a Zero Suicide Academy, etc.) or similar collaborative efforts (e.g., patient centered medical home, behavioral integration, trauma-informed systems, and improving patient care, etc.).
- Discuss the applicant Tribe, Tribal organization, or UIO experience with and capacity (or detailed plan) to provide culturally informed practices and activities for specific populations of focus.
- Explain how all departments/units/divisions are (or plan to be) involved in administering this project. You may also include how applicant organization currently (or plans to) collaborate with other organizations and agencies to provide care, including critical transition of care. Provide Letter(s) of Commitment, MOA, MOUs etc., from CEO, Tribal Health Director, Tribal Chair, etc.
- Describe the resources available for the proposed project (e.g., facilities, equipment, information technology systems, EHR capabilities, financial management systems, data sharing agreement, MOUs, etc.).
- List of all staff positions for the project, such as Project Director, project coordinator, case manager and other key personnel, and briefly describe their role and level of effort on the project.

Part 4: Data Collection and Reporting (Limit—7 Pages)

This section of the narrative should describe function of position and efforts to collect and report project data that will support and demonstrate ZSI activities. All ZSI grantees will be required to collect and report data pertaining to activities, processes, and

outcomes that support the following core elements:

Improve

- Provide a clear, specific plan for how data will be collected, managed, analyzed, and reported.
- Identify which staff will be responsible for tracking the goals and measurable objectives associated with the award.

Lead

- Review of suicide care policies and procedures.
- Review of any MOUs, MOAs, commitment letters, etc.
- ZSI Implementation team participation.
- Engagement of those that have experienced suicidal thoughts, survived a suicide attempt, cared for someone through suicidal crisis, or been bereaved by suicide.

Improve

- Assessment of fidelity to the Zero Suicide model (to include periodic administering of Organizational Self-Study).
- Periodic assessment of staff development and training needs (to include the periodic administering of the Workforce Survey).
- Sustainability.
- Measurement-based screening tools.
- Review of EHR capability.
- Patient satisfaction.

B. Budget Narrative (limit—4 pages). Provide a budget narrative that explains the amounts requested for each line item of the budget from the SF-424A (Budget Information for Non-Construction Programs). The budget narrative should specifically describe how each item will support the achievement of proposed objectives. Be very careful about showing how each item in the “Other” category is justified. For subsequent budget years, the narrative should highlight the changes from year 1 or clearly indicate that there are no substantive budget changes during the period of performance. Do NOT use the budget narrative to expand the project narrative.

3. Submission Dates and Times

Applications must be submitted through *Grants.gov* by 11:59 p.m. Eastern Time on the Application Deadline Date. Any application received after the application deadline will not be accepted for review. *Grants.gov* will notify the applicant via email if the application is rejected.

If technical challenges arise and assistance is required with the application process, contact *Grants.gov*

Customer Support (see contact information at <https://www.grants.gov>). If problems persist, contact Mr. Paul Gettys (*Paul.Gettys@ihs.gov*), Acting Director, DGM, by telephone at (301) 443-2114 or (301) 443-5204. Please be sure to contact Mr. Gettys at least ten days prior to the application deadline. Please do not contact the DGM until you have received a *Grants.gov* tracking number. In the event you are not able to obtain a tracking number, call the DGM as soon as possible.

IHS will not acknowledge receipt of applications.

4. Intergovernmental Review

Executive Order 12372 requiring intergovernmental review is not applicable to this program.

5. Funding Restrictions

- Pre-award costs are allowable up to 90 days before the start date of the award provided the costs are otherwise allowable if awarded. Pre-award costs are incurred at the risk of the applicant.
- The available funds are inclusive of direct and indirect costs.
- Only one cooperative agreement may be awarded per applicant under this announcement.

6. Electronic Submission Requirements

All applications must be submitted via *Grants.gov*. Please use the <https://www.Grants.gov> website to submit an application. Find the application by selecting the “Search Grants” link on the homepage. Follow the instructions for submitting an application under the Package tab. No other method of application submission is acceptable.

If the applicant cannot submit an application through *Grants.gov*, a waiver must be requested. Prior approval must be requested and obtained from Mr. Paul Gettys, Acting Director, DGM. A written waiver request must be sent to *GrantsPolicy@ihs.gov* with a copy to *Paul.Gettys@ihs.gov*. The waiver request must: (1) Be documented in writing (emails are acceptable) before submitting an application by some other method, and (2) include clear justification for the need to deviate from the required application submission process.

Once the waiver request has been approved, the applicant will receive a confirmation of approval email containing submission instructions. A copy of the written approval must be included with the application that is submitted to the DGM. Applications that are submitted without a copy of the signed waiver from the Acting Director of the DGM will not be reviewed. The Grants Management Officer of the DGM

will notify the applicant via email of this decision. Applications submitted under waiver must be received by the DGM no later than 5:00 p.m., Eastern Time, on the Application Deadline Date. Late applications will not be accepted for processing. Applicants that do not register for both the System for Award Management (SAM) and *Grants.gov* and/or fail to request timely assistance with technical issues will not be considered for a waiver to submit an application via alternative method.

Please be aware of the following:

- Please search for the application package in <https://www.Grants.gov> by entering the Assistance Listing (CFDA) number or the Funding Opportunity Number. Both numbers are located in the header of this announcement.

- If you experience technical challenges while submitting your application, please contact *Grants.gov* Customer Support (see contact information at <https://www.grants.gov>).

- Upon contacting *Grants.gov*, obtain a tracking number as proof of contact. The tracking number is helpful if there are technical issues that cannot be resolved and a waiver from the agency must be obtained.

- Applicants are strongly encouraged not to wait until the deadline date to begin the application process through *Grants.gov* as the registration process for SAM and *Grants.gov* could take up to twenty working days.

- Please follow the instructions on *Grants.gov* to include additional documentation that may be requested by this funding announcement.

- Applicants must comply with any page limits described in this funding announcement.

- After submitting the application, the applicant will receive an automatic acknowledgment from *Grants.gov* that contains a *Grants.gov* tracking number. The IHS will not notify the applicant that the application has been received.

Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS)

Applicants and grantee organizations are required to obtain a DUNS number and maintain an active registration in the SAM database. The DUNS number is a unique 9-digit identification number provided by D&B that uniquely identifies each entity. The DUNS number is site specific; therefore, each distinct performance site may be assigned a DUNS number. Obtaining a DUNS number is easy, and there is no charge. To obtain a DUNS number, please access the request service through <https://fedgov.dnb.com/webform>, or call (866) 705-5711.

The Federal Funding Accountability and Transparency Act of 2006, as amended (“Transparency Act”), requires all HHS recipients to report information on sub-awards. Accordingly, all IHS grantees must notify potential first-tier sub-recipients that no entity may receive a first-tier sub-award unless the entity has provided its DUNS number to the prime grantee organization. This requirement ensures the use of a universal identifier to enhance the quality of information available to the public pursuant to the Transparency Act.

System for Award Management (SAM)

Organizations that are not registered with SAM must have a DUNS number first, then access the SAM online registration through the SAM home page at <https://www.sam.gov/SAM/> (U.S. organizations will also need to provide an Employer Identification Number from the Internal Revenue Service that may take an additional 2–5 weeks to become active). Please see *SAM.gov* for details on the registration process and timeline. Registration with the SAM is free of charge but can take several weeks to process. Applicants may register online at <https://www.sam.gov/SAM/>.

Additional information on implementing the Transparency Act, including the specific requirements for DUNS and SAM, are available on the DGM Grants Management, Policy Topics web page: <https://www.ihs.gov/dgm/policytopics/>.

V. Application Review Information

Possible points assigned to each section are noted in parentheses. The 30-page project narrative should include only the first year of activities; information for multi-year projects should be included as an appendix. See “Multi-year Project Requirements” at the end of this section for more information. The narrative section should be written in a manner that is clear to outside reviewers unfamiliar with prior related activities of the applicant. It should be well organized, succinct, and contain all information necessary for reviewers to understand the project fully. Points will be assigned to each evaluation criteria adding up to a total of 100 possible points. Points are assigned as follows:

1. Evaluation Criteria

Applications will be reviewed and scored according to the quality of responses to the required application components in Sections A–E. The points listed after each heading is the maximum number of points a reviewer may assign to that section.

A. Statement of Need (10 Points)

The criteria being evaluated is the quality of your strategic approach and logical steps to implement a Zero Suicide Initiative within your health system. The following aspects will be assessed:

1. The degree to which the applicant’s description of the service area/target population demonstrates the need for a systems approach to suicide care within the health and behavioral health systems.

2. How well the applicant describes the unique characteristics of the service area and population and systems barriers/gaps that impact the delivery of comprehensive suicide care.

B. Implementation Approach & Work Plan (30 Points)

1. A viable plan to address each of the 7 Elements of the Zero Suicide model and the required activities (described in Section 1) in a systematic, measureable, and interrelated manner. Develop strategy to collect, and analyze application of evidence-based practices to screen, assess, and treat individuals’ use of culturally informed practices and activities. (See Resources for Native American and Alaska Native Populations at <https://zerosuicide.edc.org/resources/populations/native-american-and-alaska-native/>).

2. A clear description of strategies to engage the highest levels of leadership and a broad cross section of the behavioral/healthcare system in order to develop organizational commitment, participation and sustainability (Letters of Commitment, MOUs, MOAs, etc., should be included as attachments). If the program is to be managed by a consortium or Tribal organization, identify how the project office relates to the member community/communities. Should include how you plan to involve survivors of suicide attempts and suicide loss in assessing, planning, and implementing your project.

3. Address how continuity will be maintained if/when there is a change in the operational environment (e.g., health care system leadership, staff turnover, change in project leadership, change in elected officials, etc.) to ensure project stability over the period of performance. Additionally, describe the long-term plan for sustainability of the ZSI model beyond the period of performance.

C. Organizational Capacity (30 Points)

1. The extent to which the applicant describes experience (successes and/or challenges) with the Zero Suicide model

(e.g., attended a Zero Suicide Academy, etc.) or similar collaborative efforts (e.g., patient centered medical home, behavioral integration, trauma informed systems, and improving patient care, etc.), focused on a comprehensive approach to suicide care across a healthcare system.

2. The extent to which the applicant describes experience with and capacity (or detailed plan) to provide culturally informed practices and activities for specific populations of focus. Must refer to Tribal Resolution.

3. Identification of how all departments/units/divisions across the health care system will be involved in administering this project. May also include how applicant organization currently (or plans to) collaborate with other organizations and agencies to provide care, including critical transition of care.

4. Describe the resources available to implement and sustain the proposed project (e.g., facilities, equipment, information technology systems, financial management systems, data sharing agreement, MOUs, etc.).

Listing of all staff positions for the project, such as Project Director, project coordinator, and other key personnel, showing the role of each and their level of effort and qualifications. Demonstrate successful project implementation for the level of effort budgeted for Project Director, project coordinator, and other key staff.

Include position descriptions as attachments to the application. Describe the function within each position providing services in suicide care, behavioral health and primary care and other health care services, quality and process improvement, and related work within the community/communities.

5. Applicants previously funded by the IHS for ZSI implementation must report on the status of their goals/milestones in this section of the program narrative. If goals/milestones were not achieved by those applicants, they are expected to provide clear explanation of the barriers that prevented the achievement of previous goals/milestones.

D. Data Collection, Performance Assessment and Evaluation (25 Points)

In this area, applicants need to clearly demonstrate the ability to collect and report on required data elements associated with Zero Suicide and this particular project, and engage in all aspects of local and national evaluation. The following aspects will be assessed:

- Ability to collect and report on the required performance measures

specified in the Data Collection and Performance Management section.

- A clear, specific plan for data collection, management, analysis, and reporting. Indication of the staff person(s) responsible for tracking the measureable objectives that are identified above.

- Description of your plan for conducting the local performance assessment, as specified above, and evidence of your ability to conduct the assessment.

- Description of the quality improvement process that will be used to track progress towards your performance measures and objectives, and how these data will be used to inform the ongoing implementation of the project and beyond.

E. Categorical Budget and Budget Justification (5 Points)

Applicants must provide a budget and narrative justification for the proposed project budget.

1. Evidence of reasonable, allowable costs necessary to achieve the objective outlined in the project narrative.

2. Description of how the budget aligns with the overall scope of work.

3. Please use Budget/Budget Narrative Template Worksheet to support your responses in this section.

The Timeline Chart, Local Data Collection Plan Worksheet, and Budget/Budget Narrative templates can be downloaded at the ZSI website at <https://www.ihs.gov/zerosuicide/>.

Multi-Year Project Requirements

Applications must include a brief project narrative and budget (one additional page per year) addressing the developmental plans for each additional year of the project. This attachment will not count as part of the project narrative or the budget narrative.

Additional documents can be uploaded as Other Attachments in *Grants.gov*. These can include:

- Work plan, logic model, and/or timeline for proposed objectives.
- Position descriptions for staff.
- Consultant or contractor proposed scope of work and letter of commitment (if applicable).

- Current Indirect Cost Rate Agreement.

- Organizational chart.

- Map of area identifying project location(s).

- Additional documents to support narrative (i.e., data tables, key news articles, etc.).

2. Review and Selection

Each application will be prescreened for eligibility and completeness as

outlined in the funding announcement. Applications that meet the eligibility criteria shall be reviewed for merit by the Objective Review Committee (ORC) based on evaluation criteria. Incomplete applications and applications that are not responsive to the administrative thresholds (budget limit, project period limit) will not be referred to the ORC and will not be funded. The applicant will be notified of this determination.

Applicants must address all program requirements and provide all required documentation.

3. Notifications of Disposition

All applicants will receive an Executive Summary Statement from the IHS Division of Behavioral Health within 30 days of the conclusion of the ORC outlining the strengths and weaknesses of their application. The summary statement will be sent to the Authorizing Official identified on the face page (SF-424) of the application.

A. Award Notices for Funded Applications

The NoA is the authorizing document for which funds are dispersed to the approved entities and reflects the amount of Federal funds awarded, the purpose of the award, the terms and conditions of the award, the effective date of the award, and the budget/project period. Each entity approved for funding must have a user account in GrantSolutions in order to retrieve the NoA. Please see the Agency Contacts list in Section VII for the systems contact information.

B. Approved but Unfunded Applications

Approved applications not funded due to lack of available funds will be held for 1 year. If funding becomes available during the course of the year, the application may be reconsidered.

Note: Any correspondence other than the official NoA executed by an IHS grants management official announcing to the project director that an award has been made to their organization is not an authorization to implement their program on behalf of the IHS.

VI. Award Administration Information

1. Administrative Requirements

Awards issued under this announcement are subject to, and are administered in accordance with, the following regulations and policies:

- A. The criteria as outlined in this program announcement.

- B. Administrative Regulations for Grants:

- Uniform Administrative Requirements, Cost Principles, and

Audit Requirements for HHS Awards currently in effect or implemented during the period of award, other Department regulations and policies in effect at the time of award, and applicable statutory provisions. At the time of publication, this includes 45 CFR part 75, at <https://www.govinfo.gov/content/pkg/CFR-2020-title45-vol1/pdf/CFR-2020-title45-vol1-part75.pdf>.

- Please review all HHS regulatory provisions for Termination at 45 CFR 75.372, at https://www.ecfr.gov/cgi-bin/retrieveECFR?gp&SID=2970eec67399fab1413ede53d7895d99&mc=true&n=pt45.1.75&r=PART&ty=HTML&se45.1.75_1372#se45.1.75_1372.

C. Grants Policy:

- HHS Grants Policy Statement, Revised January 2007, at <https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf>.

D. Cost Principles:

- Uniform Administrative Requirements for HHS Awards, “Cost Principles,” located at 45 CFR part 75 subpart E.

E. Audit Requirements:

- Uniform Administrative Requirements for HHS Awards, “Audit Requirements,” located at 45 CFR part 75 subpart F.

F. As of August 13, 2020, 2 CFR 200 was updated to include a prohibition on certain telecommunications and video surveillance services or equipment. This prohibition is described in 2 CFR 200.216. This will also be described in the terms and conditions of every IHS grant and cooperative agreement awarded on or after August 13, 2020.

2. Indirect Costs

This section applies to all recipients that request reimbursement of indirect costs (IDC) in their application budget. In accordance with HHS Grants Policy Statement, Part II–27, IHS requires applicants to obtain a current IDC rate agreement and submit it to the DGM prior to the DGM issuing an award. The rate agreement must be prepared in accordance with the applicable cost principles and guidance as provided by the cognizant agency or office. A current rate covers the applicable grant activities under the current award’s budget period. If the current rate agreement is not on file with the DGM at the time of award, the IDC portion of the budget will be restricted. The restrictions remain in place until the current rate agreement is provided to the DGM.

Per 45 CFR 75.414(f) Indirect (F&A) costs, “any non-Federal entity (NFE)

[i.e., applicant] that has never received a negotiated indirect cost rate, . . . may elect to charge a de minimis rate of 10 percent of modified total direct costs which may be used indefinitely. As described in Section 75.403, costs must be consistently charged as either indirect or direct costs, but may not be double charged or inconsistently charged as both. If chosen, this methodology once elected must be used consistently for all Federal awards until such time as the NFE chooses to negotiate for a rate, which the NFE may apply to do at any time.”

Electing to charge a de minimis rate of 10 percent only applies to applicants that have never received an approved negotiated indirect cost rate from HHS or another cognizant Federal agency. Applicants awaiting approval of their indirect cost proposal may request the 10 percent de minimis rate. When the applicant chooses this method, costs included in the indirect cost pool must not be charged as direct costs to the grant.

Available funds are inclusive of direct and appropriate indirect costs.

Approved indirect funds are awarded as part of the award amount, and no additional funds will be provided.

Generally, IDC rates for IHS grantees are negotiated with the Division of Cost Allocation at <https://rates.psc.gov/> or the Department of the Interior (Interior Business Center) at <https://ibc.doi.gov/ICS/tribal>. For questions regarding the indirect cost policy, please call the Grants Management Specialist listed under “Agency Contacts” or the main DGM office at (301) 443–5204.

3. Reporting Requirements

The grantee must submit required reports consistent with the applicable deadlines. Failure to submit required reports within the time allowed may result in suspension or termination of an active grant, withholding of additional awards for the project, or other enforcement actions such as withholding of payments or converting to the reimbursement method of payment. Continued failure to submit required reports may result in the imposition of special award provisions and/or the non-funding or non-award of other eligible projects or activities. This requirement applies whether the delinquency is attributable to the failure of the grantee organization or the individual responsible for preparation of the reports. Per DGM policy, all reports must be submitted electronically by attaching them as a “Grant Note” in GrantSolutions. Personnel responsible for submitting reports will be required to obtain a login and password for

GrantSolutions. Please see the Agency Contacts list in section VII for the systems contact information.

The reporting requirements for this program are noted below.

A. Progress Reports

Program progress reports are required annually. The progress reports are due within 30 days after the budget period ends (specific dates will be listed in the NoA Terms and Conditions). These reports must include a brief comparison of actual accomplishments to the goals established for the period, a summary of progress to date or, if applicable, provide sound justification for the lack of progress, and other pertinent information as required, and any other specific evaluation requirements described in this funding announcement. A final report must be submitted within 90 days of expiration of the period of performance. This final report must provide a comprehensive summary of accomplishments and outcomes over the period of performance as related to each of the stated goals.

B. Financial Reports

Federal Cash Transaction Reports are due 30 days after the close of every calendar quarter to the Payment Management Services at <https://pms.psc.gov>. Failure to submit timely reports may result in adverse award actions blocking access to funds.

Federal Financial Reports are due 30 days after the end of each budget period, and a final report is due 90 days after the end of the period of performance.

Grantees are responsible and accountable for reporting accurate information on all required reports: The Progress Reports, the Federal Cash Transaction Report, and Federal Financial Report.

C. Data Collection and Reporting

In addition to the annual progress reports, the IHS will compile and provide aggregate program statistics including associated community-level Government Performance Results Act health care facility data available in the National Data Warehouse, as needed.

Awardees will be required to report on the following:

Treat

- Total number of patient visits; total number of patients screened for suicide risk;
- total number of patients assessed for suicide risk;
- total number of patients placed on suicide care pathway or registry;
- total number of patients hospitalized for suicide risk;

- total number of patients with safety plan;
- total number of patients counseled on access to lethal means.

Train

- Total number of staff trained, number of trainings, type of trainings and number of staff trained in each healthcare profession in evidenced-based treatment of suicide risk.

Awardees will also be required to submit their annual progress reports into an online reporting system funded by the IHS.

D. Federal Sub-Award Reporting System (FSRS)

This award may be subject to the Transparency Act sub-award and executive compensation reporting requirements of 2 CFR part 170.

The Transparency Act requires the OMB to establish a single searchable database, accessible to the public, with information on financial assistance awards made by Federal agencies. The Transparency Act also includes a requirement for recipients of Federal grants to report information about first-tier sub-awards and executive compensation under Federal assistance awards.

The IHS has implemented a Term of Award into all IHS Standard Terms and Conditions, NoAs, and funding announcements regarding the FSRS reporting requirement. This IHS Term of Award is applicable to all IHS grant and cooperative agreements issued on or after October 1, 2010, with a \$25,000 sub-award obligation threshold met for any specific reporting period.

For the full IHS award term implementing this requirement and additional award applicability information, visit the DGM Grants Management website at <https://www.ihs.gov/dgm/policytopics/>.

E. Compliance With Executive Order 13166 Implementation of Services Accessibility Provisions for All Grant Application Packages and Funding Opportunity Announcements

Should you successfully compete for an award, recipients of Federal financial assistance (FFA) from HHS must administer their programs in compliance with Federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex (including gender identity, sexual orientation, and pregnancy). This includes ensuring programs are accessible to persons with limited English proficiency and persons with

disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. Please see <https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html> and <https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html>.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting your legal obligation to take reasonable steps to ensure meaningful access to your programs or activities by limited English proficiency individuals, see <https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html> and <https://www.lep.gov>.

- For information on your specific legal obligations for serving qualified individuals with disabilities, including reasonable modifications and making services accessible to them, see <https://www.hhs.gov/ocr/civilrights/understanding/disability/index.html>.

- HHS funded health and education programs must be administered in an environment free of sexual harassment. See <https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html>.

- For guidance on administering your program in compliance with applicable Federal religious nondiscrimination laws and applicable Federal conscience protection and associated anti-discrimination laws, see <https://www.hhs.gov/conscience/conscience-protections/index.html> and <https://www.hhs.gov/conscience/religious-freedom/index.html>.

F. Federal Awardee Performance and Integrity Information System (FAPIIS)

The IHS is required to review and consider any information about the applicant that is in the FAPIIS at <https://www.fapiis.gov> before making any award in excess of the simplified acquisition threshold (currently \$250,000) over the period of performance. An applicant may review and comment on any information about itself that a Federal awarding agency previously entered. IHS will consider any comments by the applicant, in addition to other information in FAPIIS, in making a judgment about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 45 CFR 75.205.

As required by 45 CFR part 75 Appendix XII of the Uniform Guidance, NFEs are required to disclose in FAPIIS

any information about criminal, civil, and administrative proceedings, and/or affirm that there is no new information to provide. This applies to NFEs that receive Federal awards (currently active grants, cooperative agreements, and procurement contracts) greater than \$10,000,000 for any period of time during the period of performance of an award/project.

Mandatory Disclosure Requirements

As required by 2 CFR part 200 of the Uniform Guidance, and the HHS implementing regulations at 45 CFR part 75, the IHS must require an NFE or an applicant for a Federal award to disclose, in a timely manner, in writing to the IHS or pass-through entity all violations of Federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the Federal award.

All applicants and recipients must disclose in writing, in a timely manner, to the IHS and to the HHS Office of Inspector General all information related to violations of Federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the Federal award. 45 CFR 75.113.

Disclosures must be sent in writing to: U.S. Department of Health and Human Services, Indian Health Service, Division of Grants Management, ATTN: Paul Gettys, Acting Director, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857. (Include "Mandatory Grant Disclosures" in subject line), Office: (301) 443-5204, Fax: (301) 594-0899, Email: Paul.Gettys@ihs.gov.

AND

U.S. Department of Health and Human Services, Office of Inspector General, ATTN: Mandatory Grant Disclosures, Intake Coordinator, 330 Independence Avenue SW, Cohen Building, Room 5527, Washington, DC 20201, URL: <https://oig.hhs.gov/fraud/report-fraud/>. (Include "Mandatory Grant Disclosures" in subject line), Fax: (202) 205-0604 (Include "Mandatory Grant Disclosures" in subject line) or, Email: MandatoryGranteeDisclosures@oig.hhs.gov.

Failure to make required disclosures can result in any of the remedies described in 45 CFR 75.371 Remedies for noncompliance, including suspension or debarment (see 2 CFR part 180 and 2 CFR part 376).

VII. Agency Contacts

1. Questions on the programmatic issues may be directed to: LCDR Monique Richards, MSW, LICSW,

Public Health Advisor, Indian Health Service, Division of Behavioral Health, 5600 Fishers Lane, Mail Stop: 08N70C, Rockville, MD 20857, Telephone: (240) 252-9625, Fax: (301) 443-5610, Email: Monique.Richards@ihs.gov.

2. Questions on grants management and fiscal matters may be directed to: Sheila Miller, Grants Management Specialist, Indian Health Service, Division of Grants Management, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, Phone: (240) 535-9308, Fax: (301) 594-0899, Email: Sheila.Miller@ihs.gov.

3. Questions on systems matters may be directed to: Paul Gettys, Acting Director, Division of Grants Management, Indian Health Service, Division of Grants Management, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, Phone: (301) 443-2114; or the DGM main line (301) 443-5204, Fax: (301) 594-0899, email: Paul.Gettys@ihs.gov.

VIII. Other Information

The Public Health Service strongly encourages all grant, cooperative agreement, and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of the facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the HHS mission to protect and advance the physical and mental health of the American people.

Elizabeth A. Fowler,

Acting Director, Indian Health Service.

[FR Doc. 2021-24039 Filed 11-3-21; 8:45 am]

BILLING CODE 4165-16-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Neurological Disorders and Stroke Council.

The meeting will be open to the public. Individuals who plan to participate and need special assistance, such as sign language interpretation or other reasonable accommodations,

should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Neurological Disorders and Stroke Council.

Date: November 29, 2021.

Open: November 29, 2021, 1:00 p.m. to 2:00 p.m.

Agenda: Concept clearance of proposed initiatives.

Open session will be videocast from this link: <https://videocast.nih.gov/>.

Closed: November 29, 2021, 2:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Blvd., Rockville, MD 20852 (Virtual Meeting).

Contact Person: Robert Finkelstein, Ph.D., Director of Extramural Research, National Institute of Neurological Disorders and Stroke, NIH, 6001 Executive Blvd., Suite 3309, MSC 9531, Rockville, MD 20852, (301) 496-9248, finkelsr@ninds.nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice at least 10 days in advance of the meeting. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: www.ninds.nih.gov, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: October 29, 2021.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021-23999 Filed 11-3-21; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Diabetes Self-Care.

Date: November 15, 2021.

Time: 12:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Elena Sanovich, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7351, 6707 Democracy Boulevard, Bethesda, MD 20892-2542, 301-594-8886, sanoviche@mail.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Wearable Devices.

Date: November 16, 2021.

Time: 12:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Elena Sanovich, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7351, 6707 Democracy Boulevard, Bethesda, MD 20892-2542, 301-594-8886, sanoviche@mail.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology

and Hematology Research, National Institutes of Health, HHS)

Dated: October 29, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021-24029 Filed 11-3-21; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel; Fogarty HIV Research Training Program for Low- and Middle-Income Country Institutions.

Date: December 2–3, 2021.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Maureen Shuh, Ph.D., Scientific Review Officer, Center for Scientific Review, 6701 Rockledge Drive, Bethesda, MD 20892, 301-480-4097, maureen.shuh@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Genes, Genomes and Genetics.

Date: December 6, 2021.

Time: 12:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Elena Smirnova, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5187, MSC 7840, Bethesda, MD 20892, 301-357-9112, smirnove@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Topics Focused on Alzheimer's Disease and Alzheimer's-Related Dementia.

Date: December 7–8, 2021.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Tara Roshell Earl, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1007C, Bethesda, MD 20892, (301) 451-3946, earltr@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Respiratory Sciences.

Date: December 13–14, 2021.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Ghenima Dirami, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4122, MSC 7814, Bethesda, MD 20892, (240) 498-7546, diramig@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: October 31, 2021.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021-24053 Filed 11-3-21; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT:

Peter Soukas, J.D., 301-496-2644; peter.soukas@nih.gov. Licensing information and copies of the patent applications listed below may be obtained by communicating with the

indicated licensing contact at the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD, 20852; tel. 301-496-2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.

SUPPLEMENTARY INFORMATION:

Technology description follows.

Recombinant Chimeric Bovine/Human Parainfluenza Virus 3 Expressing SARS-CoV-2 Spike Protein and Its Use

Description of Technology

Vaccines for SARS-CoV-2 are increasingly available under emergency use authorizations; however, indications are currently limited to individuals twelve (12) years or older. They also involve intramuscular immunization, which does not directly stimulate local immunity in the respiratory tract, the primary site of SARS-CoV-2 infection, shedding and spread. While the major burden of COVID-19 disease is in adults, infection and disease also occur in infants and young children, contributing to viral transmission. Therefore, the development of safe and effective pediatric COVID-19 vaccines is important. Ideally, a vaccine should be effective as a single dose, should induce mucosal immunity with the ability to restrict SARS-CoV-2 infection and respiratory shedding, and should easily coordinate with vaccines for other illnesses, such as HPIV3.

The live-attenuated vaccine candidates are based on a recombinant chimeric bovine/human parainfluenza virus 3 (rB/HPIV3) vector expressing prefusion-stabilized versions of the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Spike (S) protein. The B/HPIV3-SARS CoV-2 vaccine candidates are designed to be administered intranasally by drops or spray to infants and young children. The vaccines are expected to induce durable and broad systemic and respiratory mucosal immunity against SARS-CoV-2 and HPIV3. Immunogenicity and protective efficacy against SARS-CoV-2 challenge was confirmed in experimental animals including non-human primates. Based on experience with this B/HPIV3 platform and other live-attenuated PIV vaccine candidates in previous pediatric clinical studies, the present candidates are anticipated to be well-tolerated in humans, including infants and young children, and are available for clinical evaluation. The National Institute of Allergy and Infectious Diseases has extensive experience and capability in

evaluating live-attenuated respiratory virus vaccine candidates in pediatric clinical studies, including PIV vaccine candidates, and opportunity for collaboration exists.

This technology is available for nonexclusive licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404, as well as for further development and evaluation under a research collaboration.

Potential Commercial Applications

- Viral diagnostics
- Vaccine research

Competitive Advantages

- Ease of manufacture
- B cell and T cell activation
- Low-cost vaccines
- Intranasal administration/needle-free delivery

Development Stage

- *In vivo* data assessment (animal)

Inventors: Ursula Buchholz (NIAID), Shirin Munir (NIAID), Cyril Le Nouen (NIAID), Xueqiao Liu (NIAID), Cindy Luongo (NIAID), Peter Collins (NIAID).

Intellectual Property: HHS Reference No. E-239-2020-0—U.S. Provisional Application No. 63/180,534, filed April 27, 2021.

Licensing Contact: Peter Soukas, J.D., 301-496-2644; peter.soukas@nih.gov.

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize for development of a vaccine for respiratory or other infections. For collaboration opportunities, please contact Peter Soukas, J.D., 301-496-2644; peter.soukas@nih.gov.

Dated: October 29, 2021.

Surekha Vathyam,

Deputy Director, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases.

[FR Doc. 2021-24028 Filed 11-3-21; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Risk Prevention and Health Behavior.

Date: November 30, 2021.

Time: 12:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Pamela Jeter, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 10J08, Bethesda, MD 20892, (301) 435-2591, pamela.jeter@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR-19-222: Small Grants for New Investigators to Promote Diversity in Health-Related Research (R21 Clinical Trial Optional).

Date: December 6, 2021.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Jonathan K. Ivins, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2190, MSC 7850, Bethesda, MD 20892, (301) 594-1245, ivinsj@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Neuropharmacology and Physiology.

Date: December 8, 2021.

Time: 12:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Christine Jean DiDonato, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1014J, Bethesda, MD 20892, (301) 435-1042, didonatocj@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: October 29, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021-24027 Filed 11-3-21; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the meeting of the Biomedical Informatics, Library and Data Sciences Review Committee.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable materials, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Biomedical Informatics, Library and Data Sciences Review Committee (BILDS).

Date: March 3, 2022.

Time: 10:00 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Contact Person: Zoe E. Huang, MD, Chief Scientific Review Officer, Scientific Review Office, Extramural Programs, National Library of Medicine, National Institutes of Health (NIH), 6705 Rockledge Drive, Suite 500, Bethesda, MD 20892-7968, 301-594-4937, huangz@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program No. 93.879, Medical Library Assistance, National Institutes of Health, HHS)

Dated: October 29, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021-24033 Filed 11-3-21; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; RC2 Hematology Applications.

Date: December 1, 2021.

Time: 4:00 p.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Video Meeting).

Contact Person: Ryan G. Morris, Ph.D., Scientific Review Officer, Review Branch, Division of Extramural Activities, NIDDK, National Institutes of Health, Room 7015, 6707 Democracy Boulevard, Bethesda, MD 20892–2542, 301–594–4721, ryan.morris@nih.gov.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; RC2 Nephrology Applications.

Date: December 2, 2021.

Time: 4:00 p.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Video Meeting).

Contact Person: Ryan G. Morris, Ph.D., Scientific Review Officer, Review Branch, Division of Extramural Activities, NIDDK, National Institutes of Health, Room 7015, 6707 Democracy Boulevard, Bethesda, MD 20892–2542, 301–594–4721, ryan.morris@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: October 29, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–24034 Filed 11–3–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health and Human Development; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Board on Medical Rehabilitation Research.

The meeting will be held as a virtual meeting and is open to the public. Individuals who plan to view the virtual meeting and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The meeting will be videocast and can be accessed from the NIH Videocasting website (<http://videocast.nih.gov>).

Name of Committee: National Advisory Board on Medical Rehabilitation Research.

Date: December 6–7, 2021.

Time: December 6, 2021, 10:00 a.m. to 2:30 p.m.

Agenda: NICHD Director's report; NCMRR Director's report; Highlighting Pediatric Rehabilitation and Robotics; Concept Clearance; Highlighting Caregiving during COVID.

Place: Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Room 2116, Bethesda, MD 20892–7510 (Virtual Meeting).

Time: December 7, 2021, 10:00 a.m. to 3:00 p.m.

Agenda: Progress on the NIH Rehabilitation Research Plan; Updates on Equity, Diversity, and Inclusion (NICHD STRIVE initiative); NIH Common Fund Activities; Highlighting Wearable Technologies and Data Analysis; Agenda Planning for Next Board Meeting in May 2022.

Place: Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Room 2116, Bethesda, MD 20892–7510 (Virtual Meeting).

Contact Person: Ralph M. Nitkin, Ph.D., Deputy, National Center for Medical Rehabilitation Research and Director, Biological Sciences and Career Development Program, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Room 2116, Bethesda, MD 20892–7510, (301) 402–4206, nitkinr@mail.nih.gov.

Information is also available on the Institute's/Center's home page: <https://www.nichd.nih.gov/about/advisory/nabmrr>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: October 31, 2021.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–24054 Filed 11–3–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[212A2100DD/AAKC001030/A0A501010.999900]

HEARTH Act Approval of Cabazon Band of Mission Indians, California Business Site Leasing Ordinance

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: The Bureau of Indian Affairs (BIA) approved the Cabazon Band of Mission Indians, California Business Site Leasing Ordinance under the Helping Expedite and Advance Responsible Tribal Homeownership Act of 2012 (HEARTH Act). With this approval, the Tribe is authorized to enter into business leases without further BIA approval.

DATES: BIA issued the approval on October 26, 2021.

FOR FURTHER INFORMATION CONTACT: Ms. Sharlene Round Face, Bureau of Indian Affairs, Division of Real Estate Services, 1001 Indian School Road NW, Albuquerque, NM 87104, sharlene.roundface@bia.gov, (505) 563–3132.

SUPPLEMENTARY INFORMATION:

I. Summary of the HEARTH Act

The HEARTH Act makes a voluntary, alternative land leasing process available to Tribes, by amending the Indian Long-Term Leasing Act of 1955, 25 U.S.C. 415. The HEARTH Act authorizes Tribes to negotiate and enter into business leases of Tribal trust lands with a primary term of 25 years, and up to two renewal terms of 25 years each, without the approval of the Secretary of the Interior (Secretary). The HEARTH Act also authorizes Tribes to enter into

leases for residential, recreational, religious, or educational purposes for a primary term of up to 75 years without the approval of the Secretary. Participating Tribes develop regulations, including an environmental review process, and then must obtain the Secretary's approval of those regulations prior to entering into leases. The HEARTH Act requires the Secretary to approve Tribal regulations if the Tribal regulations are consistent with the Department of the Interior's (Department) leasing regulations at 25 CFR part 162 and provide for an environmental review process that meets requirements set forth in the HEARTH Act. This notice announces that the Secretary, through the Assistant Secretary—Indian Affairs, has approved the Tribal regulations for the Cabazon Band of Mission Indians, California.

II. Federal Preemption of State and Local Taxes

The Department's regulations governing the surface leasing of trust and restricted Indian lands specify that, subject to applicable Federal law, permanent improvements on leased land, leasehold or possessory interests, and activities under the lease are not subject to State and local taxation and may be subject to taxation by the Indian Tribe with jurisdiction. See 25 CFR 162.017. As explained further in the preamble to the final regulations, the Federal government has a strong interest in promoting economic development, self-determination, and Tribal sovereignty. 77 FR 72440, 72447–48 (December 5, 2012). The principles supporting the Federal preemption of State law in the field of Indian leasing and the taxation of lease-related interests and activities applies with equal force to leases entered into under Tribal leasing regulations approved by the Federal government pursuant to the HEARTH Act.

Section 5 of the Indian Reorganization Act, 25 U.S.C. 5108, preempts State and local taxation of permanent improvements on trust land. *Confederated Tribes of the Chehalis Reservation v. Thurston County*, 724 F.3d 1153, 1157 (9th Cir. 2013) (citing *Mescalero Apache Tribe v. Jones*, 411 U.S. 145 (1973)). Similarly, section 5108 preempts State taxation of rent payments by a lessee for leased trust lands, because “tax on the payment of rent is indistinguishable from an impermissible tax on the land.” See *Seminole Tribe of Florida v. Stranburg*, 799 F.3d 1324, 1331, n.8 (11th Cir. 2015). In addition, as explained in the preamble to the revised leasing regulations at 25 CFR part 162, Federal

courts have applied a balancing test to determine whether State and local taxation of non-Indians on the reservation is preempted. *White Mountain Apache Tribe v. Bracker*, 448 U.S. 136, 143 (1980). The *Bracker* balancing test, which is conducted against a backdrop of “traditional notions of Indian self-government,” requires a particularized examination of the relevant State, Federal, and Tribal interests. We hereby adopt the *Bracker* analysis from the preamble to the surface leasing regulations, 77 FR at 72447–48, as supplemented by the analysis below.

The strong Federal and Tribal interests against State and local taxation of improvements, leaseholds, and activities on land leased under the Department's leasing regulations apply equally to improvements, leaseholds, and activities on land leased pursuant to Tribal leasing regulations approved under the HEARTH Act. Congress's overarching intent was to “allow Tribes to exercise greater control over their own land, support self-determination, and eliminate bureaucratic delays that stand in the way of homeownership and economic development in Tribal communities.” 158 Cong. Rec. H. 2682 (May 15, 2012). The HEARTH Act was intended to afford Tribes “flexibility to adapt lease terms to suit [their] business and cultural needs” and to “enable [Tribes] to approve leases quickly and efficiently.” H. Rep. 112–427 at 6 (2012).

Assessment of State and local taxes would obstruct these express Federal policies supporting Tribal economic development and self-determination, and also threaten substantial Tribal interests in effective Tribal government, economic self-sufficiency, and territorial autonomy. See *Michigan v. Bay Mills Indian Community*, 572 U.S. 782, 810 (2014) (Sotomayor, J., concurring) (determining that “[a] key goal of the Federal Government is to render Tribes more self-sufficient, and better positioned to fund their own sovereign functions, rather than relying on Federal funding”). The additional costs of State and local taxation have a chilling effect on potential lessees, as well as on a Tribe that, as a result, might refrain from exercising its own sovereign right to impose a Tribal tax to support its infrastructure needs. See *id.* at 810–11 (finding that State and local taxes greatly discourage Tribes from raising tax revenue from the same sources because the imposition of double taxation would impede Tribal economic growth).

Similar to BIA's surface leasing regulations, Tribal regulations under the

HEARTH Act pervasively cover all aspects of leasing. See 25 U.S.C. 415(h)(3)(B)(i) (requiring Tribal regulations be consistent with BIA surface leasing regulations). Furthermore, the Federal government remains involved in the Tribal land leasing process by approving the Tribal leasing regulations in the first instance and providing technical assistance, upon request by a Tribe, for the development of an environmental review process. The Secretary also retains authority to take any necessary actions to remedy violations of a lease or of the Tribal regulations, including terminating the lease or rescinding approval of the Tribal regulations and reassuming lease approval responsibilities. Moreover, the Secretary continues to review, approve, and monitor individual Indian land leases and other types of leases not covered under the Tribal regulations according to the Part 162 regulations.

Accordingly, the Federal and Tribal interests weigh heavily in favor of preemption of State and local taxes on lease-related activities and interests, regardless of whether the lease is governed by Tribal leasing regulations or Part 162. Improvements, activities, and leasehold or possessory interests may be subject to taxation by the Cabazon Band of Mission Indians, California.

Bryan Newland,

Assistant Secretary—Indian Affairs.

[FR Doc. 2021–24089 Filed 11–3–21; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[212A2100DD/AAKC001030/
A0A501010.999900]

HEARTH Act Approval of Sycuan Band of the Kumeyaay Nation Business Leasing Regulations

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: The Bureau of Indian Affairs (BIA) approved the Sycuan Band of the Kumeyaay Nation Business Leasing Regulations under the Helping Expedite and Advance Responsible Tribal Homeownership Act of 2012 (HEARTH Act). With this approval, the Tribe is authorized to enter into business leases without further BIA approval.

DATES: BIA issued the approval on October 29, 2021.

FOR FURTHER INFORMATION CONTACT: Ms. Sharlene Round Face, Bureau of Indian Affairs, Division of Real Estate Services, 1001 Indian School Road NW, Albuquerque, NM 87104, sharlene.roundface@bia.gov, (505) 563-3132.

SUPPLEMENTARY INFORMATION:

I. Summary of the HEARTH Act

The HEARTH Act makes a voluntary, alternative land leasing process available to Tribes, by amending the Indian Long-Term Leasing Act of 1955, 25 U.S.C. 415. The HEARTH Act authorizes Tribes to negotiate and enter into business leases of Tribal trust lands with a primary term of 25 years, and up to two renewal terms of 25 years each, without the approval of the Secretary of the Interior (Secretary). The HEARTH Act also authorizes Tribes to enter into leases for residential, recreational, religious, or educational purposes for a primary term of up to 75 years without the approval of the Secretary. Participating Tribes develop Tribal leasing regulations, including an environmental review process, and then must obtain the Secretary's approval of those regulations prior to entering into leases. The HEARTH Act requires the Secretary to approve Tribal regulations if the Tribal regulations are consistent with the Department of the Interior's (Department) leasing regulations at 25 CFR part 162 and provide for an environmental review process that meets requirements set forth in the HEARTH Act. This notice announces that the Secretary, through the Assistant Secretary—Indian Affairs, has approved the Tribal regulations for the Sycuan Band of the Kumeyaay Nation.

II. Federal Preemption of State and Local Taxes

The Department's regulations governing the surface leasing of trust and restricted Indian lands specify that, subject to applicable Federal law, permanent improvements on leased land, leasehold or possessory interests, and activities under the lease are not subject to State and local taxation and may be subject to taxation by the Indian Tribe with jurisdiction. See 25 CFR 162.017. As explained further in the preamble to the final regulations, the Federal government has a strong interest in promoting economic development, self-determination, and Tribal sovereignty. 77 FR 72440, 72447–48 (December 5, 2012). The principles supporting the Federal preemption of State law in the field of Indian leasing and the taxation of lease-related interests and activities applies with equal force to leases entered into under

Tribal leasing regulations approved by the Federal government pursuant to the HEARTH Act.

Section 5 of the Indian Reorganization Act, 25 U.S.C. 5108, preempts State and local taxation of permanent improvements on trust land. *Confederated Tribes of the Chehalis Reservation v. Thurston County*, 724 F.3d 1153, 1157 (9th Cir. 2013) (citing *Mescalero Apache Tribe v. Jones*, 411 U.S. 145 (1973)). Similarly, section 5108 preempts State taxation of rent payments by a lessee for leased trust lands, because “tax on the payment of rent is indistinguishable from an impermissible tax on the land.” See *Seminole Tribe of Florida v. Strasburg*, 799 F.3d 1324, 1331, n.8 (11th Cir. 2015). In addition, as explained in the preamble to the revised leasing regulations at 25 CFR part 162, Federal courts have applied a balancing test to determine whether State and local taxation of non-Indians on the reservation is preempted. *White Mountain Apache Tribe v. Bracker*, 448 U.S. 136, 143 (1980). The *Bracker* balancing test, which is conducted against a backdrop of “traditional notions of Indian self-government,” requires a particularized examination of the relevant State, Federal, and Tribal interests. We hereby adopt the *Bracker* analysis from the preamble to the surface leasing regulations, 77 FR at 72447–48, as supplemented by the analysis below.

The strong Federal and Tribal interests against State and local taxation of improvements, leaseholds, and activities on land leased under the Department's leasing regulations apply equally to improvements, leaseholds, and activities on land leased pursuant to Tribal leasing regulations approved under the HEARTH Act. Congress's overarching intent was to “allow Tribes to exercise greater control over their own land, support self-determination, and eliminate bureaucratic delays that stand in the way of homeownership and economic development in Tribal communities.” 158 Cong. Rec. H. 2682 (May 15, 2012). The HEARTH Act was intended to afford Tribes “flexibility to adapt lease terms to suit [their] business and cultural needs” and to “enable [Tribes] to approve leases quickly and efficiently.” H. Rep. 112–427 at 6 (2012).

Assessment of State and local taxes would obstruct these express Federal policies supporting Tribal economic development and self-determination, and also threaten substantial Tribal interests in effective Tribal government, economic self-sufficiency, and territorial autonomy. See *Michigan v. Bay Mills*

Indian Community, 572 U.S. 782, 810 (2014) (Sotomayor, J., concurring) (determining that “[a] key goal of the Federal Government is to render Tribes more self-sufficient, and better positioned to fund their own sovereign functions, rather than relying on Federal funding”). The additional costs of State and local taxation have a chilling effect on potential lessees, as well as on a Tribe that, as a result, might refrain from exercising its own sovereign right to impose a Tribal tax to support its infrastructure needs. See *id.* at 810–11 (finding that State and local taxes greatly discourage Tribes from raising tax revenue from the same sources because the imposition of double taxation would impede Tribal economic growth).

Similar to BIA's surface leasing regulations, Tribal regulations under the HEARTH Act pervasively cover all aspects of leasing. See 25 U.S.C. 415 (h)(3)(B)(i) (requiring Tribal regulations be consistent with BIA surface leasing regulations). Furthermore, the Federal government remains involved in the Tribal land leasing process by approving the Tribal leasing regulations in the first instance and providing technical assistance, upon request by a Tribe, for the development of an environmental review process. The Secretary also retains authority to take any necessary actions to remedy violations of a lease or of the Tribal regulations, including terminating the lease or rescinding approval of the Tribal regulations and reassuming lease approval responsibilities. Moreover, the Secretary continues to review, approve, and monitor individual Indian land leases and other types of leases not covered under the Tribal regulations according to the Part 162 regulations.

Accordingly, the Federal and Tribal interests weigh heavily in favor of preemption of State and local taxes on lease-related activities and interests, regardless of whether the lease is governed by Tribal leasing regulations or Part 162. Improvements, activities, and leasehold or possessory interests may be subject to taxation by the Sycuan Band of the Kumeyaay Nation.

Bryan Newland,

Assistant Secretary—Indian Affairs.

[FR Doc. 2021–24092 Filed 11–3–21; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[212A2100DD/AAK001030/
AOA501010.999900]**HEARTH Act Approval of Pascua Yaqui Tribe of Arizona Residential Leasing Ordinance****AGENCY:** Bureau of Indian Affairs, Interior.**ACTION:** Notice.

SUMMARY: The Bureau of Indian Affairs (BIA) approved the Pascua Yaqui Tribe of Arizona Residential Leasing Ordinance under the Helping Expedite and Advance Responsible Tribal Homeownership Act of 2012 (HEARTH Act). With this approval, the Tribe is authorized to enter into residential leases without further BIA approval.

DATES: BIA issued the approval on October 26, 2021.

FOR FURTHER INFORMATION CONTACT: Ms. Sharlene Round Face, Bureau of Indian Affairs, Division of Real Estate Services, 1001 Indian School Road NW, Albuquerque, NM 87104, sharlene.roundface@bia.gov, (505) 563-3132.

SUPPLEMENTARY INFORMATION:**I. Summary of the HEARTH Act**

The HEARTH Act makes a voluntary, alternative land leasing process available to Tribes, by amending the Indian Long-Term Leasing Act of 1955, 25 U.S.C. 415. The HEARTH Act authorizes Tribes to negotiate and enter into business leases of Tribal trust lands with a primary term of 25 years, and up to two renewal terms of 25 years each, without the approval of the Secretary of the Interior (Secretary). The HEARTH Act also authorizes Tribes to enter into leases for residential, recreational, religious or educational purposes for a primary term of up to 75 years without the approval of the Secretary. Participating Tribes develop Tribal leasing regulations, including an environmental review process, and then must obtain the Secretary's approval of those regulations prior to entering into leases. The HEARTH Act requires the Secretary to approve Tribal regulations if the Tribal regulations are consistent with the Department of the Interior's (Department) leasing regulations at 25 CFR part 162 and provide for an environmental review process that meets requirements set forth in the HEARTH Act. This notice announces that the Secretary, through the Assistant Secretary—Indian Affairs, has approved the Tribal regulations for the Pascua Yaqui Tribe of Arizona.

II. Federal Preemption of State and Local Taxes

The Department's regulations governing the surface leasing of trust and restricted Indian lands specify that, subject to applicable Federal law, permanent improvements on leased land, leasehold or possessory interests, and activities under the lease are not subject to State and local taxation and may be subject to taxation by the Indian Tribe with jurisdiction. See 25 CFR 162.017. As explained further in the preamble to the final regulations, the Federal government has a strong interest in promoting economic development, self-determination, and Tribal sovereignty. 77 FR 72440, 72447–48 (December 5, 2012). The principles supporting the Federal preemption of State law in the field of Indian leasing and the taxation of lease-related interests and activities applies with equal force to leases entered into under Tribal leasing regulations approved by the Federal government pursuant to the HEARTH Act.

Section 5 of the Indian Reorganization Act, 25 U.S.C. 5108, preempts State and local taxation of permanent improvements on trust land. *Confederated Tribes of the Chehalis Reservation v. Thurston County*, 724 F.3d 1153, 1157 (9th Cir. 2013) (citing *Mescalero Apache Tribe v. Jones*, 411 U.S. 145 (1973)). Similarly, section 5108 preempts State taxation of rent payments by a lessee for leased trust lands, because “tax on the payment of rent is indistinguishable from an impermissible tax on the land.” See *Seminole Tribe of Florida v. Stranburg*, 799 F.3d 1324, 1331, n.8 (11th Cir. 2015). In addition, as explained in the preamble to the revised leasing regulations at 25 CFR part 162, Federal courts have applied a balancing test to determine whether State and local taxation of non-Indians on the reservation is preempted. *White Mountain Apache Tribe v. Bracker*, 448 U.S. 136, 143 (1980). The *Bracker* balancing test, which is conducted against a backdrop of “traditional notions of Indian self-government,” requires a particularized examination of the relevant State, Federal, and Tribal interests. We hereby adopt the *Bracker* analysis from the preamble to the surface leasing regulations, 77 FR 72447–48, as supplemented by the analysis below.

The strong Federal and Tribal interests against State and local taxation of improvements, leaseholds, and activities on land leased under the Department's leasing regulations apply equally to improvements, leaseholds,

and activities on land leased pursuant to Tribal leasing regulations approved under the HEARTH Act. Congress's overarching intent was to “allow Tribes to exercise greater control over their own land, support self-determination, and eliminate bureaucratic delays that stand in the way of homeownership and economic development in Tribal communities.” 158 Cong. Rec. H. 2682 (May 15, 2012). The HEARTH Act was intended to afford Tribes “flexibility to adapt lease terms to suit [their] business and cultural needs” and to “enable [Tribes] to approve leases quickly and efficiently.” H. Rep. 112–427 at 6 (2012).

Assessment of State and local taxes would obstruct these express Federal policies supporting Tribal economic development and self-determination, and also threaten substantial Tribal interests in effective Tribal government, economic self-sufficiency, and territorial autonomy. See *Michigan v. Bay Mills Indian Community*, 572 U.S. 782, 810 (2014) (Sotomayor, J., concurring) (determining that “[a] key goal of the Federal Government is to render Tribes more self-sufficient, and better positioned to fund their own sovereign functions, rather than relying on Federal funding”). The additional costs of State and local taxation have a chilling effect on potential lessees, as well as on a Tribe that, as a result, might refrain from exercising its own sovereign right to impose a Tribal tax to support its infrastructure needs. See *id.* at 810–11 (finding that State and local taxes greatly discourage Tribes from raising tax revenue from the same sources because the imposition of double taxation would impede Tribal economic growth).

Similar to BIA's surface leasing regulations, Tribal regulations under the HEARTH Act pervasively cover all aspects of leasing. See 25 U.S.C. 415 (h)(3)(B)(i) (requiring Tribal regulations be consistent with BIA surface leasing regulations). Furthermore, the Federal government remains involved in the Tribal land leasing process by approving the Tribal leasing regulations in the first instance and providing technical assistance, upon request by a Tribe, for the development of an environmental review process. The Secretary also retains authority to take any necessary actions to remedy violations of a lease or of the Tribal regulations, including terminating the lease or rescinding approval of the Tribal regulations and reassuming lease approval responsibilities. Moreover, the Secretary continues to review, approve, and monitor individual Indian land leases and other types of leases not covered

under the Tribal regulations according to the Part 162 regulations.

Accordingly, the Federal and Tribal interests weigh heavily in favor of preemption of State and local taxes on lease-related activities and interests, regardless of whether the lease is governed by Tribal leasing regulations or Part 162. Improvements, activities, and leasehold or possessory interests may be subject to taxation by the Pascua Yaqui Tribe of Arizona.

Bryan Newland,

Assistant Secretary—Indian Affairs.

[FR Doc. 2021–24091 Filed 11–3–21; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Office of the Secretary

[DOI–2021–0011; 22XD4523WS, DWSN00000.000000, DS64800000, DP64803]

Privacy Act of 1974; System of Records

AGENCY: Office of the Secretary, Interior.

ACTION: Notice of a new system of records.

SUMMARY: Pursuant to the provisions of the Privacy Act of 1974, as amended, the Department of the Interior (DOI) is issuing a public notice of its intent to create a new Privacy Act system of records titled, “INTERIOR/DOI–92, Public Health Emergency Response Records.” This system of records notice (SORN) describes DOI’s collection, maintenance, and use of records on individuals associated with DOI efforts to respond to the Coronavirus Disease 2019 (COVID–19), a declared public health emergency, and protect the health and safety of its workforce and members of the public. This newly established system will be included in DOI’s inventory of record systems.

DATES: This new system will be effective upon publication. New routine uses will be effective December 6, 2021. Submit comments on or before December 6, 2021.

ADDRESSES: You may send comments identified by docket number [DOI–2021–0011] by any of the following methods:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for sending comments.
- *Email:* DOI_Privacy@ios.doi.gov. Include docket number [DOI–2021–0011] in the subject line of the message.
- *U.S. mail or hand-delivery:* Teri Barnett, Departmental Privacy Officer, U.S. Department of the Interior, 1849 C

Street NW, Room 7112, Washington, DC 20240.

Instructions: All submissions received must include the agency name and docket number [DOI–2021–0011]. All comments received will be posted without change to <https://www.regulations.gov>, including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to <https://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Teri Barnett, Departmental Privacy Officer, U.S. Department of the Interior, 1849 C Street NW, Washington, DC 20240, DOI_Privacy@ios.doi.gov or 202–208–1605.

SUPPLEMENTARY INFORMATION:

I. Background

The DOI Office of Occupational Safety and Health (OSH) is establishing a new Department-wide system of records, INTERIOR/DOI–92, Public Health Emergency Response Records. This system will help DOI manage records related to DOI’s response to the COVID–19 public health emergency and future high consequence public health threats, support emergency or medically related decisions affecting DOI personnel, and ensure the health and safety of the various categories of personnel, contractors, grantees, detailees, volunteers, interns, long-term trainees, and visitors at DOI owned, operated, leased or managed facilities or properties.

This system supports DOI’s COVID–19 vaccination and testing program as required by Executive Orders 14043 and 14042; Office of Management and Budget (OMB) Memorandums M–21–15 and M–21–25; COVID–19 Workplace Safety: Agency Model Safety Principles issued by the Federal Safer Federal Workforce Task Force; and other applicable law and policy. Federal labor, employment and workforce health and safety laws that govern the collection, dissemination, and retention of DOI employees’ medical information include the Americans with Disability Act (ADA), the Rehabilitation Act of 1973 (Rehab Act), and the Occupational Safety and Health Act of 1970. The Department of Health and Human Services (HHS) Secretary may, under section 319 of the Public Health Service (PHS) Act codified at 42 U.S.C 247d, declare that: (a) A disease or disorder presents a public health emergency; or (b) that a public health emergency, including significant outbreaks of infectious disease or bioterrorist attacks, otherwise exists.

The Occupational Safety and Health Act (OSHA) of 1970, Public Law 91–596, 29 U.S.C. 668, Section 19(a) requires the head of each Federal agency to establish and maintain an effective and comprehensive occupational safety and health program and safe and healthful places and conditions of employment, and to keep adequate records of all occupational accidents and illnesses for proper evaluation and necessary corrective action. OSHA also requires that Federal agencies maintain an injury and illness prevention program, which is a proactive process designed to reduce injuries, illnesses, and fatalities. State governors also have the authority to declare public health emergencies by executive order or other declaration. State declared public health emergencies could also involve a significant risk of substantial harm to DOI personnel or visitors at DOI buildings, facilities and events.

Executive Order 14043, *Requiring Coronavirus Disease 2019 Vaccination for Federal Employees*, signed September 9, 2021, establishes mandatory requirements for Federal executive agencies to implement a program to require COVID–19 vaccinations for Federal employees, with some exceptions as required by law. Additionally, Executive Order 14042, *Ensuring Adequate COVID Safety Protocols for Federal Contractors*, signed September 9, 2021, establishes requirements for Federal executive agencies to implement workplace safety protocols for contractors and subcontractors to protect the health and safety of the Federal workforce and members of the public. DOI is implementing these requirements to ensure the safety of its workforce and visitors to its facilities and sponsored events.

DOI will collect and maintain information within the scope of this system of records when it is determined that it is authorized and necessary to meet Federal requirements and respond to a declared public health emergency. To make this determination, DOI will evaluate the privacy risks for the collection of information, who the information pertains to, how the information is used and shared, the actions needed to protect individuals and respond to the public health emergency, and the laws that may apply, including the U.S. Constitution, Executive orders, Federal privacy laws, Federal labor and employment laws, and Federal workforce health and safety laws.

DOI will only collect the minimum information necessary to respond to COVID–19, or future high consequence

public health threat, and comply with Federal workforce safety requirements, when DOI determines that a significant risk of substantial harm exists to individuals working at or visiting a DOI controlled facility, or attending a DOI sponsored event in a non-DOI controlled facility. These circumstances may include mitigation response activities in response to: (1) An Executive order or mandate or health related declaration of a national emergency by the President; (2) a declared public health emergency by the HHS Secretary; (3) when designated Federal or state officials make a declaration or official determination that a public health emergency exists; or (4) when DOI determines that a significant risk of substantial harm exists to the health of DOI personnel or visitors and it is necessary to ensure their health and safety in accordance with the Centers for Disease Control and Prevention (CDC) and other Federal and local guidance on communicable disease.

DOI's responsibilities for ensuring a safe workforce and secure buildings and workspaces depend on the nature and circumstances of the public health emergency. In order to meet requirements for workforce safety and the Federal government-wide COVID-19 response, DOI must collect information on its workforce related to the COVID-19 disease to protect its workforce and customers. DOI will make all efforts to minimize the collection of information to the greatest extent possible to protect individual privacy and will only share information when authorized by the subject individuals or when authorized or required by law. Records may include personally identifiable information of individuals who have: (1) Contracted or may have been exposed to a suspected or confirmed disease or illness that is the subject of a declared public health emergency; (2) attested to their vaccination status or are required to participate in a vaccination program; or (3) are required to participate in a testing program or have undergone testing for a disease or illness that is the subject of a declared public health emergency or a Federal, state, or local public health order. Records on individuals may include circumstances and dates of suspected exposure; symptoms, referrals and results of screening or treatments; health status information; and related medical information such as vaccination records and results of testing for disease or illness. DOI may also collect location and dates of potential exposure, information related to employee

requests for reasonable accommodation, and other information that may be relevant or required for DOI to comply with Federal guidelines and prevent or slow the spread of the COVID-19 disease and mitigate health impacts to DOI personnel, visitors, and other individuals at DOI controlled facilities and sponsored events.

DOI is establishing a screening testing program for SARS-CoV-2, the virus that causes COVID-19, in limited circumstances to test personnel who work onsite and who are not fully vaccinated and have requested a legal exception under the law for reasonable accommodations due to medical reasons or religious belief. The purpose of the testing is to identify asymptomatic or presymptomatic infected individuals who may have been exposed to the SARS-CoV-2 virus to protect the health and safety of individuals in DOI buildings, facilities, and events. Employees who are fully vaccinated generally do not need to participate in the testing program. An employee's failure to comply with vaccination or testing requirements may result in disciplinary action, including an adverse action. However, records of proposed disciplinary actions are maintained in other employee personnel records under a separate SORN and will not be maintained in this system of records.

Federal civilian employee medical records are covered by a government-wide Privacy Act SORN published by the Office of Personnel Management (OPM), OPM/GOVT-10, Employee Medical File System Records (75 FR 35099, June 21, 2010; modification published at 80 FR 74815, November 30, 2015). These Federal employee confidential medical records are managed in accordance with OPM regulations at 5 CFR part 293, the OPM/GOVT-10 SORN, and its published routine uses. The OPM/GOVT-10 SORN covers Federal civilians that are identified under Title 5 U.S.C. chapter 21. The majority of DOI Federal employees fall under Title 5 and their medical records are covered by the OPM/GOVT-10 SORN and must be managed in accordance with that SORN and applicable OPM regulations.

This DOI-92 notice covers DOI employees and individuals that do not fall under Title 5 and OPM's personnel recordkeeping authority and thus are not covered by the OPM/GOVT-10 SORN. This includes DOI workers, such as Title 25 Indian education personnel and any other DOI workers, to the extent they are not Federal employees as defined under 5 U.S.C. 2105 or are not subject to OPM regulations. This system

may also include information collected or maintained on DOI personnel, contractors, partners, detailees, volunteers, interns, long-term trainees, and visitors at or on facilities, buildings, grounds, and properties that are owned, operated, leased, managed or used by DOI, or DOI sponsored meetings and events. The information collected is required to conduct health screening for COVID-19 or other high consequence public health threat, and will be used to prevent the spread of disease and reduce the risk of individuals with symptoms of a communicable disease entering a DOI building, facility, or DOI hosted event. As part of health screening efforts, DOI may be required to monitor symptoms to identify persons who may have been exposed to communicable disease, or identify and notify personnel or visitors who were present in a DOI building, facility or event that may have had physical contact with or come into close proximity with individuals who were infected or had symptoms of infection with a communicable disease.

Information in this system may be shared with other DOI bureaus and offices that have a need to know to carry out their mission-essential functions, when it is determined that the sharing is authorized under applicable laws and DOI policy and it is necessary to allow DOI to manage a vaccination and testing program and respond to a declared public health emergency. To the extent permitted by law, DOI may also share information with appropriate Federal, state, local, tribal, territorial, foreign, or international government agencies when authorized and compatible with the purpose of this system, or when proper and necessary, consistent with the routine uses set forth in this system of records notice.

II. Privacy Act

The Privacy Act of 1974, as amended, embodies fair information practice principles in a statutory framework governing the means by which Federal agencies collect, maintain, use, and disseminate individuals' records. The Privacy Act applies to records about individuals that are maintained in a "system of records." A "system of records" is a group of any records under the control of an agency from which information is retrieved by the name of an individual or by some identifying number, symbol, or other identifying particular assigned to the individual. The Privacy Act defines an individual as a United States citizen or lawful permanent resident. Individuals may request access to their own records that are maintained in a system of records in

the possession or under the control of DOI by complying with DOI Privacy Act regulations at 43 CFR part 2, subpart K, and following the procedures outlined in the Records Access, Contesting Record, and Notification Procedures sections of this notice.

The Privacy Act requires each agency to publish in the **Federal Register** a description denoting the existence and character of each system of records that the agency maintains and the routine uses of each system. The INTERIOR/DOI-92, Public Health Emergency Response Records, SORN is published in its entirety below. In accordance with 5 U.S.C. 552a(r), DOI has provided a report of this system of records to the Office of Management and Budget and to Congress.

III. Public Participation

You should be aware your entire comment including your personally identifiable information, such as your address, phone number, email address, or any other personal information in your comment, may be made publicly available at any time. While you may request to withhold your personally identifiable information from public review, we cannot guarantee we will be able to do so.

SYSTEM NAME AND NUMBER:

INTERIOR/DOI-92, Public Health Emergency Response Records.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Records are maintained by the Office of Occupational Safety and Health, U.S. Department of the Interior, 1849 C Street NW, Washington, DC 20240; all DOI bureaus and offices in Washington, DC, and in field locations; and DOI contractor facilities.

SYSTEM MANAGER(S):

Director, Office of Occupational Safety and Health, U.S. Department of the Interior, 1849 C Street NW, Office 4316, Mail Stop 4310, Washington, DC 20240.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301; Section 319 of the Public Health Service (PHS) Act (42 U.S.C. 247d); 40 U.S.C. 1315; Coronavirus Aid, Relief, and Economic Security (CARES) Act, Public Law 116-136, Div. B., Title VIII, sec. 18115, 134 Stat. 574 (codified in 42 U.S.C. 274d note); Americans with Disabilities Act, 42 U.S.C. 12112, 29 CFR 1602.14, 1630.14; the Rehabilitation Act of 1973 (Rehab Act), 29 U.S.C. 701 *et seq.*; Medical Examinations for Fitness for

Duty Requirements, including 5 CFR part 339; the Occupational Safety and Health Act of 1970, 29 U.S.C. Chapter 15, 29 CFR part 1904, 29 CFR 1910.1020, and 29 CFR 1960.66; Executive Order 13991; Executive Order 13994; Executive Order 14042; Executive Order 14043; Executive Order 12196; 5 U.S.C. 7902; 25 U.S.C. 2012, Indian Education Personnel; 25 CFR chapter I, subchapter E, Education; Section 2 of the Reorganization Plan No. 3 of 1950 (64 Stat. 1262).

PURPOSE(S) OF THE SYSTEM:

The purpose of this system is to maintain records related to DOI's response to the COVID-19 public health emergency or other high-consequence public health threat, to manage a workplace health screening and vaccination program, and document results of screening and diagnostic testing to protect the Federal workforce and stop or reduce the spread of infectious disease or illness. This system will be used to:

- (1) Comply with Executive orders, Federal Government and OSHA requirements;
- (2) Manage records as part of the COVID-19 vaccination requirement including confirming vaccination status and maintaining proof of vaccination;
- (3) Manage records related to a testing program including overseeing preventative testing to test personnel working onsite who are not fully vaccinated, and to permit entry to DOI managed or controlled facilities and events to meet Federal requirements and fulfill DOI's responsibilities to the extent permitted by law;
- (4) Conduct screening and testing for select circumstances such as employees who have a need to physically enter another Federal facility or workspace for official DOI business;
- (5) Conduct screening and testing for employees on official travel to meet local requirements where testing is a condition for entry, or for employees on official travel returning from an area of high risk of exposure as a condition of entry to a DOI facility;
- (6) Document reports of illness or communicable disease that are the subject of a declaration of public health emergency by HHS or designated state officials that may pose a significant risk of substantial harm to the health of DOI personnel and visitors;
- (7) Identify and provide notifications to personnel and visitors who may have been exposed to individuals while working onsite or visiting DOI buildings, facilities or events;
- (8) Inform Federal, state or local public health authorities as necessary to

protect public health as allowed or when required by law; and

(9) Take appropriate actions as necessary to prevent the introduction, transmission, and spread of communicable disease by persons who have contracted or were exposed to such a disease and came in close physical proximity to or had physical contact with other persons while working in or visiting a DOI facility or event.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

DOI personnel, including non-Title 5 employees, contractors, detailees, interns, volunteers, long-term trainees; DOI partners and employees and detailees from other Federal agencies; visitors or participants at DOI managed meetings, events and conferences; visitors or individuals who participate in health screening at DOI owned, operated, managed, or leased buildings and facilities; and visitors or individuals who are suspected or confirmed to have a disease or illness that is the subject of a declared public health emergency, or may have been exposed to someone who is suspected or confirmed to have a disease or illness that is the subject of a declared public health emergency.

CATEGORIES OF RECORDS IN THE SYSTEM:

Information collected for health screening includes contact information, vaccination and testing program related information, medical reports and assessments, and other related information that may be required. This information may include but is not limited to:

- Full name;
- Address;
- Bureau, office, organization, duty location, facility, work site, and specific work space(s) accessed;
- Official contact information;
- Work or personal phone number(s);
- Work or personal email address(es);
- Employee's supervisor name, address, and contact information;
- Contractor's supervisor/contracting officer representative name, address, and contact information;
- Date(s) and time(s) of entrance and exit from DOI buildings, facilities, workspaces, or events;
- Date(s) and/or circumstances of the individual's suspected or actual exposure to disease or illness including symptoms, as well as locations within DOI workplaces where an individual may have contracted or been exposed to the disease or illness;
- Names and contact information of other personnel or visitors that the individual interacted with at or on a DOI workspace, facility, or grounds

during the time the individual was suspected to or had contracted the disease or illness;

- Current work status of the individual (e.g., administrative leave, sick leave, teleworking, in the office);
- Vaccination status, dates of vaccination, type of vaccine, and proof of vaccination including copies of COVID-19 Vaccination Record Card, a copy of medical records documenting vaccination, a copy of immunization records, or other official documentation containing information on vaccination;
- Medical screening information including name, date of birth, age, medical status medical history, and other information that may be required;
- Information directly related to screening and testing for disease or illness including but not limited to testing status, date and location of testing, test type, test results, disease type, symptoms, treatments;
- Dates and source of exposure, and recent dates and DOI locations and workspaces visited; and
- Other information that may be relevant and necessary to achieve the purpose of health screening or the vaccination and testing program.

For other agency Federal employees, detailees, partners, non-DOI contractors, visitors and members of the public at or on DOI owned, operated, leased or managed buildings, facilities, and events, the following information may be collected:

- Full name;
- Preferred phone number(s);
- Preferred email address(es);
- Name(s) and contact information for DOI personnel sponsoring visitors or participants at meetings or conferences or meetings in or at DOI workspaces, facilities, buildings, parks and grounds;
- Name(s) of individuals encountered while in or at DOI workspaces, facilities, buildings, parks and grounds;
- Information directly related to screening and testing for disease or illness including but not limited to date of testing, frequency of testing, test results, symptoms, treatments;
- Dates and source of exposure, and recent dates and DOI locations and workspaces visited;
- Vaccination status, including fully vaccinated, not vaccinated, or decline to provide status; and
- Date(s) and time(s) of entrance and exit from DOI buildings, facilities, or events, or other related information. Information on entry and exit from DOI buildings may be obtained from the INTERIOR/DOI-46, Physical Security Access Files, system when relevant and necessary to achieve the purpose of this SORN.

This system may also include records on individuals created, collected or required to be reported to health officials in accordance with the requirements of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), which requires laboratories that perform or analyze a test that is intended to detect or to diagnose a possible case of COVID-19 to report the result of that testing to public health officials. This information includes:

- Full Name;
- Address; and
- Test results.

RECORD SOURCE CATEGORIES:

Records are obtained from DOI personnel, partners, other Federal agency employees, and individuals who provide relevant information on vaccination, testing or exposure to COVID-19 or other high-consequence public health threat; visitors at DOI owned, operated, leased or managed buildings, facilities or events; their family members or other potential source of exposure to COVID-19 or other high-consequence public health threat; DOI, bureau, and office records including other systems of records; contractors or service providers performing testing, screening or related services; other Federal or state agencies, public health organizations, or physicians with consent of the subject individual or when authorized by law; employers and other entities and individuals who may provide relevant information on a suspected or confirmed disease or illness that is the subject of a declared public health emergency.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, all or a portion of the records or information contained in this system may be disclosed outside DOI as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

A. To the Department of Justice (DOJ), including Offices of the U.S. Attorneys, or other Federal agency conducting litigation or in proceedings before any court, adjudicative, or administrative body, when it is relevant or necessary to the litigation and one of the following is a party to the litigation or has an interest in such litigation:

- (1) DOI or any component of DOI;
- (2) Any other Federal agency appearing before the Office of Hearings and Appeals;

(3) Any DOI employee or former employee acting in his or her official capacity;

(4) Any DOI employee or former employee acting in his or her individual capacity when DOI or DOJ has agreed to represent that employee or pay for private representation of the employee; or

(5) The United States Government or any agency thereof, when DOJ determines that DOI is likely to be affected by the proceeding.

B. To a congressional office when requesting information on behalf of, and at the request of, the individual who is the subject of the record.

C. To the Executive Office of the President in response to an inquiry from that office made at the request of the subject of a record or a third party on that person's behalf, or for a purpose compatible with the reason for which the records are collected or maintained.

D. To any criminal, civil, or regulatory law enforcement authority (whether Federal, state, territorial, local, tribal or foreign) when a record, either alone or in conjunction with other information, indicates a violation or potential violation of law—criminal, civil, or regulatory in nature, and the disclosure is compatible with the purpose for which the records were compiled.

E. To an official of another Federal agency to provide information needed in the performance of official duties related to reconciling or reconstructing data files or to enable that agency to respond to an inquiry by the individual to whom the record pertains.

F. To Federal, state, territorial, local, tribal, or foreign agencies that have requested information relevant or necessary to the hiring, firing or retention of an employee or contractor, or the issuance of a security clearance, license, contract, grant or other benefit, when the disclosure is compatible with the purpose for which the records were compiled.

G. To representatives of the National Archives and Records Administration (NARA) to conduct records management inspections under the authority of 44 U.S.C. 2904 and 2906.

H. To state, territorial and local governments and tribal organizations to provide information needed in response to court order and/or discovery purposes related to litigation, when the disclosure is compatible with the purpose for which the records were compiled.

I. To an expert, consultant, grantee, or contractor (including employees of the contractor) of DOI that performs services requiring access to these records on

DOI's behalf to carry out the purposes of the system.

J. To appropriate agencies, entities, and persons when:

(1) DOI suspects or has confirmed that there has been a breach of the system of records;

(2) DOI has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, DOI (including its information systems, programs, and operations), the Federal Government, or national security; and

(3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with DOI's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

K. To another Federal agency or Federal entity, when DOI determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in:

(1) Responding to a suspected or confirmed breach; or

(2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

L. To the Office of Management and Budget (OMB) during the coordination and clearance process in connection with legislative affairs as mandated by OMB Circular A-19.

M. To the Department of the Treasury to recover debts owed to the United States.

N. To the news media and the public, with the approval of the Public Affairs Officer in consultation with counsel and the Senior Agency Official for Privacy, where there exists a legitimate public interest in the disclosure of the information, except to the extent it is determined that release of the specific information in the context of a particular case would constitute an unwarranted invasion of personal privacy.

O. To appropriate Federal, state, local, tribal, or foreign governmental agencies or multilateral governmental organizations, to the extent permitted by law, and in consultation with legal counsel, for the purpose of protecting the vital interests of a data subject or other persons, including to assist such agencies or organizations in preventing exposure to or transmission of a communicable or quarantinable disease or to combat other significant public health threats.

P. To Federal agencies such as the Health and Human Services (HHS), State and local health departments, and other public health or cooperating medical authorities in connection with program activities and related collaborative efforts to deal more effectively with exposures to communicable diseases, and to satisfy mandatory reporting requirements when applicable.

Q. To missing person or location organizations where DOI does not have sufficient contact information to the extent necessary to obtain information to aid in locating persons who were possibly exposed or exposed others to a communicable disease at a DOI facility.

R. To a contractor or shared service provider conducting health screening, testing or notification activities on behalf of DOI, to help DOI manage vaccination and testing program records and procedures, and implementation of health screening, testing, and contact tracing.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

None.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Electronic records are stored in secure facilities. Confidential employee records are maintained with appropriate administrative, physical and technical controls to protect individual privacy. Paper records are contained in file folders stored in file cabinets in secure office locations.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records may be retrieved by any of the categories of records, including name, location, date of exposure, or work status.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

In accordance with the ADA and the Rehabilitation Act, information in this system must be maintained as confidential medical records, on separate forms and in separate medical files (42 U.S.C. 12112(d)(3)(B); 42 U.S.C. sec 2000ff-5(a); 29 CFR 1630.14(b)(1), (c)(1), (d)(4)(i); and 29 CFR 1635.9(a)). Therefore, these records must be stored separately from other personnel records and must be maintained for at least one year from creation date (29 CFR 1602.14).

Records in this system are maintained in accordance with the NARA General Records Schedule (GRS) 2.7, Item 060, Occupational individual medical case files, which covers OSHA medical records and medical surveillance

records that include personal and occupational health histories. The disposition is temporary. Short-term records are destroyed one year after employee separation or transfer (DAA-GRS-2017-0010-0010). Long-term records are destroyed 30 years after employee separation or when the employee's Official Personnel Folder is destroyed, whichever is longer (DAA-GRS-2017-0010-0009). Visitor processing records are covered by GRS 5.6, Items 110 and 111, and must be destroyed when either two or five years old, depending on security level, but may be retained longer if required for business use, pursuant to DAA-GRS-2017-0006-0014 and -0015.

Approved destruction methods for temporary records that have met their retention period include shredding or pulping paper records, and erasing or degaussing electronic records in accordance with DOI policy and NARA guidelines.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Records contained in this system are safeguarded in accordance with 43 CFR 2.226 and other applicable security and privacy rules and policies. During normal hours of operation, paper records are maintained in locked file cabinets under the control of authorized personnel. Computer servers on which electronic records are stored are located in secured DOI controlled facilities with physical, technical and administrative levels of security to prevent unauthorized access to the DOI network and information assets. Access is only granted to authorized personnel and each person granted access to the system must be individually authorized to use the system. A Privacy Act Warning Notice appears on computer monitor screens when records containing information on individuals are first displayed. Data exchanged between the servers and the system is encrypted. Backup tapes are encrypted and stored in a locked and controlled room in a secure, off-site location.

Computerized records systems follow the National Institute of Standards and Technology privacy and security standards as developed to comply with the Privacy Act of 1974, as amended, 5 U.S.C. 552a; Paperwork Reduction Act of 1995, 44 U.S.C. 3501-3521 *et seq.*; Federal Information Security Modernization Act of 2014, 44 U.S.C. 3551 *et seq.*; and the Federal Information Processing Standards 199: Standards for Security Categorization of Federal Information and Information Systems. Security controls include user identification, multi-factor

authentication, database permissions, encryption, firewalls, audit logs, and network system security monitoring, and software controls.

Access to records in the system is limited to authorized personnel who have a need to access the records in the performance of their official duties, and each user's access is restricted to only the functions and data necessary to perform that person's job responsibilities. System administrators and authorized users are trained and required to follow established internal security protocols and must complete all security, privacy, and records management training and sign the DOI Rules of Behavior. DOI has conducted privacy impact assessments on the collection of information for the vaccination program and the supporting IT system to identify and evaluate potential privacy risks and ensure appropriate safeguards are implemented to protect privacy.

RECORD ACCESS PROCEDURES:

An individual requesting records on himself or herself should send a signed, written inquiry to the System Manager identified above. The request must include the specific bureau or office that maintains the record to facilitate location of the applicable records. The request envelope and letter should both be clearly marked "PRIVACY ACT REQUEST FOR ACCESS." A request for access must meet the requirements of 43 CFR 2.238.

CONTESTING RECORD PROCEDURES:

An individual requesting corrections or the removal of material from his or her records should send a signed, written request to the System Manager identified above. The request must include the specific bureau or office that maintains the record to facilitate location of the applicable records. A request for corrections or removal must meet the requirements of 43 CFR 2.246.

NOTIFICATION PROCEDURES:

An individual requesting notification of the existence of records on himself or herself should send a signed, written inquiry to the System Manager identified above. The request must include the specific bureau or office that maintains the record to facilitate location of the applicable records. The request envelope and letter should both be clearly marked "PRIVACY ACT INQUIRY." A request for notification must meet the requirements of 43 CFR 2.235.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

None.

Teri Barnett,

Departmental Privacy Officer, Department of the Interior.

[FR Doc. 2021-24024 Filed 11-1-21; 11:15 am]

BILLING CODE 4334-63-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[22X.LLAZ920000 L13400000.KH0000]

Notice of Competitive Offer for Solar Energy Development on Public Lands in the State of Arizona

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of competitive offer.

SUMMARY: The Bureau of Land Management (BLM), Arizona State Office, Phoenix, Arizona, will accept competitive bids to lease public lands for solar energy projects on approximately 8,526 acres in the State of Arizona.

DATES: The BLM will hold a competitive live auction at 10:00 a.m. local time on December 8, 2021.

ADDRESSES: The auction will be held at: BLM Arizona State Office, 1 North Central Ave, #800, Phoenix, AZ 85004.

FOR FURTHER INFORMATION CONTACT:

Derek Eysenbach, Project Manager, BLM Arizona State Office, by telephone: 602-417-9505 or email: deysenbach@blm.gov. People who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1-800-877-8339 to contact Mr. Eysenbach during normal business hours. The FRS is available 24 hours a day, 7 days a week, to leave a message or question. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The BLM Arizona State Office has received interest to lease lands within each of its Solar Energy Zones (SEZ). The BLM will offer leases for solar energy development within the SEZs in accordance with the competitive process described in 43 CFR 2800, subpart 2809.

Based on the expressed interest, each SEZ is being offered in its entirety. The SEZs being offered for competitive solar lease sale are described as follows:

Gillespie Solar Energy Zone

Maricopa County, Arizona

The Gillespie SEZ consists of approximately 2,618 contiguous acres of public land, identified in the 2012 *Final*

Programmatic Environmental Impact Statement for Solar Energy Development in Six Southwestern States (Solar Programmatic EIS) and subsequent *Approved Resource Management Plan Amendments/Record of Decision* (ROD) as suitable for utility-scale solar energy development. The Gillespie SEZ is managed by the BLM's Lower Sonoran Field Office. Detailed information on the Gillespie SEZ, including maps, completed resource studies, and recommended design features can be viewed and downloaded at: <https://blmsolar.anl.gov/sez/az/gillespie/>.

Brenda Solar Energy Zone

La Paz County, Arizona

The Brenda SEZ consists of approximately 3,348 contiguous acres of public land, identified in the 2012 Solar Programmatic EIS and ROD as suitable for utility-scale solar energy development. The Brenda SEZ is managed by the BLM's Lake Havasu Field Office. Detailed information on the Brenda SEZ, including maps, completed resource studies, groundwater modeling, and recommended design features can be viewed and downloaded at: <https://blmsolar.anl.gov/sez/az/brenda/>.

Agua Caliente Solar Energy Zone

Yuma County, Arizona

The Agua Caliente SEZ consists of approximately 2,560 acres of public land, split into two parcels surrounding an existing solar energy facility on private lands. Agua Caliente was identified in the 2013 *Renewable Arizona: Restoration Design Energy Project Environmental Impact Statement* and subsequent ROD as suitable for utility-scale solar energy development. The Agua Caliente SEZ is managed by the BLM's Yuma Field Office. Detailed information on the Agua Caliente SEZ, including maps, completed resource studies, and recommended design features can be viewed and downloaded at: <https://blmsolar.anl.gov/sez/az/agua-caliente/>.

As provided for in 43 CFR 2809.13(a), bidding will occur in an oral auction, conducted in-person. The auction will be open to the public with potential limitations based on room capacity and the event may be live-streamed. More information will be made available at <https://go.usa.gov/xMXRG>. Interested bidders are required to pre-register no later than one week prior to the scheduled auction to allow sufficient time for the BLM to verify qualifications. Qualified bidders must meet the requirements of 43 CFR 2803.10:

- An individual, association, corporation, partnership, or similar business entity, or a Federal agency or state, Tribal, or local government;

- Technically and financially able to construct, operate, maintain, and terminate the use of the public lands you are applying for; and

- Of legal age and authorized to do business in the state where the right-of-way (ROW) you seek is located.

Technical and financial capability may be demonstrated by:

- Providing documentation of any successful experience in construction, operation, and maintenance of a similar-sized solar facility on either public or non-public lands;

- Providing documentation on the availability of sufficient capitalization to carry out development, including the preliminary study stage of the project and the environmental review and clearance process; or

- Providing documentation of conditional commitments of Federal and other loan guarantees; confirmed power purchase agreements; engineering, procurement, and construction contracts; and supply contracts with credible third-party vendors for the manufacture or supply of key components for the project facilities.

Pre-registered bidders will be confirmed and assigned a bidder number before the auction commences. Complete details and frequently asked questions on the screening and bidding process can be found online at: <https://go.usa.gov/xMXRG>.

The BLM has determined a minimum acceptable bid for each SEZ. The minimum bid represents 10 percent of the rent value of the land for 1 year under the BLM's solar rental schedule and is based on the interests acquired by a lessee in the SEZ. The minimum bid also includes an administrative fee of approximately \$2.42 per acre to cover the BLM's costs of preparing and conducting the competitive offer. Minimum bids for the three SEZs are: Gillespie—\$80,511; Brenda—\$30,728; and Agua Caliente—\$78,728. The competitive offer will start at the minimum bid, and bidders may raise with subsequent bonus bids. The bidder with the highest total bid (minimum and bonus bid) at the close of the auction will be declared the successful bidder and will be offered a ROW lease within the SEZ subject to payment terms, outlined as follows.

If you are the successful bidder, payment of the minimum bid and at least 20 percent of the winning bonus bid must be submitted to the BLM Arizona State Office by the close of

business on the day of the auction. Within 15 calendar days after the auction, you must pay the balance of the bonus bid and the first 12 months acreage rent to the respective BLM field office overseeing management of the SEZ. Any required payments must be submitted by personal check, cashier's check, certified check, ACH bank draft, or money order, or by other means deemed acceptable by the BLM, payable to the Department of the Interior—Bureau of Land Management.

The BLM will offer you a ROW lease if you are the successful bidder and you: (1) Satisfy the qualifications in 43 CFR 2803.10; (2) make the required payments listed earlier; and (3) do not have any trespass action pending against you for any activity on BLM-administered lands or have any unpaid debts owed to the Federal Government. The BLM will not offer a lease to the successful bidder and will keep all money that has been submitted if the successful bidder does not satisfy these requirements. In that event, the BLM may offer the lease to the next highest bidder; re-offer the lands through another competitive process; or make the lands available through the non-competitive application process found in 43 CFR 2803, 2804, and 2805.

The administrative fee portion of the minimum bid will be retained by the agency to recover administrative costs for conducting the competitive bid and related processes. The remainder of the minimum bid and bonus bid will be deposited with the U.S. Treasury. Neither amount will be returned or refunded to the successful bidder(s) under any circumstance.

If no bid is received for a SEZ, then no lease will be issued and the BLM may choose to make the lands available through the non-competitive application process found in 43 CFR 2803, 2804, and 2805, or by competitive process at a later date. Any lease issued will be subject to the terms and conditions specified in 43 CFR 2809.18, any additional requirements identified in the site-specific environmental review documentation, and the following project specific stipulations:

(1) The lessee will prepare the following management plans, if applicable, and submit them to the BLM as part of its plan of development (POD) for approval following the issuance of a lease for the Project and prior to the BLM issuing a Notice to Proceed (NTP) with construction:

- Bird and Bat Conservation Strategy;
- Decommissioning and Site Reclamation Plan;
- Dust Abatement Plan;

- Spill Prevention and Emergency Response Plan;
- Hazardous Materials and Waste Management Plan;
- Health and Safety Program;
- Groundwater Monitoring and Reporting Plan;
- Fire Management Plan;
- Lighting Management Plan;
- Integrated Weed Management Plan;
- Raven Management Plan;
- Site Rehabilitation and Restoration Plan;
- Stormwater Pollution Prevention Plan;
- Site Drainage Plan;
- Traffic Management Plan;
- Surface Water Quality Management Plan; and
- Worker Education and Awareness Plan.

(2) The lessee will comply with all relevant protective measures and design features established in the *Approved Resource Management Plan Amendments/Record of Decision for Solar Development in Six Southwestern States* (Solar Programmatic EIS) signed on Oct. 12, 2012, and *Approved Resource Management Plan Amendments/Record of Decision for Renewable Arizona: Restoration Design Energy Project* signed January 18, 2013.

(3) A Class III cultural survey will be required prior to any ground-disturbing activities. All historic properties found will be avoided or mitigated in consultation with State Historic Preservation Office.

(4) Any mitigation resulting from an adverse effect to historic properties will be addressed through a Memorandum of Agreement as outlined in the Solar Programmatic EIS Programmatic Agreement.

(5) Appropriate protection measures will be applied to existing improvements (e.g., canals and access to private lands) and rights-of-way within the SEZ and adjacent to other ancillary facilities (e.g., gen-tie line(s) and substation) required for development of any leased parcels.

(6) A 2-year grazing notification will be provided to all livestock permittees that will lose animal unit months to solar development, giving them 2 years to make any financial, business, or management decisions.

(7) The lessee will compensate the grazing permittees for any range improvements affected or lost by solar lease operations.

(8) The lessee will construct new fences that will continue to keep the allotments and pastures separated as needed to mitigate for the removal of allotment and pasture fences.

(9) Rights-of-way for livestock grazing driveways may be granted through solar

lease parcels if requested by grazing permittees.

(10) Any POD submitted will address mitigation and compensation strategies for impacts to livestock grazing, and any agreement with the affected grazing permittee addressing these mitigation and compensation strategies will be submitted to the BLM concurrent with the POD prior to the BLM authorizing an NTP with construction.

(11) Following submission of a POD, BLM shall initiate project-specific consultation with the United States Fish and Wildlife Service under Section 7 of the Endangered Species Act. The outcome of this consultation may result in additional design considerations that the leaseholder would be required to incorporate into final project design, construction, and decommissioning plans.

(12) The developer will be required to coordinate and confirm any stream alteration or Section 404 permitting requirements through the appropriate state or federal agency with jurisdiction.

(Authority: 43 CFR 2809)

Raymond Suazo,
State Director.

[FR Doc. 2021-24021 Filed 11-3-21; 8:45 am]

BILLING CODE 4310-32-P

DEPARTMENT OF THE INTERIOR

National Park Service

[DOI-2021-0005; PPWOPFLL0/
PS.SPPFL0085.00.1]

Privacy Act of 1974; System of Records

AGENCY: National Park Service, Interior.

ACTION: Rescinding of a system of records notice.

SUMMARY: The Department of the Interior (DOI) is issuing a public notice of its intent to rescind the National Park Service (NPS) Privacy Act system of records, INTERIOR/NPS-3, Land Acquisition Management Information System and Master Deed Listing, and removing it from its existing inventory.

DATES: These changes take effect on November 4, 2021.

ADDRESSES: You may send comments identified by docket number [DOI-2021-0005] by any of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for sending comments.
- *Email:* DOI_Privacy@ios.doi.gov. Include docket number [DOI-2021-0005] in the subject line of the message.

- *U.S. Mail or Hand-Delivery:* Teri Barnett, Departmental Privacy Officer, U.S. Department of the Interior, 1849 C Street NW, Room 7112, Washington, DC 20240.

Instructions: All submissions received must include the agency name and docket number [DOI-2021-0005]. All comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>.

You should be aware your entire comment including your personally identifiable information, such as your address, phone number, email address, or any other personal information in your comment, may be made publicly available at any time. While you may request to withhold your personally identifiable information from public review, we cannot guarantee we will be able to do so.

FOR FURTHER INFORMATION CONTACT: (1) Nadine Leisz, Chief, National Program Center, Land Resources Division, National Park Service, U.S. Department of the Interior, 1849 C Street NW, Washington, DC 20240, Nadine_Leisz@nps.gov or (2) 354-6961; or (2) Felix Uribe, Associate Privacy Officer, National Park Service, 12201 Sunrise Valley Drive, Reston, VA 20192, nps_privacy@nps.gov or (2) 354-6925.

SUPPLEMENTARY INFORMATION: Pursuant to the provisions of the Privacy Act of 1974, as amended, 5 U.S.C. 552a, the NPS is rescinding the INTERIOR/NPS-3, Land Acquisition Management Information System and Master Deed Listing, system of records notice (SORN) and removing it from its system of records inventory. During a review of NPS SORNs, NPS determined that the NPS-3 SORN was written to describe a database that has been decommissioned and no longer exists. The land acquisition management records previously maintained within this system are covered by the INTERIOR/NPS-2, Land Acquisition and Relocation Files, SORN which includes records of owners and tenants of land within National Parks. A revised INTERIOR/NPS-2 SORN will be published separately in the **Federal Register** to cover all land resources records. This rescinding will eliminate an unnecessary duplicate notice and ensure compliance with the Privacy Act of 1974 and the Office of Management and Budget (OMB) Circular A-108, *Federal Agency*

Responsibilities for Review, Reporting, and Publication under the Privacy Act.

Rescinding the INTERIOR/NPS-3, Land Acquisition Management Information System and Master Deed Listing, SORN will have no adverse impacts on individuals as the records are covered under INTERIOR/NPS-2, Land Acquisition and Relocation Files. This rescinding will also promote the overall streamlining and management of DOI Privacy Act systems of records.

SYSTEM NAME AND NUMBER:

INTERIOR/NPS-3, Land Acquisition Management Information System and Master Deed Listing.

HISTORY:

64 FR 61936 (November 15, 1999); modification published 73 FR 63992 (October 28, 2008).

Teri Barnett,

Departmental Privacy Officer, Department of the Interior.

[FR Doc. 2021-24036 Filed 11-3-21; 8:45 am]

BILLING CODE 4312-52-P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS-WASO-NAGPRA-NPS0032942;
PPWOCRADN0-PCU00RP14.R50000]

Notice of Intent To Repatriate Cultural Items: McClure Archives and University Museum, University of Central Missouri, Warrensburg, MO

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The McClure Archives and University Museum, University of Central Missouri, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, has determined that the cultural item listed in this notice meets the definition of object of cultural patrimony. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim this cultural item should submit a written request to the McClure Archives and University Museum. If no additional claimants come forward, transfer of control of the cultural item to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim this cultural item should submit a written request with information in support of the claim to the McClure

Archives and University Museum at the address in this notice by December 6, 2021.

FOR FURTHER INFORMATION CONTACT:

Olivia Thomsen, NAGPRA Preparator, McClure Archives and University Museum of JCKL 1470, 601 Missouri Street, Warrensburg, MO 64093, telephone (660) 543-4649, email thomsen@ucmo.edu.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3005, of the intent to repatriate a cultural item under the control of the McClure Archives and University Museum, University of Central Missouri, Warrensburg, MO, that meets the definition of object of cultural patrimony under 25 U.S.C. 3001.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American cultural item. The National Park Service is not responsible for the determinations in this notice.

History and Description of the Cultural Item

Sometime in the 1970s, one cultural item was purchased by the mother of Dr. Jeff Yelton from an antique store in Jefferson City, MO, as a gift upon her son's graduation from the University of Missouri. In 2019, Dr. Yelton donated the item to the McClure Archives and University Museum. The object of cultural patrimony is a basket made from woven bark strips.

Dr. Yelton had attributed the basket to the Ho-Chunk. Nevertheless, based on further study of the item by museum staff and consultation with the Winnebago Tribe of Nebraska, the Museum has determined that the basket is culturally affiliated with the Winnebago Tribe of Nebraska.

Determinations Made by the McClure Archives and University Museum, University of Central Missouri

Officials of the McClure Archives and University Museum, University of Central Missouri have determined that:

- Pursuant to 25 U.S.C. 3001(3)(D), the one cultural item described above has ongoing historical, traditional, or cultural importance central to the Native American group or culture itself, rather than property owned by an individual.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group

identity that can be reasonably traced between the object of cultural patrimony and the Winnebago Tribe of Nebraska.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim this cultural item should submit a written request with information in support of the claim to Olivia Thomsen, NAGPRA Preparator, McClure Archives and University Museum of JCKL 1470, 601 Missouri Street, Warrensburg, MO 64093, telephone (660) 543-4649, email thomsen@ucmo.edu, by December 6, 2021. After that date, if no additional claimants have come forward, transfer of control of the object of cultural patrimony to the Winnebago Tribe of Nebraska may proceed.

The McClure Archives and University Museum, University of Central Missouri is responsible for notifying the Winnebago Tribe of Nebraska that this notice has been published.

Dated: October 23, 2021.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2021-24051 Filed 11-3-21; 8:45 am]

BILLING CODE 4312-52-P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS-WASO-NAGPRA-NPS0032918; PPWOCRADN0-PCU00RP14.R50000]

Notice of Intent To Repatriate Cultural Items: American Museum of Natural History, New York, NY

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The American Museum of Natural History (AMNH), in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, has determined that the cultural items listed in this notice meet the definition of unassociated funerary objects. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request to the American Museum of Natural History. If no additional claimants come forward, transfer of control of the cultural items to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or

Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request with information in support of the claim to the American Museum of Natural History at the address in this notice by December 6, 2021.

FOR FURTHER INFORMATION CONTACT: Nell Murphy, American Museum of Natural History, Central Park West at 79th Street, New York, NY 10024, telephone (212) 769-5837, email nmurphy@amnh.org.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3005, of the intent to repatriate cultural items under the control of the American Museum of Natural History, New York, NY, that meet the definition of unassociated funerary objects under 25 U.S.C. 3001.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American cultural items. The National Park Service is not responsible for the determinations in this notice.

History and Description of the Cultural Items

In 1896, one cultural item was removed from Andrew K. Rowan Farm, Grave 1, Trench #6, Trenton, Mercer County, NJ, by Earnest Volk as part of an AMNH funded expedition. The cultural item was accessioned into the Museum's collection that same year. The one unassociated funerary object is a broken stone implement. Museum records indicate that the cultural item was removed from a grave, and artifact analysis dates the implement to the Middle Woodland Period (A.D. 200-900).

In 1897, two cultural items were removed from Andrew K. Rowan Farm, Trench #8, Grave 2, one-mile south of Trenton, Mercer County, NJ, by Earnest Volk as part of an AMNH expedition. The two cultural items were accessioned into the Museum's collection that same year. The two unassociated funerary objects are one pottery fragment and one stone implement. Museum records indicate that the two items were removed from a grave, and artifact analysis dates them to the Middle Woodland Period (A.D. 200-900).

In 1898, one cultural item was removed from A. K. Rowan Farm, in the

Delaware Valley south of Trenton, Mercer County, NJ, by Earnest Volk as part of an AMNH expedition. The cultural item was accessioned into the Museum's collection that same year. The one unassociated funerary object is a ceramic piece. Museum records indicate that the ceramic piece was removed from a grave, and artifact analysis dates the implement in the Middle Woodland Period (A.D. 200–900).

The A.K. Rowan Farm lies within the Abbott Farm Historic District, a National Historic Landmark located in Lenape territory. Archeological and linguistic data indicate a cultural continuity there that extends back to the Middle Woodland Period.

In 1898, three cultural items were removed from A.K. Rowan's Farm (terrace), near old homestead field, in the Delaware Valley, Mercer County, NJ, by Earnest Volk as part of an AMNH expedition. The cultural items were accessioned into the Museum's collection that same year. The three unassociated funerary objects are three wooden posts. A representative of the Delaware Tribe identified the three wooden posts as traditional Delaware grave markers from an area known to have Late Woodland/Historic Period burials. Radiocarbon dating of one of the posts (done at the request of the Delaware Nation, Oklahoma; Delaware Tribe of Indians, Oklahoma; and the Stockbridge-Munsee Community, Wisconsin) indicates that all three posts likely date to the 18th century, a time during which the Delaware occupied the Abbott Farm area.

Determinations Made by the American Museum of Natural History

Officials of the American Museum of Natural History have determined that:

- Pursuant to 25 U.S.C. 3001(3)(B), the seven cultural items described above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony and are believed, by a preponderance of the evidence, to have been removed from a specific burial site of a Native American individual.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the unassociated funerary objects and the Delaware Nation, Oklahoma; Delaware Tribe of Indians, Oklahoma; and the Stockbridge-Munsee Community, Wisconsin (hereafter referred to as "The Tribes").

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request with information in support of the claim to Nell Murphy, American Museum of Natural History, 200 Central Park West, New York, NY 10024, telephone (212) 769–5837, email nmurphy@amnh.org, by December 6, 2021. After that date, if no additional claimants have come forward, transfer of control of the unassociated funerary objects to The Tribes may proceed.

The American Museum of Natural History is responsible for notifying The Tribes that this notice has been published.

Dated: October 23, 2021.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2021–24047 Filed 11–3–21; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0032935; PPWOCRADN0–PCU00RP14.R50000]

Notice of Intent To Repatriate Cultural Items: McClure Archives and University Museum, University of Central Missouri, Warrensburg, MO

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The McClure Archives and University Museum, University of Central Missouri, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, has determined that the cultural items listed in this notice meet the definition of objects of cultural patrimony. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request to the McClure Archives and University Museum. If no additional claimants come forward, transfer of control of the cultural items to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request with information in support of the claim to the McClure Archives and University

Museum at the address in this notice by December 6, 2021.

FOR FURTHER INFORMATION CONTACT:

Olivia Thomsen, NAGPRA Preparator, McClure Archives and University Museum of JCKL 1470, 601 Missouri Street, Warrensburg, MO 64093, telephone (660) 543–4649, email thomsen@ucmo.edu.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3005, of the intent to repatriate cultural items under the control of the McClure Archives and University Museum, University of Central Missouri, Warrensburg, MO, that meet the definition of objects of cultural patrimony under 25 U.S.C. 3001.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American cultural items. The National Park Service is not responsible for the determinations in this notice.

History and Description of the Cultural Items

Sometime in the early 20th century, six cultural items were separated from the Gwich'in in Alaska. As a result of consultation, the Museum has determined that all six items are culturally affiliated with the Native Village of Fort Yukon.

Four of the items were collected or bought at the Native Village of Fort Yukon by Ethel Ellis, a missionary who worked in Alaska in the late 1800s and early 1900s. In 1919, Ellis donated the items to the Museum. The cultural items are a small, beaded bag, beaded mittens, beaded snow moccasins, and beaded garters whose origin is the Native Village of Fort Yukon.

A fifth item was collected or bought by Dr. George C. Stevens. Stevens did not specify from which band or native village of the Gwich'in he obtained the item. In 1968, he donated the item to the Museum. The cultural item is a pair of wooden snowshoes.

The sixth item was collected or bought by Robert Spier. Spier did not specify from which band or native village of the Gwich'in he obtained the item. Spier died in 2014, and in 2016, his widow, Carolyn Spier, donated the item to the Museum. The cultural item is a birch bark basket.

Determinations Made by the McClure Archives and University Museum, University of Central Missouri

Officials of the McClure Archives and University Museum, University of Central Missouri have determined that:

- Pursuant to 25 U.S.C. 3001(3)(D), the six cultural items described above have ongoing historical, traditional, or cultural importance central to the Native American group or culture itself, rather than property owned by an individual.

- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the objects of cultural patrimony and the Native Village of Fort Yukon.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request with information in support of the claim to Olivia Thomsen, NAGPRA Preparator, McClure Archives and University Museum of JCKL 1470, 601 Missouri Street, Warrensburg, MO 64093, telephone (660) 543-4649, email thomsen@ucmo.edu, by December 6, 2021. After that date, if no additional claimants have come forward, transfer of control of the objects of cultural patrimony to the Native Village of Fort Yukon may proceed.

The McClure Archives and University Museum, University of Central Missouri is responsible for notifying the Native Village of Fort Yukon that this notice has been published.

Dated: October 23, 2021.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2021-24049 Filed 11-3-21; 8:45 am]

BILLING CODE 4312-52-P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS-WASO-NAGPRA-NPS0032940; PPWOCRADN0-PCU00RP14.R50000]

Notice of Intent To Repatriate Cultural Items: McClure Archives and University Museum, University of Central Missouri, Warrensburg, MO

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The McClure Archives and University Museum, University of Central Missouri, in consultation with the appropriate Indian Tribes or Native

Hawaiian organizations, has determined that the cultural item listed in this notice meets the definition of object of cultural patrimony. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim this cultural item should submit a written request to the McClure Archives and University Museum. If no additional claimants come forward, transfer of control of the cultural item to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim this cultural item should submit a written request with information in support of the claim to the McClure Archives and University Museum at the address in this notice by December 6, 2021.

FOR FURTHER INFORMATION CONTACT: Olivia Thomsen, NAGPRA Preparator, McClure Archives and University Museum of JCKL 1470, 601 Missouri Street, Warrensburg, MO 64093, telephone (660) 543-4649, email thomsen@ucmo.edu.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3005, of the intent to repatriate cultural items under the control of the McClure Archives and University Museum, University of Central Missouri, Warrensburg, MO, that meet the definition of object of cultural patrimony under 25 U.S.C. 3001.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American cultural items. The National Park Service is not responsible for the determinations in this notice.

History and Description of the Cultural Item

Sometime in the 20th century, one cultural item was separated from the Tejon Indian Tribe in California. It was collected or bought by Robert Spier while doing fieldwork. Spier died in 2014, and in 2016, his widow, Carolyn Spier, donated the item to the McClure Archives and University Museum, along with many other items in her husband's personal anthropological collection. The one object of cultural patrimony is a woven bag.

The bag was originally documented to come from the Tejon Indian Tribe. Through consultation with the Tejon Indian Tribe, this cultural affiliation was confirmed.

Determinations Made by the McClure Archives and University Museum, University of Central Missouri

Officials of the McClure Archives and University Museum, University of Central Missouri have determined that:

- Pursuant to 25 U.S.C. 3001(3)(D), the one cultural item described above has ongoing historical, traditional, or cultural importance central to the Native American group or culture itself, rather than property owned by an individual.

- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the object of cultural patrimony and the Tejon Indian Tribe.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim this cultural item should submit a written request with information in support of the claim to Olivia Thomsen, NAGPRA Preparator, McClure Archives and University Museum of JCKL 1470, 601 Missouri Street, Warrensburg, MO 64093, telephone (660) 543-4649, email thomsen@ucmo.edu, by December 6, 2021. After that date, if no additional claimants have come forward, transfer of control of the object of cultural patrimony to the Tejon Indian Tribe may proceed.

The McClure Archives and University Museum, University of Central Missouri is responsible for notifying the Tejon Indian Tribe that this notice has been published.

Dated: October 21, 2021.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2021-24050 Filed 11-3-21; 8:45 am]

BILLING CODE 4312-52-P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS-WASO-NAGPRA-NPS0032946; PPWOCRADN0-PCU00RP14.R50000]

Notice of Inventory Completion: Tennessee Valley Authority, Knoxville, TN

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Tennessee Valley Authority (TVA) has completed an inventory of associated funerary objects in consultation with the appropriate Indian Tribes and Native Hawaiian organizations, and has determined that there is no cultural affiliation between the associated funerary objects and any present-day Indian Tribes or Native Hawaiian organizations. Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these associated funerary objects should submit a written request to the TVA. If no additional requestors come forward, transfer of control of the associated funerary objects to the Indian Tribes or Native Hawaiian organizations stated in this notice may proceed.

DATES: Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these associated funerary objects should submit a written request with information in support of the request to the TVA at the address in this notice by December 6, 2021.

FOR FURTHER INFORMATION CONTACT: Dr. Thomas O. Maher, Tennessee Valley Authority, 400 West Summit Hill Drive, WT11C, Knoxville, TN 37902-1401, telephone (865) 632-7458, email tomaher@tva.gov.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of associated funerary objects under the control of the Tennessee Valley Authority, Knoxville, TN. The associated funerary objects were removed from site 1MA4 in Madison County, AL.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3) and 43 CFR 10.11(d). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the associated funerary objects was made by TVA professional staff in consultation with representatives of the Absentee-Shawnee Tribe of Indians of Oklahoma; Alabama-Coushatta Tribe of Texas [previously listed as Alabama-Coushatta Tribes of Texas]; Cherokee Nation; Coushatta Tribe of Louisiana; Eastern

Band of Cherokee Indians; Poarch Band of Creek Indians [previously known as the Poarch Band of Creeks, and as the Poarch Band of Creek Indians of Alabama]; The Chickasaw Nation; The Choctaw Nation of Oklahoma; The Muscogee (Creek) Nation; The Seminole Nation of Oklahoma; and the United Keetoowah Band of Cherokee Indians in Oklahoma (hereafter referred to as "The Consulted Tribes").

History and Description of the Remains

Site 1MA4 was excavated as part of TVA's Wheeler Reservoir Project by the Alabama Museum of Natural History (AMNH) at the University of Alabama using labor provided by the Civil Works Administration, a precursor to the Works Progress Administration. Details regarding the excavation of this site may be found in "*An Archaeological Survey of Wheeler Basin on the Tennessee River in Northern Alabama*," by William S. Webb. The associated funerary objects excavated from the site listed in this notice have been in the physical custody of the AMNH at the University of Alabama since they were excavated. Human remains from site 1MA4 were listed in a Notice of Inventory Completion published in the **Federal Register** on December 21, 2018 (83 FR 65729-65734, December 21, 2018), and they were subsequently transferred to the Cherokee Nation; Eastern Band of Cherokee Indians; The Chickasaw Nation; and the United Keetoowah Band of Cherokee Indians in Oklahoma. Recently, associated funerary objects from site 1MA4 were discovered during the improvement of the curation of TVA's archeological collection at AMNH.

From February through March 1934, associated funerary objects were removed from site 1MA4, in Madison County, AL, by AMNH. TVA acquired a strip of land around the periphery of Hobbs Island encompassing this site on May 23, 1939, as part of the Wheeler Reservoir project, but the excavation was conducted with Federal funds in anticipation of the inundation of this site. The site was a shell midden 300 x 125 feet located adjacent to the island's shoreline. There are no radiocarbon dates available for this site, but artifacts from a non-mortuary context suggest Langston (A.D. 900-1200) and Hobbs Island (A.D. 1200-1450) phase occupations. The 351 associated funerary objects include one conch shell cup, 23 Mississippi Plain body sherds, one limestone-tempered sherd, one Mulberry Creek cordmarked sherd, one Mulberry Creek Plain sherd, one Bluff Creek Simple Stamped rim, and 323 shell beads.

Determinations Made by the Tennessee Valley Authority

Officials of the Tennessee Valley Authority have determined that:

- Pursuant to 25 U.S.C. 3001(3)(A), the 351 objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- Pursuant to 25 U.S.C. 3001(2), a relationship of shared group identity cannot be reasonably traced between the associated funerary objects and any present-day Indian Tribe.
- According to final judgments of the Indian Claims Commission or the Court of Federal Claims, the land from which the associated funerary objects were removed is the aboriginal land of the Cherokee Nation; Eastern Band of Cherokee Indians; and the United Keetoowah Band of Cherokee Indians in Oklahoma.
- The Treaty of September 20, 1816, indicates that the land from which the Native American human remains were removed is the aboriginal land of The Chickasaw Nation.
- Pursuant to 43 CFR 10.11(c)(4), the Tennessee Valley Authority has agreed to transfer control of the associated funerary objects to the Cherokee Nation; Eastern Band of Cherokee Indians; The Chickasaw Nation; and the United Keetoowah Band of Cherokee Indians in Oklahoma (hereafter referred to as "The Tribes").

Additional Requestors and Disposition

Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these associated funerary objects should submit a written request with information in support of the request to Dr. Thomas O. Maher, Tennessee Valley Authority, 400 West Summit Hill Drive, WT11C, Knoxville, TN 37902-1401, telephone (865) 632-7458, email tomaher@tva.gov, by December 6, 2021. After that date, if no additional requestors have come forward, transfer of control of the associated funerary objects to The Tribes may proceed.

The Tennessee Valley Authority is responsible for notifying The Consulted Tribes that this notice has been published.

Dated: October 23, 2021.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2021-24052 Filed 11-3-21; 8:45 am]

BILLING CODE 4312-52-P

DEPARTMENT OF THE INTERIOR**National Park Service**

[NPS-WASO-NAGPRA-NPS0032919;
PPWOCHADNO-PCU00RP14.R50000]

Notice of Intent To Repatriate Cultural Items: Denver Museum of Nature & Science, Denver, CO

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Denver Museum of Nature & Science, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, has determined that the cultural item listed in this notice meets the definition of a sacred object and object of cultural patrimony. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim this cultural item should submit a written request to the Denver Museum of Nature & Science. If no additional claimants come forward, transfer of control of the cultural item to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim this cultural item should submit a written request with information in support of the claim to the Denver Museum of Nature & Science at the address in this notice by December 6, 2021.

FOR FURTHER INFORMATION CONTACT: Dr. Stephen E. Nash, Director of Anthropology, Denver Museum of Nature & Science, 2001 Colorado Boulevard, Denver, CO 80205, telephone (303) 370-6056, email Stephen.Nash@dmns.org.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3005, of the intent to repatriate a cultural item under the control of the Denver Museum of Nature & Science, Denver, CO, that meets the definition of a sacred object and the definition of an object of cultural patrimony under 25 U.S.C. 3001.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American cultural items. The National Park Service is not responsible for the determinations in this notice.

History and Description of the Cultural Item

On an unknown date, Pat Read, owner of Pat Read Trading Company in Lawrence, KS, obtained a cultural item from an unknown source. On September 21, 1954, the item, a False Face mask (AC.290), was purchased from Read by Mary and Francis Crane. In November of 1972, Mary Crane donated the mask to the Denver Museum of Nature & Science (then called the Denver Museum of Natural History).

In 1974, anthropologist William Fenton stated that, based on his knowledge and expertise, the mask was "not typical of Iroquois work." Furthermore, in 1999, during consultations between Haudenosaunee representatives and Denver Museum of Nature & Science curator Joyce Herold, certain cultural experts remarked that the mask was "probably not Iroquois made" and that it "should be shown to the Seneca-Cayuga in Oklahoma." Following research conducted during 2015-2017, the Denver Museum of Nature & Science determined that, based on geographical, folkloric, oral traditional, and historical information, and consultation, this False Face Mask is culturally affiliated with the Seneca-Cayuga Nation.

Determinations Made by the Denver Museum of Nature & Science

Officials of the Denver Museum of Nature & Science have determined that:

- Pursuant to 25 U.S.C. 3001(3)(C), the one cultural item described above is a specific ceremonial object needed by traditional Native American religious leaders for the practice of traditional Native American religions by their present-day adherents.

- Pursuant to 25 U.S.C. 3001(3)(D), the one cultural item described above has ongoing historical, traditional, or cultural importance central to the Native American group or culture itself, rather than property owned by an individual.

- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the sacred object and object of cultural patrimony and the Seneca-Cayuga Nation [previously listed as Seneca-Cayuga Tribe of Oklahoma].

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim this cultural item should submit a written request with information in support of the claim to Dr. Stephen E. Nash, Director of

Anthropology, Denver Museum of Nature & Science, 2001 Colorado Boulevard, Denver, CO 80205, telephone (303) 370-6056, email Stephen.Nash@dmns.org, by December 6, 2021. After that date, if no additional claimants have come forward, transfer of control of the sacred object and object of cultural patrimony to the Seneca-Cayuga Nation [previously listed as Seneca-Cayuga Tribe of Oklahoma] may proceed.

The Denver Museum of Nature & Science is responsible for notifying the Seneca-Cayuga Nation [previously listed as Seneca-Cayuga Tribe of Oklahoma] that this notice has been published.

Dated: October 23, 2021.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2021-24048 Filed 11-3-21; 8:45 am]

BILLING CODE 4312-52-P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

[S1D1S SS08011000 SX064A000
212S180110; S2D2S SS08011000
SX064A000 21XS501520]

Grant Notification for Fiscal Year 2022

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Notice.

SUMMARY: We, the Office of Surface Mining Reclamation and Enforcement (OSMRE), are notifying the public that we intend to grant funds to eligible applicants for purposes authorized under the Surface Mining Control and Reclamation Act of 1977 (SMCRA) Title IV Abandoned Mine Land (AML) Reclamation Program (30 U.S.C. 1231-1244) and Title V Regulatory Program (30 U.S.C. 1251-1279). We will award these grants during fiscal year 2022.

DATES: Single points of contact or other interested State, Tribal, or local entities may submit written comments regarding AML Reclamation Program and Regulatory Program funding until December 3, 2021.

ADDRESSES: You may submit comments by any of the following methods:

- *Electronic mail:* Send your comments to yrichardson@osmre.gov.
- *Mail, hand-delivery, or courier:*

Send your comments to Office of Surface Mining Reclamation and Enforcement, Attn: Grants Notice, Room 4551, 1849 C Street NW, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT:

Yetunde Richardson, Office of Surface

Mining Reclamation and Enforcement,
1849 C Street NW, MS 4551,
Washington, DC 20240; Telephone (202)
208-2766.

SUPPLEMENTARY INFORMATION:

Grant Notification

We are notifying the public that we intend to grant funds to eligible applicants for purposes authorized under SMCRA's Title IV AML Reclamation Program and Title V Regulatory Program. We will award these grants during fiscal year 2022. Eligible applicants are those States and Tribes with an existing AML reclamation program and/or a regulatory program approved pursuant to SMCRA, as amended, 30 U.S.C. 1201 *et seq.*, and, as provided in 30 U.S.C. 1295, those States and Tribes that are seeking to develop a regulatory program. Consistent with Executive Order 12372, we are providing State and Tribal officials the opportunity to review and comment on these proposed Federal financial assistance activities. Of the eligible applicants, eighteen States or Tribes do not have single points of contact; therefore, we are publishing this notice as an alternate means of notification.

Description of the AML Reclamation Program

SMCRA established the Abandoned Mine Reclamation Fund to receive the AML fees that, along with funds from other sources, are used to finance reclamation of AML coal mine sites and for certain other purposes. Title IV of SMCRA authorizes OSMRE to provide grants, funded from permanent (mandatory) appropriations, to eligible States and Tribes. Recipients use these funds: To reclaim the highest priority AML coal mine sites that were abandoned prior to the enactment of SMCRA in 1977; to reclaim eligible non-coal sites; for projects that address the impacts of mineral development; and for non-reclamation projects.

Description of the Regulatory Program

Title V of SMCRA authorizes OSMRE to provide grants to States and Tribes to develop, administer, and enforce State and Tribal regulatory programs that address, among other things, the disturbances from coal mining operations. Additionally, upon our approval of a State or Tribal regulatory program, Title V authorizes that State or Tribe to assume regulatory primacy and act as the regulatory authority within the State or Tribe, and to administer and enforce its approved regulatory program. These provisions of SMCRA are implemented by our regulations at

Title 30 of the Code of Federal Regulations, Chapter VII.

Glenda H. Owens,

Deputy Director, Office of Surface Mining Reclamation and Enforcement.

[FR Doc. 2021-23998 Filed 11-3-21; 8:45 am]

BILLING CODE 4310-05-P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

**[S1D1S SS08011000 SX064A000
221S180110; S2D2S SS08011000
SX064A000 22XS501520; OMB Control
Number 1029-0051]**

Agency Information Collection Activities; State Regulatory Authority: Inspection and Enforcement

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Notice of Information Collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the Office of Surface Mining Reclamation and Enforcement (OSMRE), are proposing to renew an information collection.

DATES: Interested persons are invited to submit comments on or before December 6, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function. Please provide a copy of your comments to Mark Gehlhar, Office of Surface Mining Reclamation and Enforcement, 1849 C Street NW, Room 4556-MIB, Washington, DC 20240, or by email to mgehlhar@osmre.gov. Please reference OMB Control Number 1029-0051 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Mark Gehlhar by email at mgehlhar@osmre.gov, or by telephone at (202) 208-2716. You may also view the ICR at <http://www.reginfo.gov/public/do/PRAMain>.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995 (PRA; 44 U.S.C. 3501 *et seq.*) and 5 CFR 1320.8(d)(1), we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised,

and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

A **Federal Register** notice with a 60-day public comment period soliciting comments on this collection of information was published on July 19, 2021 (86 FR 38124). No comments were received.

As part of our continuing effort to reduce paperwork and respondent burdens, we are again soliciting comments from the public and other Federal agencies on the proposed ICR that is described below. We are especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) How might the agency 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 response.

Comments that you submit in response to this notice are a matter of public record. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: This provision requires the regulatory authority to conduct periodic inspections of coal mining activities, and prepare and maintain inspection reports and other related documents for OSMRE and public review. This information is necessary to meet the requirements of the Surface Mining Control and Reclamation Act of 1977 and its public participation provisions. Public review assures the public that the

State is meeting the requirements of the Act and approved State regulatory program.

Title of Collection: State Regulatory Authority: Inspection and Enforcement.

OMB Control Number: 1029-0051.

Form Number: None.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: State governments.

Total Estimated Number of Annual Respondents: 24.

Total Estimated Number of Annual Responses: 54,515.

Estimated Completion Time per Response: Varies from 1.5 hours to 10 hours, depending on activity.

Total Estimated Number of Annual Burden Hours: 441,795.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: One time.

Total Estimated Annual Nonhour Burden Cost: \$625.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Mark J. Gehlhar,

*Information Collection Clearance Officer,
Division of Regulatory Support.*

[FR Doc. 2021-24112 Filed 11-3-21; 8:45 am]

BILLING CODE 4310-05-P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-266 (Rescission)]

Certain Reclosable Plastic Bags and Tubing; Notice of Commission Decision To Institute a Rescission Proceeding and To Rescind the General Exclusion Order; Termination of the Rescission Proceeding

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to institute a rescission proceeding and to rescind the general exclusion order issued in the underlying investigation. The rescission proceeding is terminated.

FOR FURTHER INFORMATION CONTACT: Houda Morad, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 708-4716. Copies of non-confidential

documents filed in connection with this investigation may be viewed on the Commission's electronic docket (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 <https://www.usitc.gov>. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at <https://edis.usitc.gov>. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810.

SUPPLEMENTARY INFORMATION: On April 29, 1987, the Commission instituted this investigation under section 337 of the Tariff Act, 19 U.S.C. 1337 ("section 337"), based on a complaint filed by Minigrip, Inc. of Orangeburg, New York ("Complainant"). See 52 FR 15568-01, 1987 WL 133865 (Apr. 29, 1987). The complaint, as supplemented, alleges unfair methods of competition and unfair acts in the importation into and sale in the United States of certain reclosable plastic bags and tubing (1) manufactured abroad by a process which, if practiced in the United States, would infringe claims 1-5 of the U.S. Patent 3,945,872 ("the '872 Patent"); and (2) bearing a color line mark allegedly infringing U.S. Trademark Registration No. 946,120 ("the '120 Trademark"). See *id.* The notice of investigation names twenty (20) respondents, including: C.A.G. Enterprise Pte, Ltd. of Singapore; Chang Won Chemical Co., Ltd. of Seoul, Republic of Korea; Chung Kong Industrial Co., Ltd. of Hong Kong; Euroweld Distributing of Hazlet, New Jersey; Gideons Plastic Industrial Co., Ltd. of Tou Liu, Taiwan; Hogn Ter Product Co., Ltd. of Taipei, Taiwan; Ideal Plastic Industrial Co., Ltd. of Taipei, Taiwan; Insertion Advertising Corp. of New York, New York; Ka Shing Corp. of Mount Vernon, New York; Kwant II of Seoul, Republic of Korea; Lim Tai Chin Pahathet Co. Ltd. of Bangkok, Thailand; Lein Bin Plastics Co., Ltd. of Taipei, Taiwan; Meditech International Co. of Denver, Colorado; Nina Plastic Bags, Inc. of Orlando, Florida; Polycraft Corporation of Pomona, California; Rol-Pak Sdn Bhd, Chin Thye Sdn Bhd of Kuala Lumpur, Malaysia; Siam Import-Export Ltd. of Bangkok, Thailand; Ta Sen Plastic Industrial Co., Ltd. of Taipei, Taiwan; Tech Keung Manufacturing Ltd. of Hong Kong; and Tracon Industries Corp. of Melville, New York. See *id.* The Office

of Unfair Import Investigations is also a party to the investigation. See *id.*

On October 8, 1987, the presiding administrative law judge ("ALJ") issued an initial determination granting Complainant's motion to amend the complaint and notice of investigation to add Keron Industrial Co., Ltd. and Daewang International Corp. as respondents. See Order No. 28 (Oct. 8, 1987), *unreviewed by*, Comm'n Notice (Oct. 29, 1987).

The Commission terminated eight (8) respondents based on settlement, namely, Meditech, Polycraft, Chung Kong, Euroweld, Daewang, Keron, Gideons, and Lien Bin. See Order No. 49 (Nov. 25, 1987), *unreviewed by*, Comm'n Notice (Dec. 29, 1987). The Commission also found all but two (2) respondents (Chang Won and Kwang II) in default, namely, Hogn Ter, Insertion, Ka Shing, Nina Plastic, Siam Import, Ta Sen, Teck Keung, Tracon, C.A.G., Lim Tai, Rol-Pak, and Ideal. See Order No. 44 (Nov. 19, 1987), *unreviewed by*, Comm'n Notice (Dec. 21, 1987); Order No. 56 (Dec. 9, 1987), *unreviewed by*, Comm'n Notice (Jan. 14, 1988); Order No. 59 (Dec. 24, 1987), *unreviewed by*, Comm'n Notice (Jan. 25, 1988).

On January 29, 1988, the ALJ issued his final ID finding a violation of section 337. On March 16, 1988, the Commission determined not to review of the ID. See 53 FR 9495, 1988 WL 264423 (March 23, 1988). On April 29, 1988, the Commission issued a general exclusion order prohibiting the entry into the United States, except under license, of (1) reclosable plastic bags and tubing manufactured according to a process which, if practiced in the United States, would infringe claims 1, 3, 4, or 5 of the '872 Patent; and (2) reclosable plastic bags and tubing which infringe the '120 Trademark. See Notice of Issuance of Exclusion Order, 0089 WL 1685278, *1 (Apr. 29, 1988). The Commission did not issue cease and desist orders. See *id.* at *4.

The '872 Patent expired on March 23, 1993, 17 years after its issuance. The '120 Trademark was cancelled on March 28, 2020.

In view of the expiration of the '872 Patent and the cancellation of the '120 Trademark, and pursuant to the Commission's authority under section 337(k)(1), 19 U.S.C. 1337(k)(1), the Commission has determined to institute a rescission proceeding and to rescind the general exclusion order issued in the underlying investigation. The rescission proceeding is terminated.

The Commission's vote on this determination took place on October 29, 2021.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: October 29, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–24038 Filed 11–3–21; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1285]

Certain Barcode Scanners, Mobile Computers With Barcode Scanning Capabilities, Scan Engines, and Components Thereof; Institution of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on September 29, 2021, under section 337 of the Tariff Act of 1930, as amended, on behalf of Honeywell International Inc. of Charlotte, North Carolina; Hand Held Products, Inc. of Charlotte, North Carolina; and Metrologic Instruments, Inc. of Charlotte, North Carolina. The complaint alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain barcode scanners, mobile computers with barcode scanning capabilities, scan engines, and components thereof by reason of infringement of certain claims of U.S. Patent Nos. 7,568,628 (“the ‘628 patent”); 7,770,799 (“the ‘799 patent”); 8,794,520 (“the ‘520 patent”); 9,576,169 (“the ‘169 patent”); and 10,721,429 (“the ‘429 patent”). The complaint further alleges that an industry in the United States exists as required by the applicable Federal Statute. The complainant requests that the Commission institute an investigation and, after the investigation, issue a limited exclusion order and cease and desist orders.

ADDRESSES: The complaint, except for any confidential information contained therein, may be viewed on the Commission's electronic docket (EDIS) at <https://edis.usitc.gov>. For help accessing EDIS, please email EDIS3Help@usitc.gov. Hearing impaired

individuals are advised that information on this matter can be obtained 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 at <https://www.usitc.gov>.

FOR FURTHER INFORMATION CONTACT:

Katherine Hiner, Office of Docket Services, U.S. International Trade Commission, telephone (202) 205–1802.

SUPPLEMENTARY INFORMATION:

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2021).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on October 29, 2021, Ordered That—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain products identified in paragraph (2) by reason of infringement of one or more of claims 1–5, 9, 11, 13–15, 17–22, 24, 26, 27, 30, 32, 34–39, and 42–46 of the ‘628 patent; claims 9–12 and 14–20 of the ‘799 patent; claims 1–27 of the ‘520 patent; claims 1–3, 5–7, 9–12, 14, 16, and 18 of the ‘169 patent; and claims 1, 2, 4–11, 13–18, 20–25, and 27–30 of the ‘429 patent, and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(2) Pursuant to section 210.10(b)(1) of the Commission's Rules of Practice and Procedure, 19 CFR 210.10(b)(1), the plain language description of the accused products or category of accused products, which defines the scope of the investigation, is “barcode scan engines and scanners (such as handheld and stationary scanners), mobile computers with barcode scanning capabilities (such as handheld, tablet, and wearable computers), and components thereof (such as circuit boards with barcode scanning capabilities)”;

(3) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainant is:

Honeywell International Inc., 855 S Mint Street, Charlotte, NC 28202

Hand Held Products, Inc., 855 S Mint Street, Charlotte, NC 28202

Metrologic Instruments, Inc., 855 S Mint Street, Charlotte, NC 28202

(b) The respondents are the following entities alleged to be in violation of section 337, and are the parties upon which the complaint is to be served:

Zebra Technologies Corporation, 3 Overlook Point, Lincolnshire, IL 60069

Symbol Technologies, Inc., 1 Zebra Plaza, Holtsville, NY 11742

(4) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

The Office of Unfair Import Investigations will not participate as a party to this investigation.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(e) and 210.13(a), as amended in 85 FR 15798 (March 19, 2020), such responses will be considered by the Commission if received not later than 20 days after the date of service by the complainant of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: October 29, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–24037 Filed 11–3–21; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF LABOR**Agency Information Collection Activities; Submission for OMB Review; Comment Request; Attestation for Employers Seeking To Employ H-2B Nonimmigrant Workers**

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Employment and Training Administration (ETA)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before December 6, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) if the information will be processed and used in a timely manner; (3) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (4) ways to enhance the quality, utility and clarity of the information collection; and (5) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: Mara Blumenthal by telephone at 202-693-8538, or by email at DOL_PRA_PUBLIC@dol.gov.

SUPPLEMENTARY INFORMATION: This information collection request supports the Temporary Rule: Exercise of Time-Limited Authority to Increase the Fiscal Year 2021 Numerical Limitation for the H-2B Temporary Nonagricultural Worker Program and Portability Flexibility for H-2B Workers Seeking to Change Employers, promulgated by the Department of Labor and the Department of Homeland Security

(DHS). The regulatory requirements are codified at 8 CFR part 214 and 20 CFR part 655. The ICR originally included a form, Attestation for Employers Seeking to Employ H-2B Nonimmigrant Workers under Section 105 of Division O of the Further Consolidated Appropriations Act, 2021, Form ETA-9142-B-CAA-4 (Form ETA-9142-B-CAA-4). The Form ETA-9142-B-CAA-4 is no longer in use as the supplemental cap was reached on August 13, 2021, as announced by DHS on August 19, 2021; thus employers no longer need to complete the attestation for submission to DHS. As a result, the only remaining requirement for participating H-2B employers is to comply with record keeping requirements. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on May 25, 2021 (86 FR 28198).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. See 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL-ETA.

Title of Collection: Attestation for Employers Seeking to Employ H-2B Nonimmigrant Workers.

OMB Control Number: 1205-0547.

Affected Public: Private Sector—Businesses or other for-profits and not-for-profit institutions.

Total Estimated Number of Respondents: 3,558.

Total Estimated Number of Responses: 3,558.

Total Estimated Annual Time Burden: 890 hours.

Total Estimated Annual Other Costs Burden: \$0.

Authority: 44 U.S.C. 3507(a)(1)(D).

Dated: October 29, 2021.

Mara Blumenthal,
Senior PRA Analyst.

[FR Doc. 2021-24046 Filed 11-3-21; 8:45 am]

BILLING CODE 4510-FF-P

DEPARTMENT OF LABOR**Agency Information Collection Activities; Submission for OMB Review; Comment Request; National Compensation Survey**

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Bureau of Labor Statistics (BLS)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before December 6, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) if the information will be processed and used in a timely manner; (3) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (4) ways to enhance the quality, utility and clarity of the information collection; and (5) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: Mara Blumenthal by telephone at 202-693-8538, or by email at DOL_PRA_PUBLIC@dol.gov.

SUPPLEMENTARY INFORMATION: The National Compensation Survey (NCS) is an ongoing survey of earnings and benefits among private firms, State, and local government. Data from the NCS program include estimates of wages covering broad groups of related occupations, and data that directly links benefit plan costs with detailed plan provisions. BLS is seeking approval to increase the NCS sample size for Fiscal Years 2022 and 2023 to mitigate against the impacts of pandemic related non-

response on survey estimates and ensure a sufficient number of units are collected to calculate the Employment Cost Index. The new sample size would only take effect upon OMB approval. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on June 11, 2020 (85 FR 35667).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. See 5 CFR 1320.5(a) and 1320.6. DOL seeks authorization for this information collection under OMB Control Number 1220-0164. The current approval is scheduled to expire on May 31, 2024.

Agency: DOL-BLS.

Title of Collection: National Compensation Survey.

OMB Control Number: 1220-0164.

Affected Public: Businesses or other for-profit and not-for-profit institutions; State, local, and tribal government.

Total Estimated Number of Respondents: 16,995.

Total Estimated Number of Responses: 45,270.

Total Estimated Annual Time Burden: 36,114 hours.

Total Estimated Annual Other Costs Burden: \$0.

Authority: 44 U.S.C. 3507(a)(1)(D).

Dated: November 1, 2021.

Mara Blumenthal,

Senior PRA Analyst.

[FR Doc. 2021-24105 Filed 11-3-21; 8:45 am]

BILLING CODE 4510-24-P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Evaluation of the Pathway Home Grant Program, New Collection

AGENCY: Office of the Assistant Secretary for Policy, Chief Evaluation Office, Department of Labor.

ACTION: Notice of Information Collection; request for comment.

SUMMARY: The Department of Labor (DOL), as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the

general public and federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents is properly assessed. Currently, the Department of Labor is soliciting comments concerning the collection of data for the Evaluation of the Pathway Home Grant Program. A copy of the proposed Information Collection Request (ICR) can be obtained by contacting the office listed below in the addressee section of this notice.

DATES: Written comments must be submitted to the office listed in the addressee section below on or before January 3, 2022.

ADDRESSES: You may submit comments by either one of the following methods: *Email:* ChiefEvaluationOffice@dol.gov; *Mail or Courier:* Jessica Lohmann, Chief Evaluation Office, OASP, U.S. Department of Labor, Room S-2312, 200 Constitution Avenue NW, Washington, DC 20210. *Instructions:* Please submit one copy of your comments by only one method. All submissions received must include the agency name and OMB Control Number identified above for this information collection. Comments, including any personal information provided, become a matter of public record. They will also be summarized and/or included in the request for OMB approval of the information collection request.

FOR FURTHER INFORMATION CONTACT:

Jessica Lohmann by email at ChiefEvaluationOffice@dol.gov or by phone at (202) 693-5087.

SUPPLEMENTARY INFORMATION:

I. Background: The Chief Evaluation Office (CEO) of the U.S. Department of Labor (DOL) intends to conduct an evaluation of the DOL-funded *Pathway Home* grant program, which aims to improve the ability of people in the justice system to find meaningful employment and avoid recidivism. The goal of this four-year evaluation is to build knowledge about the implementation of the Pathway Home grants and their effectiveness in improving employment and recidivism outcomes for adults reentering the community after incarceration.

The overall study has two components: (1) An implementation evaluation of the Pathway Home grants to describe program models and

services, partnerships, and participant characteristics; and (2) an impact evaluation to examine the effectiveness of the Pathway Home grants on participants' outcomes, such as credential attainment, employment and earnings, and ongoing criminal justice involvement. DOL will submit additional ICRs for future data collection requests for this study.

This **Federal Register** Notice provides the opportunity to comment on the following proposed data collection instruments that the evaluation will use:

1. Baseline survey of study

participants. Survey of 2,500 impact study participants to collect basic demographic information.

2. Survey of grant administrators.

Survey of approximately 67 grant administrators to collect program information.

3. Survey of correctional facility administrators. Survey of approximately 128 correctional facility partner administrators to collect information about correctional facility characteristics.

4. Semi-structured interview guides for program and partner administrators and frontline staff. Site visits to up to 16 Pathway Home grantee or subgrantee sites. These visits will last three days each. During these site visits, we will conduct one-on-one or small-group, semi-structured interviews with grant program administrators, partner administrators, and frontline staff.

5. Focus group guide for pre-release program participants. In-person focus group discussions with approximately 8 pre-release participants from each of approximately 16 sites.

6. Semi-structured interview guide for post-release program participants. In-person and telephone semi-structured interviews with approximately 8 post-release participants from each of approximately 16 sites.

II. Desired Focus of Comments:

Currently, DOL is soliciting comments on the above data collection for the Pathway Home grant program. DOL is particularly interested in comments that do the following:

- Evaluate whether the proposed collection of information is necessary for the proper performance functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's burden estimate of the proposed information collection, including the validity of the methodology and assumptions;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other

technological collection techniques or other forms of information technology—for example, permitting electronic submissions of responses.

III. *Current Actions:* At this time, DOL is requesting clearance for the baseline survey of study participants, survey of grantee administrators, survey of correctional facility administrators,

interview guide for program and partner administrators and staff, focus group guide for program participants, and interview guide for program participants.

Type of Review: New information collection request.

OMB Control Number: 1290–0–NEW.

Affected Public: Program administrators and frontline staff,

program partners including correctional facility administrators, and evaluation participants.

Comments submitted in response to this request will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

ESTIMATED ANNUAL BURDEN HOURS

Type of instrument (form/activity)	Number of respondents	Number of responses per respondent	Total number of responses	Average burden time per response (hours)	Estimated burden hours
Baseline survey of study participants	¹ 833	1	833	.25	208
Survey of grantee administrators	² 22	1	22	.5	11
Survey of correctional facility administrators	³ 43	1	43	.33	14
Semi-structured interview guide: Grant administrators	⁴ 43	1	43	1.5	65
Semi-structured interview guide: Partner administrators	⁵ 53	1	53	1	53
Semi-structured interview guide: Frontline staff	⁶ 80	1	80	1.5	120
Focus group guide for program participants	⁷ 38	1	38	1.5	57
Semi-structured interview guide for program participants ...	⁸ 43	1	43	1	43
Total	1,155		1,155		571

¹ Assumes 2,500 impact study participants over the three-year clearance period.

² Assumes 67 grantee administrators over the three-year clearance period.

³ Assumes 128 correctional facility administrators over the three-year clearance period.

⁴ Assumes 112 direct grant administrators from six sites and 18 intermediary grant administrators from 16 sites over the three-year clearance period.

⁵ Assumes 160 partner administrators from 16 sites over the three-year clearance period.

⁶ Assumes 240 frontline staff from 16 sites over the three-year clearance period.

⁷ Assumes 115 pre-release participants from 16 sites over the three-year clearance period.

⁸ Assumes 128 post-release participants from 16 sites over the three-year clearance period.

Christina Yancey,

Chief Evaluation Officer, U.S. Department of Labor.

[FR Doc. 2021–24057 Filed 11–3–21; 8:45 am]

BILLING CODE 4510–HX–P

NATIONAL CREDIT UNION ADMINISTRATION

Sunshine Act Meetings

TIME AND DATE: 10 a.m., Thursday, November 4, 2021.

PLACE: Meeting will be held via videoconference.

STATUS: Closed.

Pursuant to the provisions of the “Government in Sunshine Act,” notice is hereby given that the NCUA Board unanimously determined that agency business required holding a closed meeting with less than seven days’ notice to the public, and that no earlier notice of the meeting was possible.

MATTER TO BE CONSIDERED:

1. Supervisory Action. Closed pursuant to Exemptions (8), (9)(i)(B), and (9)(ii).

CONTACT PERSON FOR MORE INFORMATION: Melane Conyers-Ausbrooks, Secretary of the Board, Telephone: 703–518–6304.

Melane Conyers-Ausbrooks,

Secretary of the Board.

[FR Doc. 2021–24177 Filed 11–2–21; 11:15 am]

BILLING CODE 7535–01–P

NATIONAL SCIENCE FOUNDATION

Sunshine Act Meeting

The National Science Board’s Executive Committee hereby gives notice of the scheduling of a teleconference for the transaction of National Science Board business, pursuant to the National Science Foundation Act and the Government in the Sunshine Act.

TIME AND DATE: Monday, November 8, 2021, from 2:00–3:00 p.m. EDT.

PLACE: This meeting will be held by teleconference through the National Science Foundation.

STATUS: Open.

MATTERS TO BE CONSIDERED: Committee Chair’s opening remarks; approval of Executive Committee minutes of June 29, 2021; and discuss issues and topics

for an agenda of the NSB meeting scheduled for December 8–9, 2021.

CONTACT PERSON FOR MORE INFORMATION:

Point of contact for this meeting is: Nirmala Kannankutty, 703/292–8000. To listen to this teleconference, members of the public must send an email to nationalsciencebrd@nsf.gov at least 24 hours prior to the teleconference. The National Science Board Office will send requesters a toll-free dial-in number. Meeting information and updates may be found at www.nsf.gov/nsb.

Chris Blair,

Executive Assistant to the National Science Board Office.

[FR Doc. 2021–24163 Filed 11–2–21; 11:15 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION**[Docket No. 50–201; NRC–2021–0175]****New York State Energy Research and Development Authority; Irradiated Nuclear Fuel Processing Plant; Western New York State Nuclear Service Center****AGENCY:** Nuclear Regulatory Commission.**ACTION:** Environmental assessment and finding of no significant impact; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing an environmental assessment (EA) and finding of no significant impact (FONSI) related to a request to amend Facility Provisional Operating License No. CSF–1 for provisional operation of the Irradiated Nuclear Fuel Processing Plant located at the Western New York Nuclear Service Center (WNYNSC), in Cattaraugus and Erie Counties, New York. The requested amendment would amend the Radiation Protection Program for the “retained premises of the licensed area” for modernization. In addition, the New York State Energy Research and Development Authority (NYSERDA), the licensee, requested that the license be amended to clarify NYSERDA’s health and safety and other responsibilities under the license. NYSERDA defines the “retained premises of the licensed area” as the area consisting of the WNYNSC, not including the U.S. Department of Energy (DOE) West Valley Demonstration Project (WVDP) premises and the State Licensed Disposal Area (SDA).

DATES: The EA and FONSI referenced in this document are available on November 2, 2021.

ADDRESSES: Please refer to Docket ID NRC–2021–0175 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- **Federal Rulemaking Website:** Go to <https://www.regulations.gov> and search for Docket ID NRC–2021–0175. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: Stacy.Schumann@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- **NRC’s Agencywide Documents Access and Management System (ADAMS):** You may obtain publicly available documents online in the

ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select “Begin Web-based ADAMS Search.” For problems with ADAMS, please contact the NRC’s Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to pdr.resource@nrc.gov. The ADAMS accession number for each document referenced in this notice (if that document is available in ADAMS) is provided the first time that a document is referenced.

- **Attention:** The PDR, where you may examine and order copies of public documents, is currently closed. You may submit your request to the PDR via email at pdr.resource@nrc.gov or call 1–800–397–4209 or 301–415–4737, between 8:00 a.m. and 4:00 p.m. (ET), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT:

Amy Snyder, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–6822; email: Amy.Snyder@nrc.gov.

SUPPLEMENTARY INFORMATION:**I. Introduction**

The NRC is considering a request to amend NYSERDA’s Facility Provisional Operating License No. CSF–1 for provisional operation of the Irradiated Nuclear Fuel Processing Plant, located at the WNYNSC in Cattaraugus and Erie Counties, New York, in accordance with Section 50.90 of title 10 of the *Code of Federal Regulations* (10 CFR), “Application for amendment of license, construction permit, or early site permit.” Consistent with 10 CFR 51.21, “Criteria for and identification of licensing and regulatory actions requiring environmental assessments,” the NRC has reviewed the requirements in 10 CFR 51.20(b) and 10 CFR 51.22(c) and determined that an EA is the appropriate form of environmental review. Based on the results of the EA, the NRC is issuing this final FONSI.

The requested changes would amend the Radiation Protection Program for the “retained premises of the licensed area” for modernization and would clarify NYSERDA’s health and safety and other responsibilities under the license. Although portions of the site are actively being decommissioned by DOE under the West Valley Demonstration Project Act, 42 U.S.C. 2021a note, Public Law 96–868, 94 Stat. 1347 (1980) (WVDP), NYSERDA retains responsibility for the portions of the site known as the “retained premises.”

NYSERDA’s Radiation Protection Program license amendment application

was submitted on February 6, 2020 (ADAMS Accession No. ML20042D497); on March 11, 2020 (ADAMS Accession No. ML20076C310), NYSERDA resubmitted the amendment application to address the requirements of 10 CFR 50.30, “Filing of application for licenses; oath or affirmation.” The NRC staff completed an initial review of the resubmitted license amendment application on March 30, 2020 (ADAMS Accession No. ML20084G641) and identified areas in which more information was necessary to complete the acceptance review. NYSERDA responded with this additional information by letter dated October 28, 2020 (ADAMS Accession No. ML20311A200). On July 15, 2021 (ADAMS Accession No. ML21202A212), NYSERDA supplemented the application in response to NRC staff requests for additional information that were transmitted by letter dated June 3, 2021 (ADAMS Accession No. ML21118A076). On September 10, 2021 (ADAMS Package Accession No. ML21281A019), NYSERDA supplemented the application in response to the NRC staff requests for additional information that were transmitted by email dated August 27, 2021. On October 12, 2021 (ADAMS Accession No. ML21286A001), NYSERDA supplemented the application in response to the NRC staff October 7, 2021 email request (ADAMS Accession No. ML21281A030) for clarification of its September 10, 2021 response.

Before issuance of the proposed license amendment, the NRC will need to make the findings required by the Atomic Energy Act of 1954, as amended, and the applicable NRC regulations. The NRC has made a determination that the NYSERDA license amendment request involves no significant hazards consideration (NSHC), under the NRC’s regulations in 10 CFR 50.92, “Issuance of amendment.” This means that provisional operation of the facility in accordance with the proposed amendment would not: (1) Involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety.

The NSHC determination was published in the **Federal Register** on March 10, 2021 (86 FR 13762), along with an opportunity to provide comments, request a hearing, or petition for leave to intervene on the proposed amendment.

Because the topics of the NSHC and this EA are related, the EA includes the NRC staff's consideration of the comments received on the initial NSHC determination, which were provided on April 8, 2021, from the West Valley Citizens Task Force and a member of the public (ADAMS Accession Nos. ML21110A058 and ML21110A059, respectively). While many of these comments pertain to ongoing DOE decommissioning and dismantlement activities under the WVDPA and are therefore outside the scope of the requested changes to the NYSEDA Radiation Protection Program for the retained premises, the in-scope comments were addressed in the NRC's EA.

II. Environmental Assessment

Description of the Proposed Action

The proposed action would permit NYSEDA personnel to conduct activities in the retained premises of the WNYNSC under the provisions of an updated Radiation Protection Program. The Radiation Protection Program commitments will ensure regulatory compliance for any licensed activities NYSEDA may perform in the retained premises. Routine maintenance activities expected to be performed within the retained premises include tree removal, fence repair, foliage trimming or removal, environmental monitoring, utility work, etc. The proposed action is in accordance with the NYSEDA license amendment application, as supplemented.

Need for the Proposed Action

The proposed action would involve the addition of license conditions to provide additional clarity on NYSEDA's authorities and responsibilities for health and safety of the retained premises of the WNYNSC under the current license and replace existing radiation protection requirements in the license pertaining to the non-SDA, non-WVDP portions of the WNYNSC where licensed radioactive materials are or may be present. The retained premises constitute generally undeveloped or open land portions of the property which may, or may not, contain legacy contamination from previous West Valley plant processes. However, there are currently no ongoing operations in these areas other than general grounds maintenance.

The NRC staff notes that the proposed NYSEDA Radiation Protection Program would not be applicable to the property currently containing the WVDP or the SDA. When DOE completes its activities and turns the WVDP property

back over to NYSEDA, significant revision to the Radiation Protection Program will be necessary before NYSEDA assumes responsibility for the remaining WVDP facilities. The radiation protection requirements for the SDA are established by the State of New York and outside of the NRC's jurisdiction. As such, the NRC staff limited its review to the current proposed NYSEDA Radiation Protection Program while also establishing a license condition that the Radiation Protection Program be reviewed, revised, and submitted for regulatory approval prior to NYSEDA assuming responsibility for any facilities that are currently part of the WVDP.

Comments on the Proposed Action

NYSEDA maintains that the radiation protection provisions contained within the current Final Safety Analysis Report, which is referenced in the license: (1) Have not been updated since 1964; (2) were intended to apply to the irradiated nuclear fuel processing plant (which is not considered part of the retained premises); and (3) are not appropriate for the planned maintenance and other licensed activities in the relatively undeveloped areas of the retained premises. The proposed update to the NYSEDA Radiation Protection Program would commit NYSEDA to the current version of 10 CFR part 20, "Standards for Protection Against Radiation," for the purpose of providing radiation protection programs and procedures in the retained premises of the WNYNSC.

The NRC received comments related to the potential for use of the current version of the 10 CFR part 20 requirements to allow higher radiological releases to the environment than presently permitted for the West Valley facility. Specifically, the comments raise a concern that the use of effective dose equivalents pursuant to 10 CFR part 20, instead of the previous dose equivalent calculations that limit the public dose to 25 millirem per year (mrem/yr) wholebody exposure, or 75 mrem/yr to the thyroid, or 25 mrem/yr to any other organ, would allow a higher public exposure limit than that currently in effect for West Valley. The NRC staff notes that the dose equivalent limits referenced in the comment (25/75/25 mrem/yr to a member of the public) are those applicable to low-level waste facilities and disposal sites as described in 10 CFR 61.41, "Protection of the general population from releases of radioactivity," as well as to fuel cycle facilities as outlined in the U.S. Environmental Protection Agency's

regulations at 40 CFR 191, "Environmental Radiation Protection Standards for Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes."

However, the retained premises of the WNYNSC are not considered a low-level waste facility, a disposal site, or a fuel cycle facility. Therefore, as long as the proposed Radiation Protection Program is not applicable to the WVDP or the SDA portions of the site, the use of the effective dose equivalent limits under the current 10 CFR part 20 requirements is appropriate for the retained premises. The NRC staff notes that when NYSEDA assumes responsibility for the remaining WVDP facilities upon completion of the DOE decommissioning and dismantlement activities, the public dose limits applicable at that time to those additional portions of the site would need to be reflected in a future update to the NYSEDA Radiation Protection Program.

The NRC also received comments related to the potential for previous contamination events or releases from WVDP activities to impact the retained premises of the WNYNSC. A similar comment was received related to ongoing and future WVDP decommissioning and demolition work that have the potential to cause accidents or spills that could impact the retained premises, and the need for NYSEDA to evaluate the potential for adverse consequences and be prepared for potential adverse events. The NRC staff previously addressed historical contamination concerns as part of a larger effort undertaken by NYSEDA to characterize and analyze offsite radioactivity after aerial surveys indicated residual radioactivity levels above background. Specifically, the NRC produced a Technical Evaluation Report, dated April 9, 2018 (ADAMS Package Accession No. ML18087A663), which indicated that the risk of offsite residual radioactivity is extremely low, while recognizing that historical releases did lead to contamination of offsite lands. The Technical Evaluation Report noted that much of this offsite radioactivity appears to have since dispersed in the environment and is at very low levels.

In addition, the NRC staff notes that the retained premises of the WNYNSC are generally undeveloped areas inadvertently contaminated by WVDP legacy operations, with very limited exposure pathways for this contamination to be released offsite. As such, it is unlikely that the proposed NYSEDA activities under the Radiation Protection Program would

produce any radiological effluent emissions of note. If an effluent were released, it would generally be constrained by the NRC's constraint for air emissions, which is 10 mrem/yr total effective dose equivalent (TEDE), and/or use the 10 CFR part 20, Appendix B, "Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage," effluent limit, which is 50 mrem/yr TEDE. Both of these limits are considerably less than the 100 mrem/yr TEDE dose limit for members of the public.

In terms of the potential for DOE's ongoing WVDP activities to impact the retained premises of the WNYNSC, any unanticipated events or potential releases that could impact any areas outside the WVDP, including the retained premises, will continue to be addressed under DOE's radiation protection programs and requirements for the WVDP, as specified by the WVDP and other applicable regulations. Because the proposed NYSEDA Radiation Protection Program is not applicable to the WVDP areas of the site, DOE radiation protection provisions will govern any decommissioning or demolition impacts on the retained premises as part of DOE's remediation efforts.

Environmental Impacts of the Proposed Action

The NRC completed its evaluation of the proposed action and determined that the proposed updates to the NYSEDA Radiation Protection Program for the retained premises of the WNYNSC would not significantly increase the probability or consequences of any accidents. In addition, the proposed action would not significantly change the types and the amounts of any effluents that may be released offsite. There would also be no significant construction or land disturbance activities or increase in occupational or public radiation exposure. Therefore, there would be no significant radiological environmental impacts associated with the proposed action.

The proposed action would not impact land, air, or water resources, including biota. In addition, the proposed action would not result in any socioeconomic or environmental justice impacts or impacts to historic and cultural resources. Therefore, there would also be no significant non-radiological environmental impacts associated with the proposed action.

Accordingly, the NRC concludes that the proposed action (license amendment) would not result in significant environmental impacts. Details of the NRC's evaluation will be provided in a letter to the licensee approving the license amendment.

Environmental Impacts of the Alternatives to the Proposed Action

As an alternative to the proposed action, the NRC staff considered denying the proposed action (*i.e.*, the "no-action" alternative). Under the no-action alternative, the NRC would not approve the NYSEDA Radiation Protection Program for the retained premises of the WNYNSC or the license amendment request because the associated regulatory requirements have not been met. Consequently, there would be no change to the current radiation protection requirements applicable to the retained premises, and NYSEDA would continue to face challenges with conducting maintenance activities under an outdated Radiation Protection Program. If the NRC was unable to approve the NYSEDA Radiation Protection Program because the regulatory requirements were not met, then the licensee would have to take the necessary actions to ensure the applicable radiation protection regulations are met.

Alternative Use of Resources

The proposed action would not involve the use of any resources.

Agencies and Persons Consulted

The staff consulted with the State of New York regarding the environmental impact of the proposed action on September 2, 2021. The State of New York responded on September 17, 2021 with no comments (ADAMS Accession No. ML21281A089).

III. Finding of No Significant Impact

Based on its review of the proposed action, and in accordance with the requirements in 10 CFR part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions," the NRC staff has determined that pursuant to 10 CFR 51.31, "Determinations based on environmental assessment," preparation of an environmental impact statement is not required for the proposed action and pursuant to 10 CFR 51.32, "Finding of no significant impact," a FONSI is appropriate.

On the basis of the information presented in this EA, the NRC concludes that the proposed action would not cause any significant

environmental impact and would not have a significant effect on the quality of the human environment. Accordingly, the NRC has determined not to prepare an environmental impact statement for the proposed action.

Other than the licensee's letter dated March 11, 2020, as supplemented, there are no other environmental documents associated with this review. These documents are available for public inspection as previously indicated.

Dated: November 1, 2021.

For the Nuclear Regulatory Commission.

Bruce A. Watson,

Chief, Reactor Decommissioning Branch, Decommissioning, Uranium Recovery and Waste Programs, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2021-24118 Filed 11-3-21; 8:45 am]

BILLING CODE 7590-01-P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2022-16 and CP2022-17]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* November 8, 2021.

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

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

SUPPLEMENTARY INFORMATION:

Table of Contents

- I. Introduction
- II. Docketed Proceeding(s)

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the market dominant or the competitive product list, or the

modification of an existing product currently appearing on the market dominant or the competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (<http://www.prc.gov>). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3011.301.¹

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern market dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3030, and 39 CFR part 3040, subpart B. For request(s) that the Postal Service states concern competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3040, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s)*: MC2022–16 and CP2022–17; *Filing Title*: USPS Request to Add Priority Mail Express, Priority Mail, First-Class Package Service & Parcel Select Contract 10 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date*: October 29, 2021; *Filing Authority*: 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative*: Jennaca D. Upperman; *Comments Due*: November 8, 2021.

This Notice will be published in the **Federal Register**.

Erica A. Barker,
Secretary.

[FR Doc. 2021–24072 Filed 11–3–21; 8:45 am]

BILLING CODE 7710–FW–P

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).

POSTAL SERVICE

Product Change—First-Class Package Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* November 4, 2021.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on October 25, 2021, it filed with the Postal Regulatory Commission a *USPS Request to Add First-Class Package Service Contract 118 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2022–14, CP2022–15.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2021–24004 Filed 11–3–21; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, First-Class Package Service, and Parcel Select Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* November 4, 2021.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on October 29, 2021, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail, First-Class Package Service, and Parcel Select Service Contract 10 to Competitive Product List*. Documents

are available at www.prc.gov, Docket Nos. MC2022–16, CP2022–17.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2021–24006 Filed 11–3–21; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail, Parcel Select, and First-Class Package Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* November 4, 2021.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on October 18, 2021, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add Priority Mail, Parcel Select, & First-Class Package Service Contract 1 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2022–11, CP2022–12.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2021–24001 Filed 11–3–21; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* November 4, 2021.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C.

3642 and 3632(b)(3), on October 20, 2021, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Contract 726 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2022–12, CP2022–13.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2021–24002 Filed 11–3–21; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and First-Class Package Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* November 4, 2021.

FOR FURTHER INFORMATION CONTACT:

Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on October 28, 2021, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & First-Class Package Service Contract 208 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2022–15, CP2022–16.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2021–24005 Filed 11–3–21; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* November 4, 2021.

FOR FURTHER INFORMATION CONTACT:

Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on October 21, 2021, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express Contract 93 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2022–13, CP2022–14.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2021–24003 Filed 11–3–21; 8:45 am]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93463; File No. SR–MIAX–2021–52]

Self-Regulatory Organizations; Miami International Securities Exchange, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Make a Minor Adjustment to the Calculation Methodology for the BRIXX™ Commercial Real Estate Indexes

October 29, 2021.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”),¹ and Rule 19b–4 thereunder,² notice is hereby given that on October 18, 2021, Miami International Securities Exchange, LLC (“MIAX Options” or “Exchange”) filed with the Securities and Exchange Commission (“Commission”) a proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing a proposal to make a minor adjustment to the calculation methodology for the BRIXX™ Commercial Real Estate Indexes (the “BRIXX Indexes”), on which the Exchange may list and trade options.

The text of the proposed rule change is available on the Exchange's website at <http://www.miaxoptions.com/rule-filings/> at MIAX Options' principal office, and at the Commission's Public Reference Room.

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to make a minor adjustment to the calculation methodology for each of the sector BRIXX Indexes—the BRIXX Office Index, BRIXX Retail Index, BRIXX Residential Index, and BRIXX Hospitality Index (collectively, the “BRIXX Sector Indexes”), on which the Exchange may list and trade options.³ The Exchange does not propose to amend the methodology for the BRIXX Composite Index at this time.

Background

On April 17, 2020, the Exchange filed its proposal to list and trade options on five AF CRE Indexes (the AF CRE Residential Index, AF CRE Retail Index, AF CRE Office Index, AF CRE Hospitality Index and AF CRE Composite Index),⁴ all of which have since been rebranded as the BRIXX Indexes.⁵ In the AF CRE Index Notice, the Exchange described, among other things, the component selection criteria in order for an equity real estate

³ On April 16, 2020, the Exchange filed a Form 19b–4(e) with the Commission pursuant to Rule 19b–4(e) of the Act to list and trade options on the Advanced Fundamentals Commercial Real Estate Indexes (the “AF CRE Indexes”), which have since been rebranded as the BRIXX Indexes. See Securities Exchange Act Release No. 91542 (April 13, 2021), 86 FR 20426 (April 19, 2021) (SR–MIAX–2021–09). The Exchange has not yet listed options for trading on the BRIXX Indexes for business reasons. The Exchange notes that it will file a new Form 19b–4(e) with the Commission pursuant to Rule 19b–4(e) of the Act to list and trade options on the BRIXX Indexes at the time the Exchange anticipates it will begin listing options for trading.

⁴ See Securities Exchange Act Release No. 88767 (April 29, 2020), 85 FR 26743 (May 5, 2020) (SR–MIAX–2020–08) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change to List and Trade Options That Overlie Five Advanced Fundamentals LLC Commercial Real Estate Indexes) (the “AF CRE Index Notice”).

⁵ See *supra* note 3.

investment trust (“REIT”) to be included in the calculation of each index.

In particular, the composition of each index is determined in a reconstitution on a quarterly basis from audited REIT company public filings and supplemental filings with the Commission, updated each quarter and intra-quarter based on 8–K, 10–Q, and 10–K filings. The components in each of the indexes are determined from the REITs that have the largest enterprise value (“Enterprise Value”)⁶ within each individual sector and that meet the following minimum eligibility requirements. To be eligible for inclusion in each of the BRIXX Sector Indexes, a REIT must: (i) Be classified as an equity REIT; (ii) be listed on a U.S. securities exchange; (iii) have a minimum Enterprise Value of \$1 billion; (iv) have at least 85% of its revenue derived from the associated asset class; and (v) have issued a quarterly filing or annual report after its initial listing.

Proposal

The Exchange now proposes to modify the condition in romanette (iv), above, for an equity REIT to be eligible for inclusion in each of the BRIXX Sector Indexes. With the proposed change, to be eligible for inclusion in each of the BRIXX Sector Indexes, an equity company/REIT must have at least 70% of its revenue derived from the associated asset class. The Exchange does not propose to amend any other criteria for inclusion in the BRIXX Sector Indexes. The purpose of this change is to ensure a broad scope of REITs that may be included in the calculation of each BRIXX Sector Index while continuing to maintain that each component REIT derive substantial revenue from the associated asset class. The Exchange believes that with the proposed change, there will be a greater pool of equity REITs that may qualify for inclusion in each of the BRIXX Sector Index calculations, while continuing to ensure that the integrity of each BRIXX Sector Index will not be compromised.

Further, with the proposed change, each BRIXX Sector Index will continue to be comprised of equity REITs representative of each particular sector of commercial real estate. The Exchange also believes that this proposal will continue to provide transparency

regarding the calculation methodology for the BRIXX Sector Indexes. The Exchange represents that the proposed change will have no impact on the accuracy and dissemination of the BRIXX Sector Index values, which will continue to be disseminated and available to market participants in the same manner and in the same intervals. The proposed change will be made before the Exchange launches options on the BRIXX Sector Indexes.

The Exchange intends that this filing is to provide market participants with an update regarding the proposed change to one condition of the component selection criteria, which criteria was included in the initial filing to list and trade options on the AF CRE Indexes (since rebranded as the BRIXX Indexes), as described in the AF CRE Index Notice.⁷ The Exchange notes that this filing does not propose to amend any of the Exchange’s generic initial and maintenance listing criteria, as set forth in Exchange Rules 1802(b)–(e). Further, the Exchange notes that with the proposed change to modify one of the conditions to the component selection criteria, the BRIXX Sector Indexes will continue to satisfy the Exchange’s initial and maintenance listing criteria for narrow-based indexes pursuant to the Exchange’s current rules.⁸

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.⁹ Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)¹⁰ 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)¹¹ requirement that the rules of an exchange not be designed

to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that the proposed rule changes remove impediments to and perfects the mechanism of a free and open market a national market system, and protects investors and the public interest by updating the methodology to determine which component securities are eligible for inclusion in each of the BRIXX Sector Indexes. The proposed change will have no impact on the dissemination of BRIXX Sector Index values; rather, the proposed change is intended to provide an update to market participants regarding the wider eligibility of certain components in the calculation of each index. The Exchange believes that by broadening the scope of potential equity REITs that may be included in each of the BRIXX Sector Indexes, this will ensure that no single equity REIT dominates each index. The Exchange believes this proposal perfects the mechanism of a free and open market a national market system, and protects investors and the public interest because, with the proposed change, there will be no change to the initial or maintenance listing criteria, expiration months, settlement or exercise style of options on the BRIXX Sector Indexes. Further, the Exchange believes that the proposed change will have no impact on the accuracy and dissemination of the BRIXX Sector Index values, which will continue to be disseminated and available to market participants in the same manner and in the same intervals. The Exchange notes that it has not listed options on the BRIXX Indexes at this time.

The Exchange believes that the proposal satisfies the requirements of Section 6(b)(5)¹² of the Act because, with the proposed change, each of the BRIXX Sector Indexes will continue to satisfy the initial listing criteria for narrow-based indexes pursuant to the Exchange’s current rules.¹³ The Exchange notes that the initial listing criteria in Exchange Rule 1802(b) covers the following categories of requirements, in general, for each of the BRIXX Sector Indexes: That options are A.M.-settled; each index is modified-market capitalization weighted; specified minimum market capitalizations for each component security; specified minimum trading volumes over certain time periods for each component security; specified maximum weighting for the combined weight of the five highest weighted component securities in each index;

⁶ The term “Enterprise Value” refers to the measure of a company’s total value, calculated by adding the company’s market capitalization, total liabilities and preferred equity, then subtracting all cash and cash equivalents. See <https://www.investopedia.com/terms/e/enterprise-value.asp>.

⁷ See *supra* note 4, pages 10–11.

⁸ See Exchange Rule 1802(b)–(c).

⁹ 15 U.S.C. 78f(b).

¹⁰ 15 U.S.C. 78f(b)(5).

¹¹ *Id.*

¹² 15 U.S.C. 78f(b)(5).

¹³ See Exchange Rule 1802(b).

specified maximum weights for each individual component security; that each component security is an “NMS stock” as defined in Rule 600 of Regulation NMS under the Act; and, that each index is widely disseminated at least once every 15 seconds by OPRA, CTA/CQ, NIDS or one or more major market data vendors.¹⁴ The Exchange also believes that, with the proposed modified eligibility criteria, that each of the BRIXX Sector Indexes will continue to satisfy the maintenance listing standards set forth in Exchange Rule 1802(c). The Exchange notes that the maintenance listing criteria in Exchange Rule 1802(c) covers the following categories of requirements, in general, for each of the BRIXX Sector Indexes: That the initial listing criteria set forth in Exchange Rule 1802(b)(1), (3), (6)–(12) continue to be satisfied; specified percentages that the total number of component securities may increase or decrease by from the time of initial listing; and specified trading volumes over six months.¹⁵ Notwithstanding the proposed change in component selection criteria, there will be no change to the current generic initial and maintenance listing criteria. This proposed change will have no impact on, or effect application and interpretation of, the initial and maintenance listing criteria in Exchange Rules 1802(b)–(c). The purpose of this proposed change is to update potential market participants regarding the component selection criteria used for each of the BRIXX Sector Indexes.

The Exchange represents that it will continue to have the necessary systems capacity to support the new option series for each of the BRIXX Sector Indexes given the proposed modification once the Exchange determines to list options on the BRIXX Sector Indexes.

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.

Intra-Market Competition

The Exchange does not believe that the proposed change will impose any burden on intra-market that is not necessary or appropriate in furtherance of the purposes of the Act because the proposed change is not intended to address a competitive issue. Rather, the proposed change is to update one piece

of the calculation methodology for the BRIXX Sector Indexes, on which the Exchange is authorized to list options. The proposed rule change has no impact on the dissemination of index values for the BRIXX Indexes. Further, the Exchange has not yet listed options for trading on the BRIXX Indexes at this time.

Inter-Market Competition

The Exchange does not believe the proposed change will impose any burden on inter-market competition because the proposed rule change will continue to facilitate the listing and trading of novel options products that will enhance competition for commercial real estate securities among market participants, to the benefit of investors and the marketplace. This proposal furthers the Exchange’s goal of listing options on the BRIXX Indexes, which will enhance competition by providing investors with an additional investment vehicle, in a fully-electronic trading environment, through which investors can gain and hedge exposure to various sectors of the commercial real estate market. Further, these products could offer a competitive alternative to other existing investment products that seek to allow investors to gain broad market exposure via equity REITs in the same individual sectors as the BRIXX Indexes.

C. Self-Regulatory Organization’s Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate, it has become effective pursuant to 19(b)(3)(A) of the Act¹⁶ and Rule 19b–4(f)(6)¹⁷ 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 shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission’s internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR–MIAX–2021–52 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–MIAX–2021–52. 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

¹⁴ See *id.*

¹⁵ See Exchange Rule 1802(c).

¹⁶ 15 U.S.C. 78s(b)(3)(A).

¹⁷ 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

submissions should refer to File Number SR-MIAX-2021-52 and should be submitted on or before November 26, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁸

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021-24012 Filed 11-3-21; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meetings

TIME AND DATE: 1:30 p.m. on Tuesday, November 9, 2021.

PLACE: The meeting will be held via remote means and/or at the Commission's headquarters, 100 F Street NE, Washington, DC 20549.

STATUS: This meeting will be closed to the public.

MATTERS TO BE CONSIDERED:

Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the closed meeting. Certain staff members who have an interest in the matters also may be present.

In the event that the time, date, or location of this meeting changes, an announcement of the change, along with the new time, date, and/or place of the meeting will be posted on the Commission's website at <https://www.sec.gov>.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(3), (5), (6), (7), (8), 9(B) and (10) and 17 CFR 200.402(a)(3), (a)(5), (a)(6), (a)(7), (a)(8), (a)(9)(ii) and (a)(10), permit consideration of the scheduled matters at the closed meeting.

The subject matter of the closed meeting will consist of the following topics:

- Institution and settlement of injunctive actions;
- Institution and settlement of administrative proceedings;
- Resolution of litigation claims; and
- Other matters relating to examinations and enforcement proceedings.

At times, changes in Commission priorities require alterations in the scheduling of meeting agenda items that may consist of adjudicatory, examination, litigation, or regulatory matters.

CONTACT PERSON FOR MORE INFORMATION: For further information; please contact

Vanessa A. Countryman from the Office of the Secretary at (202) 551-5400.

Authority: 5 U.S.C. 552b.

Dated: November 2, 2021.

Vanessa A. Countryman,

Secretary.

[FR Doc. 2021-24222 Filed 11-2-21; 4:15 pm]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-93472; File No. SR-NYSEArca-2021-91]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing of Proposed Rule Change to Amend Rule 6.87-O

October 29, 2021.

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 October 20, 2021, 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 amend Rule 6.87-O to improve the operation of the Rule. 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.

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b-4.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this rule change is to amend Rule 6.87-O "Nullification and Adjustment of Options Transactions including Obvious Errors" to improve the operation of the Rule. Following discussions with other exchanges and a cross-section of industry participants and in coordination with the Listed Options Market Structure Working Group ("LOMSWG") (collectively, the "Industry Working Group"), the Exchange proposes: (1) To amend section (b)(3) of the Rule to permit the Exchange to determine the Theoretical Price of a Customer option transaction in a wide market so long as a narrow market exists at any point during the 10-second period after an opening or re-opening; and (2) to amend section (c)(4)(B) of the Rule to adjust, rather than nullify, Customer transactions in Obvious Error situations, provided the adjustment does not violate the limit price. The Exchange understands that upon approval of this proposal, other options exchanges will also submit substantively identical proposals to the Commission.

Proposed Change to Section (b)(3)

Rule 6.87-O has been part of various harmonization efforts by the Industry Working Group.⁴ These efforts have often centered around the Theoretical Price for which an options transaction should be compared to determine whether an Obvious Error has occurred. For instance, all options exchanges have adopted language comparable to Commentary .06,⁵ which explains how an exchange is to determine Theoretical Price at the open, when there are no valid quotes, and when there is a wide quote. This includes at times the use of a singular third-party vendor, known as a TP Provider (currently CBOE Livevol, LLC).

Similarly, section (b)(3) of Rule 6.87-O was previously harmonized across all options exchanges to handle situations where executions occur in markets that are wide (as set forth in the rule).⁶ Under that section, the Exchange

⁴ See, e.g., Securities Exchange Act Release Nos. 74921 (May 8, 2015), 80 FR 27747 (May 14, 2015) (SR-NYSEArca-2015-41); 80496 (April 20, 2017), 82 FR 19282 (April 26, 2017) (SR-NYSEArca-2017-42).

⁵ See, e.g., Securities Exchange Act Release No. 81580 (September 12, 2017), 82 FR 43578 (September 18, 2017) (SR-NYSEArca-2017-101).

⁶ See, e.g., Securities Exchange Act Release No. 74921 (May 8, 2015), 80 FR 27747 (May 14, 2015) (SR-NYSEArca-2015-41).

¹⁸ 17 CFR 200.30-3(a)(12).

determines the Theoretical Price if the NBBO for the subject series is wide immediately before execution and a narrow market (as set forth in the rule) existed “during the 10 seconds prior to the transaction.” The rule goes on to clarify that, should there be no narrow quotes “during the 10 seconds prior to the transaction,” the Theoretical Price for the affected series is the NBBO that existed at the time of execution (regardless of its width).

In recent discussions, the Industry Working Group has identified proposed changes to section (b)(3) of Rule 6.87–O that would improve the Rule’s functioning. Currently, section (b)(3) does not permit the Exchange to determine the Theoretical Price unless there is a narrow quote 10 seconds prior to the transaction. However, in the first seconds of trading, there is no 10-second period “prior to the transaction.” Further, the Industry Working Group has observed that prices in certain series can be disjointed at the start of trading. Accordingly, the Exchange proposes to provide additional protections to trading in certain circumstances immediately after the opening before liquidity has had a chance to enter the market. The Exchange proposes to amend section (b)(3) to allow the Exchange to determine the Theoretical Price in a wide market so long as a narrow market exists at any point during the 10-second period after an opening or re-opening.

Specifically, the Exchange proposes that the existing text of section (b)(3) would become sub-section “A.” The Exchange proposes to add the following heading and text as sub-section “B.”:

B. Customer Transactions Occurring Within 10 Seconds or less After an Opening or Re-Opening:

(i) The Exchange will determine the Theoretical Price if the bid/ask differential of the NBB and NBO for the affected series just prior to the Customer’s erroneous transaction was equal to or greater than the Minimum Amount set forth in paragraph A above and there was a bid/ask differential less than the Minimum Amount during the 10 seconds prior to the transaction.

(ii) If there was no bid/ask differential less than the Minimum Amount during the 10 seconds prior to the transaction, then the Exchange will determine the Theoretical Price if the bid/ask differential of the NBB and NBO for the affected series just prior to the Customer’s erroneous transaction was equal to or greater than the Minimum Amount set forth in paragraph A above and there was a bid/ask differential less than the Minimum Amount anytime during the 10 seconds after an opening or re-opening.

(iii) If there was no bid/ask differential less than the Minimum Amount during the 10 seconds following an Opening or Re-Opening, then the Theoretical Price of an

option series is the last NBB or NBO just prior to the Customer transaction in question, as set forth in paragraph (b) above.

(iv) Customer transactions occurring more than 10 seconds after an opening or re-opening are subject to paragraph A above.

The following examples illustrate the functioning of the proposed rule change. Consider that the NBBO of a series opens as \$0.01 at \$4.00. A marketable limit order to buy one contract arrives one second later and is executed at \$4.00. In the third second of trading, the NBBO narrows from \$0.01 at \$4.00 to \$2.00 at \$2.10. While the execution occurred in a market with wide widths, there was no tight market within the 10 seconds prior to execution. Accordingly, under the current rule, the trade would not qualify for obvious error review, in part due to the fact that there was only a single second of trading before the execution. Under the proposal, since a tight market existed at some point in the first 10 seconds of trading (*i.e.*, in the third second), the Exchange would be able to determine the Theoretical Price as provided in Commentary .06.

As another example, the NBBO for a series opens as \$0.01 at \$4.00. In the seventh second of trading, a marketable limit order is received to buy one contract and is executed at \$4.00. Five seconds later (*i.e.*, in the twelfth second of trading), the NBBO narrows from \$0.01 at \$4.00 to \$2.00 at \$2.10. While the execution occurred in a market with wide widths, there was no tight market within 10 seconds prior to execution. Accordingly, under the current rule, the trade would not qualify for obvious error review. Under the proposal, since no tight market existed at any point during the first 10 seconds of trading (*i.e.*, the narrow market occurred in the twelfth second), the trade would not qualify for obvious error review.

The proposed rule change would also better harmonize section (b)(3) with section (b)(1) of the Rule. Under section (b)(1), the Exchange is permitted to determine the Theoretical Price for transactions occurring as part of the opening auction process (as defined in Rule 6.64–O) if there is no NBB or NBO for the affected series just prior to the erroneous transaction. However, under the current version of section (b)(3), a core trading transaction could occur in the same wide market but the Exchange would not be permitted to determine the Theoretical Price. Consider an example where one second after the Exchange opens a selected series, the NBBO is \$1.00 at \$5.00. At 9:30:03, a customer submits a marketable buy order to the Exchange and pays \$5.00. At 9:30:03, a different exchange runs an opening auction that results in a customer

paying \$5.00 for the same selected series. At 9:30:06, the NBBO changes from \$1.00 at \$5.00 to \$1.35 at \$1.45. Under the current version of section (b)(3), the Exchange would not be able to determine the Theoretical Price for the trade occurring during core trading. However, the trade on the other exchange could be submitted for review under (b)(1) and that exchange would be able to determine the Theoretical Price. If the proposed change to section (b)(3) were approved, both of the trades occurring at 9:30:03 (on the Exchange during core trading and on another exchange via auction) would also be entitled to the same review regarding the same Theoretical Price based upon the same time.

The proposal would not change any obvious error review beyond the first 10 seconds of an opening or re-opening.

Proposed Change to Section (c)(4)(B)

The Exchange proposes to amend section (c)(4)(B)—the “Adjust or Bust” rule for Customer transactions in Obvious Error situations—to adjust rather than nullify such orders, provided the adjustment does not violate the Customer’s limit price.

Currently, the Rule provides that in Obvious Error situations, transactions involving non-Customers should be adjusted, while transactions involving Customers are nullified, unless a certain condition applies.⁷ The Industry Working Group has concluded that the treatment of these transactions should be harmonized under the Rule, such that transactions involving Customers may benefit from adjustment, just as non-Customer transactions currently do, except where such adjustment would violate the Customer’s limit price; in that instance, the trade would be nullified.

Specifically, the Exchange proposes to amend the text of section (c)(4)(B) to add that where at least one party to the Obvious Error is a Customer, “the execution price of the transaction will be adjusted by the Official pursuant to the table immediately above. Any Customer Obvious Error exceeding 50 contracts will be subject to the Size Adjustment Modifier defined in subparagraph (a)(4) above. However, if such adjustment(s) would result in an execution price higher (for buy

⁷ Specifically, the current Rule provides at section (c)(4)(C) that if an OTP Holder has 200 or more Customer transactions under review concurrently and the orders resulting in such transactions were submitted during the course of 2 minutes or less, where at least one party to the Obvious Error is a non-Customer, then the Exchange will apply the non-Customer adjustment criteria found in section (c)(4)(A).

transactions) or lower (for sell transactions) than the Customer's limit price," the trade will be nullified. The "table immediately above" referenced in the proposed text refers to the table at current Section (c)(4)(A), which provides for the adjustment of prices a specified amount away from the Theoretical Price, rather than adjusting the Theoretical Price.

The Exchange proposes no other changes at this time.

Implementation Date

The Exchange will announce the effective date of the proposed changes in a Trader Update distributed to all OTP Holders and OTP Firms. The effective date will be no sooner than six months from the approval of this proposal.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,⁸ in general, and furthers the objectives of Section 6(b)(5) of the Act,⁹ in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest and because it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that the proposed change to section (b)(3) of the Rule would remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, protect investors and the public interest because it provides a method for addressing Obvious Error Customer transactions that occur in a wide market at the opening of trading. Generally, a wide market is an indication of a lack of liquidity in the market such that the market is unreliable. Current section (b)(3) recognizes that a persistently wide quote (*i.e.*, more than 10 seconds) should be considered the reliable market regardless of its width, but does not address transactions that occur in a wide market in the first seconds of trading, where there is no preceding 10-second period to reference. Accordingly, in the first 10 seconds of trading, there

is no opportunity for a wide quote to have persisted for a sufficiently lengthy period such that the market should consider it a reliable market for the purposes of determining an Obvious Error transaction.

The proposed change would rectify this disparity and permit the Exchange to consider whether a narrow quote is present at any time during the 10-second period after an opening or re-opening. The presence of such a narrow quote would indicate that the market has gained sufficient liquidity and that the previous wide market was unreliable, such that it would be appropriate for the Exchange to determine the Theoretical Price of an Obvious Error transaction. In this way, the proposed rule harmonizes the treatment of Customer transactions that execute in an unreliable market at any point of the trading day, by making them uniformly subject to Exchange determination of the Theoretical Price.

The Exchange believes that the proposed change to section (c)(4)(B) of the Rule would remove impediments to and perfect the mechanism of a free and open market and a national market system and enhance the protection of investors by harmonizing the treatment of non-Customer transactions and Customer transactions under the Rule. Under the current Rule, Obvious Error situations involving non-Customer transactions are adjusted, while those involving Customer transactions are generally nullified, unless they meet the additional requirements of section (c)(4)(C) (*i.e.*, where an OTP Holder has 200 or more Customer transactions under review concurrently and the orders resulting in such transactions were submitted during the course of 2 minutes or less). The proposal would harmonize the treatment of non-Customer and Customer transactions by providing for the adjustment of all such transactions, except where such adjustment would violate the Customer's limit price.

When it proposed the current rule in 2015, the Exchange believed there were sound reasons for treating non-Customer transactions and Customer transactions differently. At the time, the Exchange stated its belief that "Customers are not necessarily immersed in the day-to-day trading of the markets, are less likely to be watching trading activity in a particular option throughout the day, and may have limited funds in their trading accounts," and that nullifying Obvious Error transactions involving Customers would give Customers "greater protections" than adjusting such transactions by eliminating the possibility that a Customer's order will

be adjusted to a significantly different price. The Exchange also noted its belief that "Customers are . . . less likely to have engaged in significant hedging or other trading activity based on earlier transactions, and thus, are less in need of maintaining a position at an adjusted price than non-Customers."¹⁰

Those assumptions about Customer trading and hedging activity no longer hold. The Exchange and the Industry Working Group believe that over the course of the last five years, Customers that use options have become more sophisticated, as retail broker-dealers have enhanced the trading tools available. Pursuant to OCC data, volumes clearing in the Customer range have expanded from 12,022,163 ADV in 2015 to 35,081,130 ADV in 2021. This increase in trading activity underscores the greater understanding of options by Customers as a trading tool and its use in the markets. Customers who trade options today largely are more educated, have better trading tools, and have better access to financial news than any time prior.¹¹ The proposed rule would extend the hedging protections currently enjoyed by non-Customers to Customers, by allowing them to maintain an option position at an adjusted price, which would in turn prevent a cascading effect by maintaining the hedge relationship between the option transaction and any other transactions in a related security.

The Exchange believes that extending such hedging protections to Customer transactions would remove impediments to and perfect the mechanism of a free and open market and a national market system and enhance the protection of investors by providing greater certainty of execution for all participants to options transactions. Under the current Rule, a Customer that believes its transaction was executed pursuant to an Obvious Error may be disincentivized from submitting the transaction for review, since during the review process, the Customer would be uncertain whether the trade would be nullified, and if so, whether market conditions would still permit the opportunity to execute a related order at a better price after the nullification ruling is finalized. In contrast, under the proposed rule, the Customer would know that the only likely outcomes of submitting a trade to Obvious Error review would be that the

¹⁰ Securities Exchange Act Release No. 74921 (May 9, 2015), 80 FR 27747, 27761 (May 14, 2015) (SR-NYSEArca-2015-41).

¹¹ See "Retail Traders Adopt Options En Masse" by Dan Raju, available at <https://www.nasdaq.com/articles/retail-traders-adopt-options-en-masse-2020-12-08>.

⁸ 15 U.S.C. 78f(b).

⁹ 15 U.S.C. 78f(b)(5).

trade would stand or be re-executed at a better price; the trade would only be nullified if the adjustment would violate the order's limit. Similarly, under the current Rule, during the review period, a market maker who traded contra to the Customer would be uncertain if it should retain any position executed to hedge the original trade, or attempt to unwind it, possibly at a significant loss. Under the proposed rule change, this uncertainty is largely eliminated, and the question would be whether the already-executed and hedged trade would be adjusted to a better price for the Customer, or if it would stand as originally executed. In this way, the proposed rule enhances the protection of investors and removes impediments to and perfects the mechanism of a free and open market and a national market system.

The proposed rule also addresses the concern the Exchange cited in its 2015 filing that adjusting, rather than nullifying, Customer transactions could lead to a Customer's order being adjusted to a significantly different price. To address that concern, the proposed rule would prevent Customer transactions from being adjusted to a price that violates the order's limit; if the adjustment would violate a Customer's limit, the trade would instead be nullified. The Exchange believes it is in the best interest of investors to expand the availability of adjustments to Customer transactions in all Obvious Error situations except where the adjustment would violate the Customer's limit price.

Further, the Exchange believes that, with respect to such proposed adjustments to Customer transactions, it is appropriate to use the same form of adjustment as is currently in place with respect to non-Customer transactions as laid out in the table in section (c)(4)(A). That is, the Exchange believes that it is appropriate to adjust to prices a specified amount away from the Theoretical Price rather than to adjust the Theoretical Price, even though the Exchange has determined a given trade to be erroneous in nature, because the parties in question should have had some expectation of execution at the price or prices submitted. Also, it is common that by the time it is determined that an Obvious Error has occurred, additional hedging and trading activity has already occurred based on the executions that previously happened. The Exchange believes that providing an adjustment to the Theoretical Price in all cases would not appropriately incentivize market participants to maintain appropriate controls to avoid potential errors, while

adjusting to prices a specified amount away from the Theoretical Price would incentivize such behavior.

The Exchange believes that the proposal is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The proposed change to section (b)(3) would apply to all instances of a wide market occurring within the first 10 seconds of trading followed by a narrow market at any point in the subsequent 10-second period, regardless of the types of market participants involved in such transactions. The proposed change to section (c)(4)(B) would harmonize the treatment of Obvious Error transactions involving Customers and non-Customers, no matter what type of market participants those parties may be.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes that the proposal will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of Section 6(b)(8) of the Act.¹² The Exchange anticipates that the other options exchanges will adopt substantively similar proposals, such that there would be no burden on intermarket competition from the Exchange's proposal. Accordingly, the proposed change is not meant to affect competition among the options exchanges. For these reasons, the Exchange believes that the proposed rule change reflects this competitive environment and does not impose any undue burden on intermarket competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or up to 90 days.

(A) By order approve or disapprove the proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

¹² 15 U.S.C. 78f(b)(8).

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-NYSEArca-2021-91 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to File Number SR-NYSEArca-2021-91. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-NYSEArca-2021-91 and should be submitted on or before November 26, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹³

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021-24018 Filed 11-3-21; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-93467; File No. SR-NASDAQ-2021-083]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Exempt Certain Categories of Investment Companies Registered Under the Investment Company Act of 1940 From the Requirements To Obtain Shareholder Approval Prior to the Issuance of Securities in Connection With Acquisitions of the Stock or Assets of an Affiliated Registered Investment Company Under Certain Conditions

October 29, 2021.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the “Act”),¹ and Rule 19b-4 thereunder,² notice is hereby given that on October 21, 2021, The Nasdaq Stock Market LLC (“Nasdaq” or “Exchange”) 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.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to exempt certain categories of investment companies registered under the Investment Company Act of 1940 (the “1940 Act”) from the requirement to obtain shareholder approval prior to the issuance of securities in connection with certain acquisitions of the stock or assets of another company.

The text of the proposed rule change is available on the Exchange’s website at <https://listingcenter.nasdaq.com/rulebook/nasdaq/rules>, at the principal office of the Exchange, and at the Commission’s Public Reference Room.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Nasdaq Rule 5615 to exempt certain categories of investment companies registered under the 1940 Act from the requirement to obtain shareholder approval prior to the issuance of securities in connection with certain acquisitions of the stock or assets of another company. The proposal is substantially similar to a recent rule change made by NYSE Arca, Inc. (“Arca”).³

Nasdaq proposes a minor restructuring of the subparagraphs in Nasdaq Rule 5615(a)(1) relating to the current exemptions to the corporate governance requirements for asset-backed issuers and other passive issuers. Specifically, renumbering the corporate governance requirements set forth in Nasdaq Rule 5615(a)(1) to Nasdaq Rule 5615(a)(1)(A), renumbering the current exemption for asset-backed issuers from Nasdaq Rule 5615(a)(1)(A) to Nasdaq Rule 5615(a)(1)(A)(i), and renumbering the current exemption for other passive issuers from Nasdaq Rule 5615(a)(1)(B) to Nasdaq Rule 5615(a)(1)(A)(ii). Nasdaq also proposes to amend Nasdaq Rule 5615(a) by adding new subsection (1)(C), as well as inserting a new second paragraph under Nasdaq Rule 5615(a)(5) between the existing two paragraphs. Nasdaq Rule 5615(a)(5) will provide the proposed

exemptions for certain management investment companies,⁴ while Nasdaq Rule 5615(a)(1)(C) will provide for the proposed exemption of Nasdaq Rule 5615(a)(1) applicable to issuers of Portfolio Depository Receipts, as provided under Nasdaq Rule 5705(a).

By way of background, Nasdaq Rule 5635(a) requires issuers to obtain shareholder approval in connection with the acquisition of the stock or assets of another company, in the following circumstances:

(1) Where, due to the present or potential issuance of common stock, including shares issued pursuant to an earn-out provision or similar type of provision, or securities convertible into or exercisable for common stock, other than a public offering for cash:

(A) the common stock has or will have upon issuance voting power equal to or in excess of 20% of the voting power outstanding before the issuance of stock or securities convertible into or exercisable for common stock; or

(B) the number of shares of common stock to be issued is or will be equal to or in excess of 20% of the number of shares of common stock outstanding before the issuance of the stock or securities; or

(2) any director, officer or Substantial Shareholder (as defined by Nasdaq Rule 5635(e)(3)) of the Company has a 5% or greater interest (or such persons collectively have a 10% or greater interest), directly or indirectly, in the Company or assets to be acquired or in the consideration to be paid in the transaction or series of related transactions and the present or potential issuance of common stock, or securities convertible into or exercisable for common stock, could result in an increase in outstanding common shares or voting power of 5% or more.

Nasdaq Rule 5615 exempts certain categories of issuers from certain corporate governance requirements.

Now, the Exchange proposes to amend Nasdaq Rule 5615(a) to exempt certain categories of investment companies registered under the 1940 Act from the requirement to comply with Nasdaq Rule 5635(a) in connection with the acquisition of the stock or assets of an affiliated registered investment company in a transaction that complies with Rule 17a-8⁵ (Mergers of affiliated companies) (“Rule 17a-8”) under the 1940 Act and does not otherwise require shareholder approval under the 1940 Act and the rules thereunder or any other Exchange rule.⁶ Specifically, the Exchange

³ See Securities Exchange Act No. 91901 (May 14, 2021) 86 FR 27487 (May 20, 2021) (SR-NYSEArca-2020-54) (Order approving of a proposed rule change, as modified by amendment no. 2, to amend NYSE Arca Rule 5.3E to exempt registered investment companies that list certain categories of securities defined as derivative and special purpose securities under NYSE Arca Rules from having to obtain shareholder approval prior to the issuance of securities in connection with certain acquisitions of the stock or assets of an affiliated registered investment company (the “Arca Approval Order”).

⁴ See *infra* footnote 6.

⁵ 17 CFR 270.17a-8.

⁶ The Exchange proposes to exempt both Portfolio Depository Receipts (Nasdaq Rule 5705(a) and certain management investment companies that are Index Fund Shares (Nasdaq Rule 5705(b)), Managed Fund Shares (Nasdaq Rule 5735), Managed Portfolio Shares (Nasdaq Rule 5760), Exchange Traded Fund

¹³ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b 4.

proposes to exempt from the shareholder approval provision described herein Portfolio Depository Receipts, as provided under Nasdaq Rule 5705(a)(1) by the addition of subsection (C) to Nasdaq Rule 5615(a)(1), as well as amending Nasdaq Rule 5615(a)(5) by inserting a new second paragraph between the existing two paragraphs to exempt from the shareholder approval provision described herein management investment companies that are Index Fund Shares (as defined in Nasdaq Rule 5705(b)), Managed Fund Shares (as defined in Nasdaq Rule 5735), Managed Portfolio Shares (as defined in Nasdaq Rule 5760), Exchange Traded Fund Shares (as defined in Nasdaq Rule 5704), and Proxy Portfolio Shares (as defined in Nasdaq Rule 5750), respectively.⁷

In general, the requirement to obtain shareholder approval prior to the issuance of securities in connection with certain acquisitions of the stock or asset of another company is designed to give existing shareholders a vote on the issuance of stock that may dilute their voting or economic rights. The Exchange notes that Nasdaq Rule 5635(a)(2) is also intended to give shareholders a vote on transactions where a director, officer, or substantial shareholder of the listed company has a significant interest in the company or assets to be acquired or the consideration to be paid and therefore may benefit from the transaction. For the reasons described below, as well as the protections embedded in Rule 17a–8, the Exchange believes that these concerns are limited with respect to 1940 Act Securities. Therefore, the Exchange believes it is appropriate to exempt issuers of 1940 Act Securities from having to obtain shareholder approval under Exchange rules which can be both time consuming and expensive.

The Exchange believes that the potential economic and voting dilution

concerns sometimes associated with a large share issuance are unlikely to be present when an issuer of a 1940 Act Security issues shares in connection with the acquisition of the stock or assets of an affiliated registered investment company. As described above, the proposed exemption will only apply to issuers of investment companies organized under the 1940 Act. Sections 17(a)(1)–(2) of the 1940 Act prohibit, among other things, certain transactions between registered investment companies and affiliated persons.⁸ Rule 17a–8 provides an exemption from Sections 17(a)(1)–(2) for certain mergers of affiliated companies provided that the board of directors of each investment company, including a majority of the directors that are not interested persons, affirmatively determine that (i) participation in the merger is in the best interest of their respective investment company, and (ii) the interests of their shareholders will not be diluted as a result of the transaction.⁹ Because the shares issued by the acquiring investment company are issued at a price equal to the fund's net asset value,¹⁰ the board of directors is able to make an affirmative determination that the merger is not dilutive to existing shareholders.¹¹ With respect to potential concerns about voting dilution, holders of Portfolio Depository Receipts and management investment companies that are Index Fund Shares, Managed Fund Shares, Managed Portfolio Shares, Exchange Traded Fund Shares, and Proxy Portfolio Shares either do not have the right to elect directors at annual meetings or have the right to elect directors only in very limited circumstances.

The Exchange believes that the same provisions of Rule 17a–8 that protect against dilution also provide safeguards for existing shareholders when the transaction involves a director, officer, or substantial shareholder of the listed company that has a significant interest

in the company or assets to be acquired or the consideration to be paid and therefore may benefit from the transaction. Because the board of each merging company must make an affirmative decision that the transaction is in the best interest of its respective company and that the transaction will not result in dilution for existing shareholders, the Exchange believes there is reduced concern that existing shareholders will be disenfranchised as a result of the Exchange's proposed exemption.

Under Rule 17a–8, an affiliated merger must be approved by a majority of the outstanding voting securities of the merging company that is not the surviving company unless certain conditions are met. However, Rule 17a–8 does not require the surviving company (*i.e.*, the fund issuing shares in the merger) to obtain the approval of its shareholders. When the Commission proposed amendments to Rule 17a–8, it specifically sought comment on whether the outstanding voting securities of the fund that will survive the merger should also be required to approve the merger.¹² Importantly, the Commission ultimately did not include a requirement of approval of shareholders of the surviving company in its final rule.

Given that Rule 17a–8 does not require a surviving company issuer of 1940 Act Securities to obtain shareholder approval in the context of a merger of affiliated companies, the Exchange believes it is appropriate to exempt such issuers of 1940 Act Securities from having to comply with Nasdaq Rule 5615(a)(1). As described above, the Exchange only proposes to exempt issuers of 1940 Act Securities from having to comply with Nasdaq Rule 5615(a)(1) if they are issuing shares to acquire the stock or assets of an affiliated registered investment company. Notwithstanding the proposed exemption, the Exchange notes that other provisions of Exchange rules or the 1940 Act and the rules thereunder may require shareholder approval and will still apply. In particular, the Exchange notes that the adopting release for Rule 17a–8 specifically noted that nothing in Rule 17a–8 relieves a fund of its obligation to obtain shareholder approval as may be required by state law or a fund's organizational documents.¹³ Thus, an

Shares (Nasdaq Rule 5704), and Proxy Portfolio Shares (Nasdaq Rule 5750) (collectively, with Portfolio Depository Receipts, the "1940 Act Securities"). Each of the listed categories are issued by an entity organized under the 1940 Act. In proposing this exemption, the Exchange notes that the adopting release for Rule 17a–8 specifically noted that nothing in Rule 17a–8 relieves a fund of its obligation to obtain shareholder approval as may be required by state law or a fund's organizational documents. See Investment Company Act Release No. 25666 at Footnote 18.

⁷ Index Fund Shares listed pursuant to Nasdaq Rule 5705(b) are substantively similar to Investment Company Units listed pursuant to Arca Rule 5.2–E(j)(3). Similarly, Proxy Portfolio Shares listed pursuant to Nasdaq Rule 5750 are substantively similar to Active Proxy Portfolio Shares listed pursuant to Arca Rule 8.601–E.

⁸ 15 U.S.C. 80a–17(a)(1)–(2). See also the definition of "affiliated person" in the 1940 Act at 15 U.S.C. 80a–2(a)(3).

⁹ 17 CFR 270.17a–8.

¹⁰ The Exchange notes that the proposing releases for Rule 17a–8 specifically contemplated that, in certain circumstances, the price paid may deviate from a fund's net asset value due to adjustments for tax purposes. See Investment Company Act Release No. 25259 at Footnote 26.

¹¹ The Exchange notes that the shares are issued at a fund's net asset value when the fund is registered. Rule 17a–8 also includes requirements to protect against dilution when the fund to be acquired is unregistered. Notwithstanding these requirements applicable when a fund is unregistered, the Exchange's exemption will only apply when each fund that is a party to the merger is registered.

¹² See Investment Company Act Release No. 25259 at Section II(A)(2)(a): "Should the outstanding voting securities of the fund that will survive the merger also be required to approve the merger?"

¹³ See *supra* footnote 6.

issuer of a 1940 Act Security may still be required to obtain shareholder approval in connection with the acquisition of the stock or assets of an affiliated company even if such transaction complies with Rule 17a–8 if such transaction would require shareholder approval under other applicable Exchange Rules, another provision of the 1940 Act or the rules and regulations thereunder, state law, or a fund's organizational documents.

Based on the above proposed changes, Nasdaq proposes to amend Nasdaq Rule 5615(a) by adding new subsection (1)(C), as well as inserting a new second paragraph under Nasdaq Rule 5615(a)(5) between the existing two paragraphs. Nasdaq Rule 5615(a)(5) will provide the proposed exemptions for certain management investment companies,¹⁴ while Nasdaq Rule 5615(a)(1)(C) will provide for the proposed exemption of Nasdaq Rule 5615(a)(1) applicable to issuers of Portfolio Depository Receipts, as provided under Nasdaq Rule 5705(a).

2. Statutory Basis

The Exchange believes that the proposal is consistent with Section 6(b) of the Act¹⁵ in general and Section 6(b)(5) of the Act¹⁶ in particular in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)¹⁷ requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that the proposed amendment is consistent with the protection of investors as protections afforded by Rule 17a–8, mean that (i) there is limited risk of dilution to existing shareholders as a result of an issuance of shares by an issuer of 1940 Act Securities in connection with the acquisition of the stock or assets of an affiliated company, and (ii) existing shareholders have a reduced risk of being disenfranchised as a result of a Rule 17a–8-compliant transaction that involves a director, officer, or substantial shareholder of the

listed company that has a significant interest in the company or assets to be acquired or the consideration to be paid. With respect to potential concerns about voting dilution, holders of Portfolio Depository Receipts and management investment companies that are Index Fund Shares, Managed Fund Shares, Managed Portfolio Shares, Exchange Traded Fund Shares, and Proxy Portfolio Shares either do not have the right to elect directors at annual meetings or have the right to elect directors only in very limited circumstances.

The Exchange further believes its proposal is consistent with the protection of investors because its proposal is limited to registered investment companies that are organized under the 1940 Act. In the case of a merger of affiliated investment companies, the board of directors of each investment company, including a majority of the directors that are not interested persons of the respective investment company, must affirmatively determine that (i) participation in the merger is in the best interest of their respective investment company, and (ii) the interests of their shareholders will not be diluted as a result of the transaction. Where the shares issued by the surviving investment company are issued at a price equal to the fund's net asset value, the board of directors is able to conclude that the interests of shareholders in such a transaction will not be diluted. With respect to voting dilution, the Exchange notes that holders of 1940 Act Securities have very limited voting rights, including no right to vote on the annual election of a board of directors.

The Exchange believes that the same provisions of Rule 17a–8 that protect against dilution also provide safeguards for existing shareholders when the transaction involves a director, officer, or substantial shareholder of the listed company that has a significant interest in the company or assets to be acquired or the consideration to be paid and therefore may benefit from the transaction. Because the board of each merging company must make an affirmative determination that the transaction is in the best interest of its investment company that the transaction will not result in dilution for existing shareholders, there is reduced concern that existing shareholders will be disenfranchised as a result of the Exchange's proposed exemption.

The Exchange notes that while shareholders of the non-surviving company must approve the merger under certain circumstances, Rule 17a–8 does not require the shareholders of

the surviving company to approve the transaction. Accordingly, the Exchange believes it is appropriate to exempt issuers of 1940 Act Securities from the requirements of Nasdaq Rule 5615 in this same limited circumstance.

Notwithstanding the proposed exemption described above, the Exchange notes that other provisions of Exchange rules or the 1940 Act and the rules thereunder may require shareholder approval and will still apply. In particular, the Exchange notes that the adopting release for Rule 17a–8 specifically noted that nothing in Rule 17a–8 relieves a fund of its obligation to obtain shareholder approval as may be required by state law or a fund's organizational documents.¹⁸

The Exchange believes it is not unfairly discriminatory to offer the exemption only to issuers of 1940 Act Securities completing a merger with an affiliated registered investment company, as opposed to all issuers of securities listed pursuant to Nasdaq Rule 5700, because only 1940 Act Securities are subject to the requirements of the 1940 Act which offer the protections against dilution and self-dealing described herein.

Lastly, the Exchange believes that the proposal is reasonable as it is substantially similar to a recent rule amendment made by Arca.¹⁹

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 purpose of the Act. The proposed amendment will not impose any burden on competition, as they simply propose to offer 1940 Act Securities a limited exemption for the Exchange's shareholder approval rule in a specific circumstance where the Exchange believes there is a low risk of dilution to existing shareholders. Further, the proposed rule change is substantively similar to Arca Rule 5.3E.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the proposed rule change does not: (i) Significantly affect the

¹⁴ *Id.*

¹⁵ 15 U.S.C. 78f.

¹⁶ 15 U.S.C. 78f(b)(5).

¹⁷ *Id.*

¹⁸ See *supra* footnote 6.

¹⁹ See *supra* footnote 3.

protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act²⁰ and Rule 19b-4(f)(6) thereunder.²¹

A proposed rule change filed under Rule 19b-4(f)(6)²² normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b-4(f)(6)(iii),²³ the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange states that waiver of the operative delay will provide certain investment companies registered under the 1940 Act immediate relief from certain shareholder approval requirements if the conditions of the rule as described above are met.

The Commission previously approved a substantively similar rule change for Arca and found it consistent with the Section 6(b)(5) of the Act.²⁴ For these reasons, the Commission believes that the proposed rule change presents no novel issues and that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposal operative upon filing.²⁵

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)²⁶ 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-NASDAQ-2021-083 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to File Number SR-NASDAQ-2021-083. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File

Number SR-NASDAQ-2021-083, and should be submitted on or before November 26, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁷

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021-24015 Filed 11-3-21; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-93484; File No. 4-698]

Joint Industry Plan; Order Disapproving an Amendment to the National Market System Plan Governing the Consolidated Audit Trail

October 29, 2021.

I. Introduction

On December 18, 2020, the Operating Committee for Consolidated Audit Trail, LLC ("CAT LLC"), on behalf of the following parties to the National Market System Plan Governing the Consolidated Audit Trail (the "CAT NMS Plan" or "Plan"):¹ BOX Exchange LLC; Cboe BYX Exchange, Inc., Cboe BZX Exchange, Inc., Cboe EDGA Exchange, Inc., Cboe EDGX Exchange, Inc., Cboe C2 Exchange, Inc., Cboe Exchange, Inc., Financial Industry Regulatory Authority, Inc. ("FINRA"), Investors Exchange LLC, Long-Term Stock Exchange, Inc., Miami International Securities Exchange LLC, MEMX, LLC, MIAX Emerald, LLC, MIAX PEARL, LLC, Nasdaq BX, Inc., Nasdaq GEMX, LLC, Nasdaq ISE, LLC, Nasdaq MRX, LLC, Nasdaq PHLX LLC, The NASDAQ Stock Market LLC, New York Stock Exchange LLC, NYSE American LLC, NYSE Arca, Inc., NYSE Chicago, Inc., and NYSE National, Inc. (collectively, the "Participants," "self-regulatory organizations," or "SROs") filed with the Securities and Exchange Commission ("SEC" or "Commission") pursuant to Section 11A(a)(3) of the Securities Exchange Act of 1934 ("Exchange Act"),² and Rule 608 thereunder,³ a proposed amendment ("Proposed Amendment" or "Proposal") to the CAT NMS Plan that would authorize CAT LLC to revise the

²⁰ 15 U.S.C. 78s(b)(3)(A).

²¹ 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6)(iii) requires the Exchange to give the Commission written notice of the Exchange's intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has complied with this requirement.

²² 17 CFR 240.19b-4(f)(6).

²³ 17 CFR 240.19b-4(f)(6)(iii).

²⁴ See *supra* note 5 Error! Bookmark not defined..

²⁵ For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule change's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

²⁶ 15 U.S.C. 78s(b)(2)(B).

²⁷ 17 CFR 200.30-3(a)(12).

¹ The CAT NMS Plan is a national market system plan approved by the Commission pursuant to Section 11A of the Exchange Act and the rules and regulations thereunder. See Securities Exchange Act Release No. 79318 (November 15, 2016), 81 FR 84696 (November 23, 2016) ("CAT NMS Plan Approval Order").

² 15 U.S.C. 78k-1(a)(3).

³ 17 CFR 242.608.

Consolidated Audit Trail Reporter Agreement (the “Reporter Agreement”) and the Consolidated Audit Trail Reporting Agent Agreement (the “Reporting Agent Agreement” and collectively, the “Reporter Agreements”) to insert limitation of liability provisions (the “Limitation of Liability Provisions”).⁴ The proposed plan amendment was published for comment in the **Federal Register** on January 6, 2021.⁵

On April 6, 2021, the Commission instituted proceedings pursuant to Rule 608(b)(2)(i) of Regulation NMS,⁶ to determine whether to disapprove the Proposed Amendment or to approve the Proposed Amendment with any changes or subject to any conditions the Commission deems necessary or appropriate after considering public comment (the “OIP”).⁷ On June 25, 2021, the Commission designated a longer period within which to conclude proceedings regarding the Proposed Amendment.⁸ On September 2, 2021, the Commission further designated a longer period within which to conclude proceedings regarding the Proposed Amendment.⁹ This order disapproves the Proposed Amendment.

II. Background

On July 11, 2012, the Commission adopted Rule 613 of Regulation NMS, which required the SROs to submit a national market system (“NMS”) plan to create, implement and maintain a consolidated audit trail (the “CAT” or “CAT System”) that would capture customer and order event information for orders in NMS securities.¹⁰ The Commission approved the CAT NMS Plan in 2016.¹¹

On August 29, 2019, the Operating Committee for CAT LLC approved a Reporter Agreement that included a

provision that would have limited the total liability of CAT LLC or any of its representatives to a CAT Reporter under the Reporter Agreement for any calendar year to the lesser of the total of fees paid by the CAT Reporter to CAT LLC for the calendar year in which the claim arose or five hundred dollars. The Participants required each Industry Member¹² to execute a CAT Reporter Agreement before reporting data to CAT. Prior to the commencement of initial equities reporting for Industry Members, the Securities Industry and Financial Markets Association (“SIFMA”) filed on April 22, 2020, pursuant to Sections 19(d) and 19(f) of the Exchange Act, an application for review of actions taken by CAT LLC and the Participants (the “Administrative Proceedings”). SIFMA alleged that by requiring Industry Members to execute Reporter Agreements as a prerequisite to submitting data to the CAT, the Participants improperly prohibited or limited SIFMA members with respect to access to the CAT System in violation of the Exchange Act. On May 13, 2020, the Participants and SIFMA reached a settlement and terminated the Administrative Proceedings, allowing Industry Members to report data to the CAT pursuant to a Reporter Agreement that does not contain a limitation of liability provision. Since that time, Industry Members have been transmitting data to the CAT.¹³

III. Description of the Proposal

The Participants propose to amend the CAT NMS Plan to authorize CAT LLC to revise the Reporter Agreement and Reporting Agent Agreement with the proposed Limitation of Liability Provisions. As proposed, the Limitation of Liability Provisions would: (1) Provide that CAT Reporters and CAT Reporting Agents accept sole responsibility for their access to and use of the CAT System, and that CAT LLC makes no representations or warranties regarding the CAT System or any other matter; (2) limit the liability of CAT LLC, the Participants, and their respective representatives to any individual CAT Reporter or CAT Reporting Agent to the lesser of the fees actually paid to CAT for the calendar year or \$500; (3) provide that CAT LLC, the Participants, and their respective representatives shall not be liable for all direct and indirect damages of any kind

or nature; and (4) provide that CAT LLC, the Participants, and their respective representatives shall not be liable for the loss or corruption of any data submitted by a CAT Reporter or CAT Reporting Agent to the CAT System.¹⁴

In support of the Proposed Amendment, the Participants state, among other things, that: (1) The proposed Limitation of Liability Provisions reflect longstanding principles of allocation of liability between Industry Members and SROs;¹⁵ (2) the proposed Limitation of Liability Provisions “fall squarely within industry norms” and are consistent with exchange rules that limit liability for losses that members incur through their use of exchange facilities, provisions that FINRA members must agree to in order to comply with Order Audit Trail System (“OATS”) reporting, and other provisions in the context of regulatory and NMS reporting facilities;¹⁶ (3) previously granted exemptive relief that eliminated the requirement that CAT collect certain personally identifiable information, including social security numbers, makes the customer data stored in the CAT comparable to the data reported to other regulatory reporting facilities;¹⁷ (4) the proposed Limitation of Liability Provisions are necessary to ensure the financial stability of CAT because even though “CAT LLC has obtained the maximum extent of cyber-breach insurance coverage available and has implemented a full cybersecurity program to safeguard data stored in the CAT,” there is “the potential for substantial losses that may result from certain categories of low probability cyberbreaches.”¹⁸

CAT LLC retained Charles River Associates to conduct an economic analysis of the liability issues presented by a potential CAT breach (the “CRA Paper”).¹⁹ The Participants state that the analyses presented in the CRA Paper support the Participants’ proposal to adopt a limitation of liability provision in the CAT Reporter Agreement and shows the importance of limiting CAT LLC’s and each Participant’s liability.²⁰ The CRA Paper asserts, among other things, that, based on an examination of potential breach scenarios and a consideration of the economic and public policy elements of various regulatory and litigation approaches to mitigate cyber risk for the CAT, a

⁴ The Participants are requiring each CAT reporter or CAT reporting agent that reports order and trade data to the CAT System to execute a CAT Reporter Agreement or a CAT Reporting Agent Agreement. See, e.g., CAT FAQ O14, available at: <https://www.catnmsplan.com/faq>.

⁵ See Notice of Filing of Amendment to the National Market System Plan Governing the Consolidated Audit Trail, Release No. 90826 (December 30, 2020), 86 FR 591 (January 6, 2021) (“Notice”).

⁶ 17 CFR 242.608(b)(2)(i).

⁷ See Securities Exchange Act Release No. 91487 (April 6, 2021), 86 FR 19054 (April 12, 2021) (“OIP”). Comments received in response to the Notice and OIP can be found on the Commission’s website at <https://www.sec.gov/comments/4-698/4-698.htm>.

⁸ See Securities Exchange Act Release No. 92266 (June 25, 2021), 86 FR 35142 (July 1, 2021).

⁹ See Securities Exchange Act Release No. 92854 (September 2, 2021), 86 FR 50201 (September 7, 2021).

¹⁰ 17 CFR 242.613.

¹¹ See note 1, *supra*.

¹² Industry Member means a member of a national securities exchange or a member of a national securities association. See CAT NMS Plan at Section 1.1.

¹³ For a more detailed description of the background for the Proposed Amendment, see Notice, *supra* note 5, at 591–93.

¹⁴ See Notice, *supra* note 5, at 593.

¹⁵ See Notice, *supra* note 5, at 593–95.

¹⁶ See Notice, *supra* note 5, at 593–94.

¹⁷ See Notice, *supra* note 5, at 595.

¹⁸ See Notice, *supra* note 5, at 595.

¹⁹ See Notice, *supra* note 5, at 599–624.

²⁰ See Notice, *supra* note 5, at 595–597.

limitation of liability provision would serve the public interest by facilitating the regulation of the U.S. equity and option markets at lower overall costs and higher economic efficacy than other approaches, and that the proposed limitation on liability would not undermine CAT LLC's existing and significant incentives to protect the data stored in the CAT System. The CRA Paper asserts that regulation by the Commission already properly incentivizes the Participants to recognize and address the risks that a CAT cyber breach poses to third parties such as Industry Members. Thus, according to the Participants, permitting litigation by Industry Members will not meaningfully increase CAT's incentives to manage its exposure to cyber risk but will significantly increase costs, which will ultimately be passed on to retail investors. Because of this, the CRA Paper asserts that solely an "ex-ante regulation" approach leads to the socially optimal outcome, in comparison to an "ex post litigation" approach in which litigation influences behaviors before a loss-producing event occurs by assigning liability afterwards, or combination of both approaches.

IV. Discussion

A. The Applicable Standard of Review

Under Rule 608(b)(2) of Regulation NMS, the Commission shall approve a national market system plan or proposed amendment to an effective national market system plan, with such changes or subject to such conditions as the Commission may deem necessary or appropriate, if it finds that such plan or amendment is necessary or appropriate in the public interest, for the protection of investors and the maintenance of fair and orderly markets, to remove impediments to, and perfect the mechanisms of, a national market system, or otherwise in furtherance of the purposes of the Exchange Act.²¹ Under Rule 700(b)(3) of the Commission's Rules of Practice, the "burden to demonstrate that a proposed rule change is consistent with the Exchange Act and the rules and regulations issued thereunder . . . is on the self-regulatory organization that proposed the rule change."²² The Commission shall disapprove a national market system plan or proposed amendment if it does not make such a finding.²³

For the reasons described below, the Commission believes that the Participants have not met their burden to demonstrate that the Proposed Amendment is consistent with the Exchange Act.²⁴ Accordingly, the Commission cannot make the finding that the Proposed Amendment is necessary or appropriate in the public interest, for the protection of investors and the maintenance of fair and orderly markets, to remove impediments to, and perfect the mechanisms of, a national market system, or otherwise in furtherance of the purposes of the Exchange Act.²⁵

B. Impact of Proposed Amendment on Incentives of Participants Incentives To Invest in Security of the CAT

The Commission received several comments, including a letter from SIFMA attaching an economic analysis prepared by Craig Lewis ("Lewis Paper") of the Proposed Amendment,²⁶ expressing concern that shifting liability through a limitation of liability provision would reduce the incentives of Participants to develop robust data security and risk mitigation mechanisms, and may even incentivize the Participants to de-prioritize data security.²⁷ Commenters also state that it

shall be by order. *Id.* In addition, Rule 700(b)(3)(ii) of the Commission's Rules of Practice states that "[t]he burden to demonstrate that a NMS plan filing is consistent with the Exchange Act and the rules and regulations issued thereunder that are applicable to NMS plans is on the plan participants that filed the NMS plan filing." 17 CFR 201.700(b)(3)(ii). "Any failure of the plan participants that filed the NMS plan filing to provide such detail and specificity may result in the Commission not having a sufficient basis to make an affirmative finding that a NMS plan filing is consistent with the Exchange Act and the rules and regulations issued thereunder that are applicable to NMS plans." *Id.*

²⁴ 17 CFR 201.700(b)(3).

²⁵ 17 CFR 242.608(b)(2).

²⁶ See Letter from Ellen Greene, Managing Director, Equity and Options Market Structure, SIFMA, to Vanessa Countryman, Secretary, dated February 19, 2021, available at <https://www.sec.gov/comments/4-698/4698-8394069-229410.pdf>, attaching Economic Analysis of Proposed Amendment to National Market System Plan Governing the Consolidated Audit Trail, Craig M. Lewis, Ph.D., February 2021.

²⁷ See Lewis Paper at 5–9, 14; Letter from Ellen Greene, Managing Director, Equity and Options Market Structure, SIFMA, to Vanessa Countryman, Secretary, dated January 27, 2021, available at <https://www.sec.gov/comments/4-698/4698-8298026-228278.pdf> ("SIFMA Letter"), at 7, 9; Letter from Peggy L. Ho, Executive Vice President, Government Relations, LPL Financial LLC, to Vanessa Countryman, Secretary, dated January 27, 2021, available at <https://www.sec.gov/comments/4-698/4698-8298412-228298.pdf> ("LPL Financial Letter"), at 1; Letter from Thomas R. Tremaine, Executive Vice President, Chief Operations Officer, Raymond James & Associates, Inc., to Vanessa Countryman, Secretary, dated February 8, 2021, available at <https://www.sec.gov/comments/4-698/4698-8347733-229000.pdf> ("Raymond James

is "unfair" for Industry Members to be liable for breaches of the CAT or CAT Data²⁸ because the Participants, through CAT LLC, and FINRA CAT, the Plan Processor,²⁹ are the parties responsible for controlling and securing CAT Data and Industry Members face potential harm due to the compromise of CAT Data over which they have no control and are not responsible for security.³⁰ The Lewis Paper argues that aligning control and liability incentivizes the optimal amount of data security and would ultimately benefit all investors.³¹ Along the same lines, another commenter asserts that "[a]ligning control and liability is not only fair and equitable; it is also good policy, because it maximizes efficiencies in managing data risks inherent in the CAT System."³²

Letter"), at 2; Letter from Joanna Mallers, Secretary, FIA Principal Traders Group, to Vanessa Countryman, Secretary, dated February 8, 2021, available at <https://www.sec.gov/comments/4-698/4698-8345389-228979.pdf> ("FIA PTG Letter"), at 2; Letter from Thomas M. Merritt, Deputy General Counsel, Virtu Financial, Inc., to Vanessa Countryman, Secretary, dated January 27, 2021, available at <https://www.sec.gov/comments/4-698/4698-8298023-228258.pdf> ("Virtu Letter"), at 3; Letter from Christopher A. Iacovella, Chief Executive Officer, American Securities Association, to Vanessa Countryman, Secretary, dated January 29, 2021, available at <https://www.sec.gov/comments/4-698/4698-8311307-228499.pdf> ("ASA Letter"), at 2; Letter from Matthew Price, Fidelity Investments, to Vanessa Countryman, Secretary, dated February 2, 2021, available at <https://www.sec.gov/comments/4-698/4698-8343750-228940.pdf> ("Fidelity Letter"), at 2; Letter from Daniel Keegan, Managing Director, Head of North America Markets & Securities Services, to Vanessa Countryman, Secretary, dated February 25, 2021, available at <https://www.sec.gov/comments/4-698/4698-8419819-229522.pdf> ("Citi Letter"), at 2.

²⁸ "CAT Data" means data derived from Participant Data, Industry Member Data, SIP Data, and such other data as the Operating Committee may designate as "CAT Data" from time to time. See CAT NMS Plan at Section 1.1.

²⁹ "Plan Processor" means the Initial Plan Processor or any other Person selected by the Operating Committee pursuant to SEC Rule 613 and CAT NMS Plan, Article IV, Section 4.3(b)(i) and Article VI, Section 6.1, and with regard to the Initial Plan Processor, the Selection Plan, to perform the CAT processing functions required by SEC Rule 613 and set forth in this Agreement. See CAT NMS Plan at Section 1.1.

³⁰ See Lewis Paper at 3, 6; SIFMA Letter, at 4; FIA PTG Letter, at 1 (stating it "supports the comments previously filed by SIFMA"); Raymond James Letter, at 2 (stating that it "strongly supports the points raised by SIFMA in their letter."); LPL Financial Letter, at 1; ASA Letter, at 2; Virtu Letter, at 2; Fidelity Letter, at 2; Citi Letter, at 2; Letter from Ellen Greene, Managing Director, Equity and Options Market Structure, SIFMA, to Vanessa Countryman, Secretary, dated May 3, 2021 ("SIFMA Letter II") at 2; 4; Letter from Kelvin To, Founder and President, Data Boiler Technologies, LLC, to Vanessa Countryman, Secretary, dated May 3, 2021 ("Data Boiler Letter II") at 5.

³¹ See Lewis Paper at 5–7; see also SIFMA Letter II at 2–3, 9–10.

³² See SIFMA Letter at 4. One commenter states that the CAT System is a particularly attractive

Continued

²¹ 17 CFR 242.608(b)(2).

²² 17 CFR 201.700(b)(3).

²³ 17 CFR 242.608(b)(2). Approval or disapproval of a national market system plan, or an amendment to an effective national market system plan (other than an amendment initiated by the Commission),

Commenters argue that the CRA Paper's specific conclusion that *ex-ante* regulation is most appropriate is wrong, and that CAT cybersecurity would benefit from both *ex-ante* regulation and *ex-post* litigation.³³ Another commenter characterizes shifting liability to Industry Members who, unlike SROs, have no control over the security of the CAT as creating a "moral hazard" and stated that permitting litigation against Participants and their representatives when they are acting outside their regulatory capacity is "crucial" as it would give the Participants very strong financial incentives to invest heavily to prevent or minimize the likelihood of such failures.³⁴ Similarly, the Lewis Paper asserts that liability for potential litigation would mitigate the moral hazard problem for CAT LLC and make CAT LLC more willing to invest in improvements in data security and more quickly react to changing trends and threats in cybersecurity.³⁵

In response to the Lewis Paper's contention that the threat of *ex-post* litigation is necessary, the CRA Response asserts that the "inconsequential and speculative" benefits of litigation in addition to the existing regulatory regime do not exceed the likely substantial costs.³⁶ The CRA Response further asserts that there is no asset reserve on the balance sheet of

target for nation states and other bad actors that have become increasingly sophisticated, which could lead to significant harm to market participants, serious competitive harm to Industry Members, and significant legal risk and potential liability. See SIFMA Letter II at 9.

³³ See Letter from Stephen John Berger, Managing Director, Global Head of Government & Regulatory Policy, Citadel Securities, to Vanessa Countryman, Secretary, dated February 23, 2021, available at <https://www.sec.gov/comments/4-698/4698-8411798-229501.pdf> ("Citadel Letter"), at 1–2, 7; Lewis Paper at 7–9. SIFMA states that the Lewis Paper, submitted by SIFMA, concludes that the Proposal would reduce investor welfare by: (1) Providing less incentive to the SROs as the operators of the CAT to invest in data security to protect investors' personally identifiable information and trading data in the CAT, which would place investors at greater risk of having their data compromised; and (2) leading to the inefficient purchase of insurance with additional costs likely passed downstream to investors by requiring industry members to absorb litigation-related expenses for an event over which they have no direct control. See SIFMA Letter II at 3.

³⁴ See Citi Letter at 2, 7, 9–10.

³⁵ See Lewis Paper at 7–9.

³⁶ See Report from Charles River Associates, "CRA Response to: Economic Analysis of Proposed Amendment to the National Market System Plan Governing the Consolidated Audit Trail by Craig M. Lewis, Ph.D. and Selected Points in Public Comment Letters," dated April 5, 2021, available at <https://www.sec.gov/comments/4-698/4698-8634778-230925.pdf> ("CRA Response") at 9. The CRA Response further states that the Lewis Paper mischaracterized this argument as meaning that the CRA Paper said there are no benefits to adding the threat of litigation. *Id.*

CAT LLC sufficient to cover a substantial cyber loss, and thus, adding a threat of litigation may not provide any additional incentives to invest in preventative care.³⁷

The Participants argue that securities industry norms do not support the principle that the party in possession of data should bear liability in the event of a data breach, particularly where the parties in possession of the data are acting in regulatory capacities pursuant to Commission rules.³⁸ In this regard, the Participants state that Industry Members, despite controlling sensitive data that could be compromised during a data breach, "routinely" disclaim liability to their underlying customers including their own retail customers in certain cases.³⁹

The Participants also assert that the Commission's regulatory regime, backed by its examination and enforcement functions, provide valuable incentives for the Participants, CAT LLC and FINRA CAT to take adequate cyber security precautions.⁴⁰ These incentives include the Commission's enforcement regime, severe reputational harm, financial and reputational harm to Amazon Web Services, satisfying underwriting standards, and the fact that a data breach could compromise the Participants' ability to use CAT Data.⁴¹ The Participants believe that commenters have not offered any explanation as to why the Commission's regulatory regime—which includes cybersecurity protocols developed and refined based on feedback from Industry Members—is insufficient to ensure adequate cybersecurity for CAT Data, or what deficiencies in the Commission's oversight necessitate that Industry Members be afforded an unprecedented

³⁷ See CRA Response at 4. See also CRA Response at 9 (stating that CAT LLC's "cost-only business model" provides no mechanism to establish safety reserves that might allow it to build a cash reserve to pre-fund catastrophic losses from a cyber breach).

³⁸ See Letter from Michael Simon, CAT NMS Plan Operating Committee Chair, to Vanessa Countryman, Secretary, dated April 1, 2021 ("Response Letter"), at 10.

³⁹ See Response Letter at 10; see also *id.* at 20 (stating that the Lewis Paper does not address the fact that Industry Members routinely disclaim liability to those underlying customers).

⁴⁰ See, e.g., Letter from Michael Simon, CAT NMS Plan Operating Committee Chair, to Vanessa Countryman, Secretary, dated May 18, 2021, available at <https://www.sec.gov/comments/4-698/4698-8811359-238002.pdf> ("Second Response Letter"), at 3, 5–7. The Participants state that CAT LLC, the Participants and FINRA CAT are subject to stringent oversight by the Commission. In addition, the Division of Examinations examines FINRA CAT's and the Participant's cybersecurity policies, procedures, systems, and controls. See Second Response Letter at 6–7 (also citing Second Circuit decision in support).

⁴¹ See Second Response Letter at 5–6. See also CRA Response at 1, 3–4, 6–7, 10.

private right of action against their regulators.⁴² The Participants further argue that commenters have not demonstrated that the Commission lacks the ability to adequately regulate the CAT and the Participants, and that allowing Industry Member litigation would not result in any meaningful benefit to the CAT's cybersecurity.⁴³ In addition, the CRA Response states that the Lewis Paper disregards the potential for enforcement action by the Commission against Participants and does not recognize that regulatory and reputational considerations motivate appropriate *ex-ante* actions to reduce risk.⁴⁴

Commenters also state that the CRA Paper suggests certain mechanisms, such as a third-party compensation program, cyber-related industry loss warranties or cyber catastrophe bonds that could be used in the event of a CAT breach to compensate third parties, but the SROs have not proposed the adoption of any of these mechanisms.⁴⁵ These commenters believe that without liability risk, CAT LLC and the SROs will have no incentive to develop any mechanisms for compensating third parties injured if the CAT System is breached or CAT Data is misused while under the control of CAT LLC and the SROs.⁴⁶ These commenters assert that the Participants, are effectively conceding that without these other mechanisms described in the CRA Paper, the current regulatory regime is insufficient to protect parties that are injured as a result of a CAT breach.⁴⁷

⁴² See Response Letter at 26.

⁴³ See Second Response Letter at 3.

⁴⁴ See CRA Response at 5–6. The CRA Response states that there are several weaknesses with the Lewis Paper's and the Citadel Letter's argument that litigation as well as regulation is necessary to give CAT LLC an added incentive to stay ahead of the Commission's regulation since the underlying technology changes come too fast for the Commission to keep its regulatory apparatus up to date: (1) Lewis and Citadel ignore that Participants and FINRA CAT are required to monitor CAT's cyber security and promptly address vulnerabilities in accordance with Commission regulation; (2) Industry Members can influence CAT LLC and Commission regarding cybersecurity as a result of CAT LLC governance and operating mechanisms; (3) Commission has unique access to highly sophisticated cyber security and cyber warfare assets, which give them access to the most up-to-date technology; (4) CAT's technology suppliers (e.g., AWS) have reputational incentives to maintain CAT cyber defenses; (5) the ability to litigate might increase CAT cyber risk by potentially weakening Industry Members' incentives to provide feedback to the Participants; (6) Participants still face litigation risk including from Commission enforcement actions. See CRA Response at 13–14.

⁴⁵ See SIFMA Letter at 10; LPL Financial Letter at 1; FIA PTG Letter at 2; Raymond James Letter at 2.

⁴⁶ See *id.*

⁴⁷ See *id.*

The Participants acknowledge that the CRA Paper explains that the regulatory regime is generally silent with respect to the most efficient method to compensate injured parties and that the CRA Paper offered several suggestions to cover potential losses including insurance, industry loss warranties, and catastrophe bonds.⁴⁸ The Participants, however, state that they are willing to discuss any of these compensation mechanisms with Industry Members and they would welcome a discussion with the Commission to address the viability of these mechanisms and how they might be funded.⁴⁹

Cyber Insurance

Commenters assert that the proposal would allow CAT LLC to under-invest in data security and cyber insurance.⁵⁰ Commenters argue that the Proposed Limitation of Liability Provisions would ultimately result in higher costs borne by investors.⁵¹ According to commenters, under the proposal, every firm submitting data to the CAT System would effectively be forced, where possible, to obtain its own insurance to address the same core risks of data breach or misuse within the CAT System and CAT LLC and the Participants may not be appropriately incentivized to invest in insurance and other risk mitigation mechanisms.⁵² Commenters believe that it would be more appropriate for CAT LLC to purchase insurance instead of Industry Members each purchasing the same overlapping policies.⁵³ One of these commenters argues that CAT LLC is able to insure more efficiently than Industry Members because CAT LLC has access to and control over CAT Data and systems and can subject itself to monitoring by an insurer.⁵⁴ One

commenter states that while the Participants assert that CAT LLC has obtained the “maximum extent of cyber-breach insurance coverage,” the Participants have not disclosed any information about the extent or cost of the coverage obtained,⁵⁵ and do not analyze whether Participants should seek insurance or the effect such insurance could have on the Participants’ incentives to protect data that they extract from the CAT and store outside the CAT.⁵⁶ The commenter states that it is not at all clear that CAT LLC could not obtain additional insurance.⁵⁷

The Participants reiterate that CAT LLC has purchased the maximum amount of cyber insurance coverage that the current market will reasonably provide. The Participants also state that they will regularly evaluate CAT LLC’s insurance and intend to purchase additional coverage to the extent it becomes reasonably available.⁵⁸ The Participants argue that disclosing the amount of insurance purchased by CAT LLC could potentially incentivize bad actors to target the CAT with ransom demands.⁵⁹ The Participants assert that CAT LLC is not equipped to compensate Industry Members in the event of a data breach because funding is designed to cover costs only and it is difficult to imagine how CAT LLC could ensure solvency if substantial exclusions are included in a limitation of liability.⁶⁰ The CRA Response states that the Lewis Paper’s conclusion that the Participants should purchase additional cyber-insurance relies on two propositions for which the Lewis Paper provides no basis: (1) CAT LLC can purchase additional and more targeted cyber insurance to pre-finance possible cyber claims from Industry Members and that (2) the decrease in cyber security risks and insurance rates to Industry Members would outweigh the increase in CAT LLC’s cyber insurance rates.⁶¹

The CRA Response asserts that the Lewis Paper’s claim that the Limitation

of Liability Provisions will force clients’ claims onto Industry Members and burden Industry Members with purchasing additional insurance coverage is erroneous.⁶² Specifically, according to the CRA Response, the Lewis Paper does not explain how Industry Members’ clients can sue Industry Members for a cyberbreach of CAT, does not consider that many Industry Members have similar provisions in their customer agreements, and does not explain how an insurer would write liability coverage for Industry Members paying claims to clients for an adverse cyber event.⁶³ In addition, the CRA Response states that the Lewis Paper and commenters assume, without support, that Industry Members will face litigation risk from customers due to a cyberbreach at the CAT.⁶⁴

Visibility and Input of Industry Members Into the Security of the CAT

One commenter argues that the CRA Paper significantly overemphasizes the visibility and input into the workings of CAT provided to the industry, and asserts that there is no visibility into the security aspects of CAT.⁶⁵ The Participants state that Industry Members have had extensive opportunities to provide input regarding the CAT’s cybersecurity at every stage of the development and operation of the CAT.⁶⁶ The CRA Response states that commenters fail to acknowledge that providing Industry Members a right to litigate may reduce Industry Members’ incentives to undertake their monitoring and influencing activities in favor of relying upon the threat of litigation, thereby weakening the overall cyber program of the CAT.⁶⁷ The CRA Response also states that limiting Industry Members’ ability to recover damages provides greater incentives for them to provide feedback to CAT management through the Advisory Committee.⁶⁸

⁴⁸ See CRA Response Letter at 27 (citing CRA Paper at 50–53).

⁴⁹ See Response Letter at 27–28. The Participants also state that creating mechanisms to compensate Industry Members in the event of a data breach would not obviate the need for the proposed Limitation of Liability Provisions. See *id.* at 28.

⁵⁰ See SIFMA Letter II at 2–3, 9–10; Lewis Paper.

⁵¹ See SIFMA Letter II at 2–3, 9–10; Lewis Paper.

⁵² See SIFMA Letter II at 10. See also Data Boiler Letter II at 3 (provisions discourage Participants from advancing the security and design of CAT and CAT Data).

⁵³ See Lewis Paper at 11; SIFMA Letter at 4–5, 8–9, 10–11; Virtu Letter at 3. See also LPL Financial Letter at 1; FIA PTG Letter at 2; Raymond James Letter at 2. One commenter expresses skepticism that Industry Members could even obtain insurance policies under the current CAT System construct, because Industry Members have no control over the data they are by law required to submit, its security or the CAT System. See Virtu Letter at 3.

⁵⁴ See Lewis Paper at 12–13. See also SIFMA Letter at 4–5 (stating that requiring Industry Members to pay for and implement separate and overlapping insurance policies, if available, is

inefficient and would result in substantially higher costs borne by Industry Members and by extension their customers).

⁵⁵ See SIFMA Letter II at 9.

⁵⁶ See Citadel Letter at 7–8. See also Lewis Paper at 13–14.

⁵⁷ See SIFMA Letter II at 9. SIFMA also discusses the state of negotiations with the Participants. See SIFMA Letter II at 11.

⁵⁸ See Second Response Letter at 17.

⁵⁹ See Second Response Letter at 17. The Participants noted that they were reviewing a May 3, 2021 term sheet from SIFMA setting forth terms upon which Industry Members would be willing to resolve the dispute regarding the allocation of liability in the event of a CAT data breach. *Id.*

⁶⁰ See Second Response Letter at 15.

⁶¹ See CRA Response at 5.

⁶² See CRA Response at 5–6.

⁶³ See CRA Response at 5–6. However, purchasing cyber liability insurance to protect against potential first-party risk exposure might be part of a reasonable and sound approach to managing first-party risk exposure. *Id.* at 13.

⁶⁴ See CRA Response at 13.

⁶⁵ See Citadel Letter at 9.

⁶⁶ See Response Letter at 14. This includes prior to approval of the CAT NMS Plan, feedback through the Advisory Committee, and the ability of Industry Members to directly petition the Commission or provide comments on any proposals offered by the Commission. *Id.*

⁶⁷ See CRA Response at 2, 9, and 11.

⁶⁸ See CRA Response at 19. The Participants also assert that Industry Members have ample opportunities to contribute their perspectives

Regulatory Immunity

Commenters argue that the SROs have failed to explain why limitation of their liability should be imposed by contract because the SROs have immunity from liability when acting in a regulatory capacity.⁶⁹ Commenters further assert that the effort to impose liability limitations by contract “raises significant questions about whether the SROs seek to avoid liability in circumstances in which they misuse CAT Data while acting in a commercial capacity.”⁷⁰ Another commenter frames the issue as not whether the Participants should be liable for conduct undertaken during the course of their regulatory responsibilities, but whether the Participants should be insulated from potential liability for activities not covered by regulatory immunity.⁷¹ One commenter states that it believes that court precedent “strongly indicates that the courts are likely to view any regulatory activity the SROs conduct through CAT LLCs as being subject to this judicial immunity even though it is being conducted in a legal entity that is separate from the SROs.”⁷²

In response to comments about regulatory immunity, the Participants state that regulatory immunity does not preclude the use of contractual limitation of liability provisions and the divergent and shifting positions from Industry Members on the applicability of regulatory immunity underscores the need for a contractual limitation of liability.⁷³ The Participants state that some comments generally argue that a contractual limitation of liability is unnecessary in light of the doctrine of regulatory immunity, while other comments state the Participants should not receive either regulatory immunity or the protection of a limitation of liability provision.⁷⁴ The Participants state that the proposed Limitation of

Liability Provisions are necessary despite any regulatory immunity because even litigation which holds that regulatory immunity applies may result in significant disruption and expense (which ultimately will be passed along to Industry Members as part of CAT LLC’s joint funding), and there is no guarantee that all courts would agree that the Participants’ immunity defense extends to the particular claims at issue.⁷⁵ The Participants believe that the Proposed Limitation of Liability Provisions are necessary to avoid the uncertainty inherent in litigation and to avoid the costs associated with defending against potential lawsuits.⁷⁶ In addition, litigation would be costly and resource intensive and ultimately distract the Participants and FINRA CAT from their important regulatory oversight mandate.⁷⁷ The Participants state that several commenters misstate the scope of the Proposed Amendment by suggesting that the Proposed Amendment would extinguish liability.⁷⁸ The Participants state that the Proposed Amendment only concerns the allocation of liability between Industry Members and the Participants and the Proposed Amendment would not impact the rights or obligations of third parties, including Industry Members’ customers and would not extinguish the broad regulatory oversight that the Commission exercises over the CAT or potential investigation and potential enforcement action for any cybersecurity-related violations.⁷⁹

The Participants believe that commenter concerns that the regulatory process might not keep pace with emerging and evolving cyber threats fails to consider Commission regulatory requirements and oversight, including the CAT NMS Plan requirement that Participants and FINRA CAT proactively monitor the CAT’s cybersecurity and promptly address any vulnerabilities.⁸⁰ Participants state, in contrast, litigation would require the Commission to share responsibility with the courts and is a lengthy process that is unlikely to outpace regulation.⁸¹ In addition, the Commission has means other than the formal rule-making process to address emerging cyber

threats.⁸² In addition, the Participants assert that allowing Industry Member litigation would undoubtedly result in substantial additional costs and that the CRA Paper demonstrates that the costs of litigating a potential CAT Data breach are likely to be both substantial and unquantifiable on an ex-ante basis.⁸³ It would also create additional costs and distract the Participants from the regulatory mission of CAT, and these costs would ultimately be passed along to investors.⁸⁴ The Participants state that commenters are asking that their primary regulators bear any and all liability for hypothetical “black swan” cyber breaches and that such an extraordinary ask is without precedent, and that Participants, implementing a regulatory mandate in their regulatory capacities, should receive liability protections that they are customarily afforded when implementing their regulatory responsibilities pursuant to the direction and oversight of the Commission.⁸⁵

CRA Paper Does Not Capture All Data Breach Risks and Costs

Commenters believe that the CRA Paper does not capture all data breach risks, stating that the CRA Paper only focuses on a breach by external actors and fails to address the risk of misuse of CAT Data by personnel at CAT LLC and the SROs.⁸⁶ In addition, one commenter emphasizes that the CRA Paper focuses on databases maintained by CAT LLC, not the “larger concern,” which is the potential for hackers to access CAT Data from Participant

regarding the CAT’s cybersecurity. *See* Second Response Letter at 10.

⁶⁹ *See* Citadel Letter at 1, 3–5; SIFMA Letter at 8; LPL Financial Letter at 1; FIA PTG Letter at 2; Raymond James Letter at 2; SIFMA Letter II at 5; 6–7.

⁷⁰ *See* SIFMA Letter at 8. *See also* LPL Financial Letter at 1; FIA PTG Letter at 2; Raymond James Letter at 2.

⁷¹ *See* Citadel Letter at 5.

⁷² *See* SIFMA Letter II at 7. *See also* Data Boiler Letter II at 4.

⁷³ *See* Response Letter at 22–25; *see also* Second Response Letter at 4, 11–12. The Participants also state that SIFMA has not indicated that it and constituent Industry Members will abandon their extensive efforts to challenge the regulatory immunity doctrine in court or cease lobbying Congress to abrogate it by statute. *Id.* at 3–4, 11.

⁷⁴ *See* Response Letter at 21–23. The Participants state that SIFMA’s longstanding position is that Congress should abrogate regulatory immunity by statute. *Id.* at 23–24.

⁷⁵ *See* Response Letter at 23–25. *See also* Second Response Letter at 4, 11.

⁷⁶ *See* Second Response Letter at 11–12.

⁷⁷ *See id.*

⁷⁸ *See* Response Letter at 25 (citing Citi Letter at 2 and SIFMA Letter at 9).

⁷⁹ *See* Response Letter at 25–26.

⁸⁰ *See* Second Response Letter at 7.

⁸¹ *See* Second Response Letter at 8.

⁸² *See* Second Response Letter at 8. The Participants state that the Commission and its staff have “multiple tools at their disposal to motivate regulated entities” to “expeditiously modify their cybersecurity regimes.” “For example, the Division of Examinations, which has prioritized cybersecurity issues, often releases risk alerts in response to emerging concerns.” *Id.*

⁸³ *See* Second Response Letter at 3–4, 16.

⁸⁴ *See* Second Response Letter at 4, 16.

⁸⁵ *See* Second Response Letter at 4; *see also* Response Letter at 20 (stating that the Lewis Paper appears to advocate that CAT LLC should be strictly liable for all costs associated with any CAT data breach, regardless of the facts and circumstances, without any economic analysis as to why the longstanding allocation of liability between the Participants and Industry Members should not apply here). The Participants note that both the Participants and Industry Members are acting pursuant to Commission mandate, but the Participants are also fulfilling a regulatory oversight role and there is no basis for the Participants to assume liability. *See* Response Letter at 21. *See also* Second Response Letter at 4.

⁸⁶ *See* Citadel Letter at 6; SIFMA Letter at 9; LPL Financial Letter at 1; FIA PTG Letter at 2; Raymond James Letter at 2; Virtu Letter at 5. One commenter states that the CRA Paper does not provide any support for the argument that broker-dealers should be accountable for the wrongdoing or misuse of data by SRO employees or contractors. *See* ASA Letter at 2.

databases that have extracted data from the CAT.⁸⁷ Two commenters further criticize the breach scenarios discussed in the CRA Paper as insufficient to capture the risks. One of these commenters suggests that a breach of CAT by foreign actors, or CAT being internally compromised could lead to the “downfall” of U.S. capital markets and that the breach scenarios in the CRA Paper “grossly” underestimate national security threats.⁸⁸ Another commenter states that the CRA Paper “avoids any serious discussion” of the risk posed by “nation state actors, like China and Russia.”⁸⁹

Participants and the CRA Response dispute commenters’ claims that the CRA Paper does not include all potential data breaches.⁹⁰ The Participants argue that certain commenters misconstrue the CRA Paper’s analysis.⁹¹ Specifically, these commenters assert that the CRA Paper did not address certain categories of hypothetical data breaches, and in particular breaches that originate from within FINRA CAT or Participants. The Participants state that the CRA Paper did not make any assumptions regarding the identity of potential bad actors or where they may work, and the CRA Paper was not intended to predict every possible scenario, but instead intended to provide an illustrative framework to assess the economic exposures that flow from the gathering, storage, and use of CAT Data.⁹² The Participants state that the CRA Paper concludes, in light of the CAT’s extensive cybersecurity and other reasons, most potential breaches are relatively low-frequency events because they are either difficult to implement, unlikely to be meaningfully profitable, or both.⁹³ The Participants also believe that the CRA Paper’s conclusion that allowing Industry Members to litigate against CAT LLC, the Participants, and FINRA CAT would provide minimal

benefits while imposing substantial costs is not undermined to the extent that commenters identify potential breaches that were not included in the CRA Paper’s scenario analysis.⁹⁴

The Participants believe that comments that criticize the CRA Paper for failing to consider the costs to individual Industry Members in the event of a CAT Data breach are based on a misunderstanding of the relevant economic principles.⁹⁵ Specifically, the CRA Paper’s focus was on whether the risks of the use of CAT Data for regulatory purposes was best managed through *ex ante* regulation or *ex post* litigation, or a combination of both, and this analysis largely turns on identifying the most effective and efficient mechanisms for incentivizing CAT LLC, the Participants and FINRA CAT to take appropriate precautions.⁹⁶ The Participants state that the CRA Paper demonstrates that the extensive regulatory regime that the Commission has enacted creates appropriate and strong incentives for the Participants to take sufficient cybersecurity precautions and to ensure that the CAT is secure, and that allowing Industry Members to litigate against Participants would create substantial costs without any corresponding benefit.⁹⁷

The CRA Response states that allowing Industry Members to litigate against CAT LLC and Participants entails potentially substantial costs and uncertainty in the operation of the CAT that, ultimately, could be borne by Industry Members’ underlying customers,⁹⁸ as a result of the Commission-approved joint funding of CAT LLC by Industry Members and Participants, a fact the CRA Response believes that the Lewis Paper ignores. According to the CRA Response, a limitation of liability also protects Industry Members from the possibility of funding both catastrophic losses and substantial litigation costs.⁹⁹

Participants and the CRA Response argue that the Lewis Paper’s argument that CAT LLC is in a better position to insure against a CAT Data breach fails because, among other reasons, it is based on a premise that a cyberbreach would impact all Industry Members

simultaneously¹⁰⁰ and ignores the fact that CAT LLC has already purchased the maximum insurance coverage that was feasibly available.¹⁰¹ The CRA Response states that the CRA Paper’s scenario analysis does not support the Lewis Paper’s assertion that a breach is likely to be a single event that affects all Industry Members simultaneously, and the Lewis Paper does not explain why a single event instead of multiple events affecting subsets of Industry Members might make a difference.¹⁰² The Commission acknowledges that a number of factors impact the Participants’ incentives to invest in, or prioritize, the security of the CAT. These factors include, but are not limited to (in no specific order): The cost of security; regulatory requirements, including Commission supervision and enforcement, fines, penalties and potential loss of their SRO licenses; reputation; the threat of litigation; and the amount of potential payments to those impacted by a security breach. Given the sensitivity of CAT Data, as well as the importance of the CAT for regulatory purposes, the Commission believes it is important to evaluate the incentives to invest in, or prioritize, the security of the CAT. The burden is on Participants to demonstrate that the Proposed Amendment is necessary or appropriate in the public interest, for the protection of investors and the maintenance of fair and orderly markets, to remove impediments to, and perfect the mechanisms of, a national market system, or otherwise in furtherance of the purposes of the Exchange Act.¹⁰³ Accordingly, the Commission believes that the Participants must demonstrate that the Proposed Amendment satisfies this standard in light of its potential impact on the Participants’ incentives to invest in or prioritize the security of CAT.

By essentially eliminating any potential liability to Industry Members in the event of a security breach, the Participants limit the risk to themselves should they decide to reduce their investments in the security of the CAT, and such a reduction could increase the potential for a breach of CAT or

⁸⁷ See Citadel Letter, at 6–7.

⁸⁸ See Letter from Kelvin To, Founder and President, Data Boiler Technologies, LLC, to Vanessa Countryman, Secretary, dated January 27, 2021, at 1 and 6, available at <https://www.sec.gov/comments/4-698/4698-8311309-228460.pdf>.

⁸⁹ See ASA Letter at 2.

⁹⁰ See Response Letter at 15. The Participants explain that the CRA Paper contain two principal analyses: (i) A “scenario analysis” in which it identified specific hypothetical breaches and assessed the relative difficulty of implementation, relative frequency, and conditional severity of each; and (ii) a consideration whether the cyber risk presented by the CAT should be addressed by regulation, litigation, or a combination of both approaches.

⁹¹ See Response Letter at 15.

⁹² See Response Letter at 15–16 (citing CRA Paper 2).

⁹³ See Response Letter at 16 (citing CRA Paper at 18–32).

⁹⁴ See Response Letter at 16.

⁹⁵ See Response Letter at 16.

⁹⁶ See *id.*

⁹⁷ See Response Letter at 16–17. The Participants also dispute an assertion that the CRA Paper delivered a “pre-determined conclusion.” See *id.* at 17 (citing ASA Letter at 2–3).

⁹⁸ See CRA Response at 8.

⁹⁹ See CRA Response at 2, 8.

¹⁰⁰ The Participants state that the Lewis Paper does not include a scenario analysis like the CRA Paper. See Response Letter at 16 at 20–21.

¹⁰¹ See CRA Response at 2, 4–5.

¹⁰² See CRA Response at 16. The CRA Response also states that the Lewis Paper also implies that a single event is unlike a typical situation where pooling of risk can reduce the volatility around claims, but the CRA Response further argues this is a narrow view as insurers can spread correlated risks through reinsurance contracts across the global insurance industry ultimately bringing the benefits of diversification to all who are insured. *Id.*

¹⁰³ 17 CFR 201.700(b)(3).

unauthorized release of CAT Data. The Participants characterize one of the potential liabilities that they need to be insulated from as “the potential for substantial losses that may result from certain categories of low probability cyberbreaches,”¹⁰⁴ and the CRA Paper estimates an exposure of at least \$100 million per incident as a “reasonable” estimate for a data breach scenario in which an algorithmic trading firm’s strategy was reverse engineered, which it also describes as very difficult to implement and occurring infrequently.¹⁰⁵ The Proposed Amendment would almost completely insulate the Participants from any liability to member firms for those damages. Due to potentially lower costs should such a breach occur, the Commission believes the proposed Limitation of Liability Provisions would have a negative impact on the incentives of Participants to secure the CAT to prevent breaches, including purportedly low probability events.¹⁰⁶ Also, absent the proposed Limitation of Liability Provisions, the Participants might be incentivized to make further investments in data security beyond those mandated by the CAT NMS Plan and Commission rulemakings, such as internal controls designed to decrease the likelihood of misuse of CAT Data beyond the requirements of the CAT NMS Plan.

The CRA Response states that the benefits of litigation in addition to the existing regulatory regime are “inconsequential and speculative” and do not exceed the likely substantial costs.¹⁰⁷ However, the CRA Response acknowledges that the threat of liability does incentivize behavior, arguing that limiting Industry Members’ ability to recover damages provides greater incentives for them to provide feedback to CAT management through the Advisory Committee.¹⁰⁸ The Commission believes that although Industry Members do have avenues to provide feedback such as through the Advisory Committee, Industry Members do not have access to the information they would need, such as security audit results and design specifications, to evaluate the security of CAT and identify meaningful deficiencies. The Commission also believes that the CRA Response’s argument applies to Participants, in that their behavior

would change to the extent there is a decreased threat of liability. Specifically, with the proposed Limitation of Liability Provisions, the Participants’ potential liability to Industry Members would decrease and thus reduce Participants’ incentives to ensure robust cybersecurity of CAT and CAT Data in an effort to reduce or avoid the potential liability.

Participants argue that security industry norms do not support the principle that the party in possession of the data should bear liability in the event of a data breach, especially when acting in a regulatory capacity pursuant to Commission rules,¹⁰⁹ and that Industry Members “routinely” disclaim liability to their underlying customers.¹¹⁰ The Commission did not approve provisions in Industry Member contracts for OATS or Industry Member contracts with underlying customers. The Participants also refer to limitation of liability provisions in SROs’ rules that were previously approved by the Commission.¹¹¹ In the case of the SROs’ rules, these rules relate to liability to members with respect to the business operations of exchanges and were established for different types of systems with different risks than the CAT.¹¹² The Commission believes that given the amount and sensitivity of the data in the CAT System, it is important that the Participants’ incentives to invest in robust cybersecurity, including potential liability in the event of a breach, are not reduced. Based on the record before it, the Commission believes that the proposed Limitation of Liability Provisions would reduce Participants’ incentives to invest in CAT Data security.

The CRA Response also states that providing Industry Members a right to litigate may reduce Industry Members’ incentives to undertake their monitoring and influencing activities in favor of relying upon the threat of litigation, thereby weakening the overall cyber program of the CAT.¹¹³ The Commission also believes that these comments suggest that Industry Members can have a significant role in determining the strength of the overall cyber program of CAT, and if a reduction in Industry Member

“monitoring and influencing activities” would weaken the overall cyber program of the CAT, the absence of essentially any liability to Industry Members would also weaken the overall cyber program of CAT.¹¹⁴ The Participants expressed concern that CAT LLC is not equipped to compensate Industry Members in the event of a data breach because funding is designed to cover costs only.¹¹⁵ The Participants further assert that it is difficult to imagine how CAT LLC could ensure solvency if substantial exclusions are included in a limitation of liability.¹¹⁶ However, these are not compelling reasons to include the proposed Limitation of Liability Provisions. The Commission believes that there are mechanisms in place to ensure CAT LLC will not fail to compensate Industry Members or become insolvent. Specifically, the Participants are obligated to maintain a CAT and cannot dissolve CAT LLC without Commission approval.¹¹⁷ Due to its obligation to maintain the CAT, the Participants would need to fund CAT LLC by recovering any shortfall from the Participants and/or Industry Members.¹¹⁸ To the extent the Participants seek to recover any shortfall from Industry Members, the Commission will assess those fees to assure that they are reasonable.¹¹⁹

Even in the absence of the proposed Limitation of Liability Provisions, the Participants may have limited liability to Industry Members through court-established regulatory immunity.¹²⁰ To the extent it is available, regulatory

¹¹⁴ The CRA Response emphasizes that Industry Members and other interested parties are able to monitor and suggest improvements for CAT’s cyber security and “history is replete with examples.” See CRA Response at 3–4.

¹¹⁵ See Second Response Letter at 15.

¹¹⁶ See Second Response Letter at 15. See also CRA Response at 9 (stating that CAT LLC’s “cost-only business model” provides no mechanism to establish safety reserves that might allow it to build a cash reserve to pre-fund catastrophic losses from a cyber breach).

¹¹⁷ See CAT NMS Plan, Article X, Section 10.1.

¹¹⁸ See CAT NMS Plan, Article XI, Section 11.1(b) and 11.2. Specifically, Section 11.1(b) states that subject to Section 11.2, the Operating Committee shall have discretion to establish funding for the CAT LLC, including: (i) Establishing fees that the Participants shall pay; and (ii) establishing fees for Industry Members that shall be implemented by Participants. Section 11.2 sets forth funding principles that the Operating Committee should consider in establishing the funding of the Company. Specifically, Section 11.2(f) states that the Operating Committee should consider building financial stability to support the Company as a going concern.

¹¹⁹ See CAT NMS Plan, Article X, Section 11.1(b).

¹²⁰ See Section IV.C.1, *supra*. The Participants assert that regulatory immunity applies to their use of CAT. See Response Letter at 23; Second Response Letter at 4.

¹⁰⁴ See Notice, *supra* note 5, at 595.

¹⁰⁵ See Notice, *supra* note 5, at 597, 599–600, 603.

¹⁰⁶ See also Economic Analysis at Section V.A.

¹⁰⁷ See CRA Response at 9. Neither the Participants nor the CRA Paper or CRA Response provides specifics regarding estimated costs of litigation.

¹⁰⁸ See CRA Response at 19.

¹⁰⁹ See Response Letter at 10.

¹¹⁰ See Response Letter at 10; see also Response Letter at 20 (stating that the Lewis Paper does not address the fact that Industry Members routinely disclaim liability to those underlying customers).

¹¹¹ See Response Letter at 5–7.

¹¹² CAT Data, unlike an SRO’s trading data, includes comprehensive trading data from all exchange SROs and order and customer information submitted by Industry Members.

¹¹³ See CRA Response at 2, 9, and 11.

immunity may create the same incentive as the proposed Limitation of Liability Provisions for Participants to reduce their investment in CAT cybersecurity. Regulatory immunity, however, is not applicable in all scenarios (*i.e.*, commercial use or intentional misconduct). The Commission does not believe that the Participants have adequately explained why, in cases where regulatory immunity may not be applicable because Participant use of CAT data is improper (*e.g.*, commercial use or intentional misconduct), they should be permitted to limit their liability. The potential consequences of such behavior, however, could also fall on Industry Members who have no control over the security of CAT Data they have submitted to the CAT. The Commission believes that the presence of liability risk would provide Participants an additional incentive to invest in CAT data security to prevent such behavior from occurring.¹²¹ The Commission believes that the Participants have not met their burden to demonstrate that the Proposed Amendment is necessary or appropriate in the public interest, for the protection of investors and the maintenance of fair and orderly markets, to remove impediments to, and perfect the mechanisms of, a national market system, or otherwise in furtherance of the purposes of the Exchange Act.¹²²

C. Breadth of the Proposed Limitation of Liability Provisions

Several commenters are critical of the scope of the proposed Limitation of Liability Provisions and in particular the language that prohibits Industry Members from pursuing claims against CAT LLC and the Participants if there is “willful misconduct, gross negligence, bad faith or criminal acts of CAT LLC, the SROs or their representatives or employees.”¹²³ As one commenter states, the proposal would shield the Participants from liability, “not only for a breach of the CAT System by malicious third-party actors but even from the theft or other misuse of CAT Data by SRO employees” and would “effectively extinguish the liability of CAT LLC and the SROs even in instances of gross negligence or

intentional misconduct.”¹²⁴ Another commenter states that the proposal “would effectively hold brokers responsible for the malfeasance and incompetence of the SROs and their contractors” and that this would be “extremely unreasonable.”¹²⁵

A commenter suggests that if the limitation of liability language was adopted as proposed, “CAT LLC would only have \$500 in liability if an SRO employee stole CAT Data and posted it on the internet.”¹²⁶ A commenter believes that liability cap should only apply when CAT LLC and the Participants are acting solely in their regulatory capacity, for which they have proposed a definition, and should exclude willful misconduct, gross negligence, bad faith, or criminal acts.¹²⁷

The Participants state that the proposed Limitation of Liability Provisions fall squarely within industry norms, referencing a comparison to the allocation of liability between Industry Members and SROs in other regulatory contexts, including NMS plans, regulatory reporting facilities, SRO rules and liability provisions that Industry Members use to protect themselves when they possess sensitive customer and transaction data.¹²⁸ The Participants believe that the proposed Limitation of Liability Provisions are “substantively identical” to the liability provisions to which Industry Members regularly agree in connection with OATS reporting.¹²⁹

Commenters, however, dismiss comparisons made in the Proposed Amendment to OATS limitation of liability provisions because (1) CAT captures significantly more information than OATS, including personally identifiable information, and data reported to OATS is reported to and only used by FINRA; and (2) OATS does not have account-level data, which the CAT will collect and which could present the risk of reverse engineering of trading strategies.¹³⁰ One commenter

stated that the limitation of liability provisions for OATS were signed in 1998, and since then the landscape of cybersecurity has changed, and the frequency and scale of data breaches has increased dramatically.¹³¹

In response, the Participants reject the suggestion that any limitation of liability provision should allow liability for willful misconduct, gross negligence, bad faith or criminal acts of CAT LLC, the SROs or their representatives or employees.¹³² The Participants assert that the exclusion of “gross negligence, willful misconduct, bad faith, or criminal acts” is not appropriate and would be inconsistent with other limitation of liability provisions for other NMS plans (including OATS) and SRO rules.¹³³ The Participants state that in the limited instances in which SRO liability rules permit claims for gross negligence or willful misconduct, Industry Members are often prohibited from suing an SRO for damages unless the alleged gross negligence or willful misconduct also constituted a securities law violation for which Congress has authorized a private right of action.¹³⁴ The Participants further argue that modifying the proposed Limitation of Liability Provisions is not supported by the CRA Paper, because such modifications would likely result in

2; FIA PTG Letter at 2; Virtu Letter at 4; SIFMA Letter II at 7.

¹³¹ See Lewis Paper at 10.

¹³² See Response Letter at 7 (citing SIFMA Letter at 7–8); Second Response Letter at 4; 13–15.

¹³³ See Second Response Letter at 4, 13–15. The Participants assert that the proposed Limitation of Liability Provisions are consistent with SRO limitation of liability rules, emphasizing that under those rules the SROs generally have the discretion, but not obligation, to compensate harmed Industry Members, and that this discretion only applies in very limited circumstances—namely, for system failures that impact the execution of individual order. See Response Letter at 5–6. The Participants also note that during negotiations, the Participants submitted to SIFMA a term sheet that provided for a discretionary compensation mechanism modeled after SRO rules, which was rejected by SIFMA. See Response Letter at 6. See also Second Response Letter at 13–14. The Participants state that no SRO limitation of liability rule contemplates SRO liability for “catastrophic” damages resulting from the theft of Industry Members’ proprietary trading algorithms. See Response Letter at 6.

¹³⁴ See Response Letter at 6–7. Thus, the Participants believe that these provisions would not provide for liability against the self-regulatory organizations in the event of a data breach. *Id.* at 7–8. See also Second Response Letter at 13–14 (stating that SRO rules that contain exclusions generally are modified by other rules that broadly prohibit Industry Members from suing the exchanges or their representatives, except for violations of the federal securities laws for which a private right of action exists, and thus the Participants do not believe these provisions would provide for liability against the SROs in the event of a data breach).

¹²⁴ See SIFMA Letter at 5; see also LPL Financial at 1; FIA PTG Letter at 2; Raymond James Letter at 2.

¹²⁵ See ASA Letter at 2.

¹²⁶ See SIFMA Letter II at 8.

¹²⁷ See SIFMA Letter II at 11.

¹²⁸ See Response Letter at 5–11.

¹²⁹ *Id.* at 6–7. Commenters assert that the proposed Limitation of Liability Provisions are inconsistent with industry standards, citing among other things SRO limitation of liability rules which exclude protection for willful misconduct, gross negligence, bad faith or criminal acts. See SIFMA Letter at 7; LPL Financial Letter at 1; FIA PTG Letter at 2; Raymond James Letter at 2; Fidelity Letter at 2.

¹³⁰ See Lewis Paper at 9–10; SIFMA Letter at 8; LPL Financial Letter at 2; Raymond James Letter at

¹²¹ See also Economic Analysis at Section V.A.

¹²² 17 CFR 201.700(b)(3).

¹²³ See SIFMA Letter at 5, 7–8. See also LPL Financial at 1; FIA PTG Letter at 2; Raymond James Letter at 2; Citadel Letter, at 3 (stating that the provisions would protect Participants and their representatives from any and all potential misuse, including intentional misuse, of CAT Data); SIFMA Letter II at 8–9.

litigation over liability¹³⁵ and litigation to prove these elements even if non-existent.¹³⁶

The CRA Response also states that the comment letters do not acknowledge that behavior falling in these categories is already subject to enforcement by the Commission.¹³⁷ The Participants state that the Commission's regulatory enforcement regime and the potential for severe reputational harm already sufficiently incentivize the Participants not to engage in bad faith, recklessness, gross negligence, and intentional misconduct, and so adding exclusions to the proposed Limitation of Liability Provisions would not result in any meaningful improvement to the CAT's cybersecurity.¹³⁸

As noted in the previous section,¹³⁹ commenters believe that the CRA Paper only focuses on a breach by external actors and fails to address the risk of misuse of CAT Data by personnel at CAT LLC and the SROs.¹⁴⁰ The CRA Response argues that the CRA Paper did not specifically address the misuse of CAT Data by CAT personnel and other internal sources because whether a perpetrator is external or internal makes

no difference to the scenario analysis.¹⁴¹ The CRA Response also argues that the purported concerns about the threat of "internal" breaches are exaggerated and that all Participant users of CAT Data are subject to comparable cyber security procedures and protocols, and only trading data, not customer data, can be downloaded in bulk.¹⁴²

The Commission does not believe that the Participants have demonstrated that it is necessary or appropriate to foreclose all potential Industry Member claims, including those arising from "gross negligence, willful misconduct, bad faith, or criminal acts" to a maximum of \$500 per Industry Member per calendar year as proposed.¹⁴³ The Commission believes that the damages to Industry Members for breaches of CAT could potentially far exceed that amount, and Participants and the CRA Response acknowledge the possibility for low frequency events with extreme severity.¹⁴⁴ For example, as discussed above, the CRA Paper estimates an exposure of at least \$100 million per incident would be reasonable if an algorithmic trading firm's strategy was reverse engineered, and if the Proposed Amendment were adopted the Participants would only have \$500 in liability to the trading firm even if the trading strategy was exposed through gross negligence, willful misconduct, bad faith, or criminal acts. This means that the proposed Limitation of Liability Provisions would shield the Participants from liability to Industry Members even if a Participant intentionally used CAT Data for competitive business purposes, or an employee of CAT LLC sold CAT Data to a foreign government.

As noted above, Participants can assert regulatory immunity to the extent that the doctrine applies if there is a security breach that exposes CAT Data and Industry Members seek damages

from the responsible Participants.¹⁴⁵ However, the Commission believes that for situations where regulatory immunity may not be applicable (e.g., commercial use or intentional misconduct), the Participants have not met their burden to justify a nearly complete elimination of liability to Industry Members as consistent with the Exchange Act and the rules and regulations as required by Rule 608 of Regulation NMS, as discussed above. The Commission cannot make a finding that the proposed amendment is consistent with the Exchange Act and the rules and regulations issued thereunder.¹⁴⁶

V. Impact on Efficiency, Competition, and Capital Formation

In determining whether to approve a CAT NMS Plan amendment, and whether such amendment is in the public interest, Rule 613 requires the Commission to consider the potential effects of the proposed amendment on efficiency, competition and capital formation.¹⁴⁷ The Commission has reviewed the arguments about such effects put forth by the Participants and commenters and independently analyzed the likely effects of the Proposed Amendment on efficiency, competition and capital formation.. Many of those effects hinge on assumptions about the applicability of the doctrine of regulatory immunity in the case of litigation related to a breach of CAT Data, the influence of such immunity on the incentives of the Participants to protect the CAT Data, and the potential redundancy of a limitation on liability if immunity applies. Commenters have addressed the applicability of this doctrine directly in their comments,¹⁴⁸ many of which relate to two studies: The CRA Paper submitted by the Participants as part of their filing, and the Lewis Paper submitted by SIFMA as part of its commentary;¹⁴⁹ both of these studies make assumptions regarding regulatory immunity that impact their respective conclusions. In the case of the CRA Paper, many conclusions stem from an assumption that regulatory immunity would not apply and thus Participants would be faced with significant risk of litigation in the case of a CAT data breach that resulted from the collection of CAT Data into the central repository or the use of that CAT Data by a

¹³⁵ See, e.g., Response Letter at 9; CRA Response at 18.

¹³⁶ See Response Letter at 9; Second Response Letter at 4, 14–15. According to the Participants, although they, CAT LLC, and FINRA CAT may ultimately be found not liable, such litigation would be expensive, time-consuming, would distract Participants from their regulatory oversight mandate, and may open the doors of discovery to potentially malicious actors. See Response Letter at 9.

¹³⁷ See CRA Response at 18. The CRA Response also argues that including commenters' proposed exclusions to the Proposed Limitation on Liability Provisions would potentially generate substantial litigation and that reducing expected liability costs may provide additional resources to enhance CAT's cybersecurity, purchase more cyber liability insurance (as it becomes available), or invest in competing CAT priorities. See CRA Response at 18–19.

¹³⁸ See Response Letter at 9. The Participants note that enforcement actions could be brought for cybersecurity-related violations (e.g., failure to comply with Regulation SCI) and violations of the CAT NMS Plan (e.g., for violating the CAT NMS Plan by using CAT Data for non-regulatory purposes). See *id.* at 25–26. The Participants also state that the purpose of the CAT and the Participants' mandate under the CAT NMS Plan is the fulfillment of regulatory functions, and not operation in connection with business activities. *Id.* at 22. In addition, the CRA Response states that the comment letters do not acknowledge that behavior falling to these categories is already subject to enforcement by the Commission. See CRA Response at 18.

¹³⁹ See *infra* Section IV.A.

¹⁴⁰ See Citadel Letter at 6; SIFMA Letter at 9; LPL Financial Letter at 1; FIA PTG Letter at 2; Raymond James Letter at 2; Virtu Letter at 5. One commenter states that the CRA Paper does not provide any support for the argument that broker-dealers should be accountable for the wrongdoing or misuse of data by SRO employees or contractors. See ASA Letter at 2.

¹⁴¹ See CRA Response at 19. As noted earlier, Participants also state that the CRA Paper did not make any assumptions regarding the identity of potential bad actors or where they may work, and the CRA Paper was not intended to predict every possible scenario, but instead intended to provide an illustrative framework to assess the economic exposures that flow from the gathering, storage, and use of CAT Data. See Response Letter at 15–16 (citing CRA Paper 2).

¹⁴² See CRA Response at 20.

¹⁴³ As discussed above, a number of factors impact the Participants' incentives to invest in, or prioritize, the security of the CAT. See Section IV.B., *supra*. The Commission does not believe that the Participants have met their burden of establishing that it is appropriate to foreclose liability to Industry Members for potential claims arising from "gross negligence, willful misconduct, bad faith, or criminal acts" because of the Commission's regulatory enforcement regime and the potential for severe reputational harm.

¹⁴⁴ See notes 104 and 105, *supra*, and accompanying text.

¹⁴⁵ See Section IV.B, *supra*.

¹⁴⁶ 17 CFR 201.700(b)(3); 17 CFR 242.608(b)(2).

¹⁴⁷ 17 CFR 242.613(a)(5).

¹⁴⁸ See, e.g., Citadel Letter at 1, 3–5; SIFMA Letter at 8; LPL Financial Letter at 1; FIA PTG Letter at 2; Raymond James Letter at 2.

¹⁴⁹ See Lewis Paper, *supra*, note 27.

Participant that was performing its regulatory duties. In the case of the Lewis Paper, many of the conclusions are based on an assumption that, if the Proposed Amendment were allowed, Industry Members, as opposed to Participants, would bear significant liability in the case of a data breach because the limitation of liability would be absolute, the Lewis Paper does not address the doctrine of regulatory immunity¹⁵⁰ as it might apply to Participants.¹⁵¹

In summary, the Commission believes that, if approved, the Proposed Amendment would likely have significant negative effects on efficiency, though minor positive effects that are unlikely to significantly mitigate the negative effects are also discussed below.¹⁵² The Commission believes the Participants are best poised due to information asymmetry to understand the risks inherent in collecting and using CAT Data, and, because of moral hazard, to mitigate those risks through operational measures to promote CAT data security and securing insurance to mitigate financial risks associated with CAT data security. Efficiency is likely to be reduced to the extent the Proposed Amendment disincentivizes the Participants from investing in CAT data security and thus potentially increases the likelihood of a data breach. The Commission believes this effect would be only partially mitigated as discussed below and believes the net effect may remain significant. The Commission believes that the Proposed Amendment might have negative effects on competition and capital formation, but believes these effects would be partially mitigated. These conclusions are discussed in the analysis which follows.

A. Efficiency

The Commission believes that the Proposed Amendment would likely have a significant effect on efficiency, although minor positive effects that are unlikely to significantly mitigate the negative effects are also discussed below. These mixed effects would likely be dominated by the negative effects of reducing the Participants' incentives to invest in CAT data security. Generally, the Commission believes that the

Proposed Amendment would reduce the Participants' incentives to invest in CAT data security. The Commission believes that taking measures that may prevent a data breach is inherently more efficient than remediating the consequences of a data breach after it has occurred.¹⁵³ Consequently, liability rules that incentivize appropriate security measures are likely to increase efficiency while rules that potentially disincentivize Participants from securing CAT Data may reduce efficiency. As noted, the magnitude of this effect hinges on the Participants' beliefs about the applicability of the doctrine of regulatory immunity. If the Participants do not believe regulatory immunity applies to all aspects of their collection and use of CAT Data, or have significant uncertainty that it would apply to some or all aspects, the Proposed Amendment would represent to the Participants a shift of liability from the Participants to Industry Members, the magnitude of which would be a function of the level of Participant uncertainty about their regulatory immunity.¹⁵⁴ Absent the Proposed Amendment, the Participants might make further investments in data security beyond those mandated by the CAT NMS Plan and Commission rulemakings such as implementing internal controls designed to decrease the likelihood of misuse of CAT Data. But the assurance of limited liability provided by the Proposed Amendment could disincentivize such actions or even incentivize a reduction in existing investments in cybersecurity.

The CRA Paper maintains that additional investment in security such as providing additional insurance, may not be efficient. The CRA Paper states, “. . . the prospect of litigation arising from the absence of the limitation on liability provision has the prospect for prompting overpayment for cyber security on the part of the CAT and the Plan Processor beyond the economically optimal level of protection, despite the analysis we present above suggesting that such litigation would provide no incremental benefit. The prospect of third-party litigation may prompt CAT LLC to expend resources on cyber security systems that supplement the detailed (and regularly updated)

framework implemented by the Commission, but that do not reduce the cyber risk commensurate with the costs.”¹⁵⁵ The CRA Paper further argues that the threat of third-party litigation may result in risk-aversion that prevents the Participants from adopting policies or technologies that decrease costs or increase efficiencies.¹⁵⁶ The Commission agrees with the CRA Paper that there are likely to exist certain security investments that do not provide sufficient benefits to warrant their adoption, particularly in light of the Commission's belief that investors may ultimately bear the costs of these investments—as well as costs of potential litigation.¹⁵⁷ However, the Commission disagrees that litigation risk provides no incremental benefit because the threat of such litigation may incentivize the Participants to implement security measures such as the adoption of internal controls that decrease the likelihood of an employee or contractor making commercial or other misuse of CAT Data.¹⁵⁸ Further, the Commission recognizes that while the Participants face costs in the event of a CAT data breach, these costs are likely to fall upon broker-dealers and investors as well, while these groups have limited ability to participate in decisions related to investments in CAT security. This partitioning of decision-making authority from the financial consequences of the decision creates an agency problem that may limit the Participants' incentives to select the welfare-maximizing level of security investment. This agency problem may be partially mitigated by the Participants' perception of litigation risk in the event of a data breach by better aligning their incentives regarding security decisions with other parties that are likely to be harmed if such a breach occurs.

The Commission recognizes that the risk of the Proposed Amendment disincentivizing the Participants from taking additional measures to ensure security is likely to be partially mitigated by other incentives that are not impacted by the limitation on liability. Independent of potential regulatory immunity,¹⁵⁹ Participants

¹⁵⁰ The Commission recognizes that the Participants believe regulatory immunity would apply in the event of a breach concerning CAT Data (see Response Letter at 23; Second Response Letter at 4), but the Participants also believe that there is no guarantee that all courts will agree that the Participants' immunity extends to the claims at issue. The Commission acknowledges that beliefs about regulatory immunity may influence the outcomes it describes in this analysis.

¹⁵¹ See, e.g., Lewis Paper at 4.

¹⁵² See Section V.A., *infra*.

¹⁵³ See, e.g., Securities Exchange Act Release No. 89632 (Aug. 21, 2020), 85 FR 65990, 66091 (Oct. 16, 2020) (proposing amendments to the CAT Plan to enhance data security).

¹⁵⁴ The proposed Limitation of Liability Provisions would limit liability to \$500 per CAT Reporter or CAT Reporting Agent in a calendar year. See Notice, *supra* note 5, 86 FR at 593. See Section V.A., *infra*, for discussion of liability for Industry Members that do not carry customer accounts.

¹⁵⁵ The CRA Paper discusses reasons why the incremental benefit from litigation from Industry Members may be reduced, but does not show that there is no incremental benefit. See Notice, *supra* note 5, at 616–17.

¹⁵⁶ See Notice, *supra* note 5, at 617–18.

¹⁵⁷ The Commission has the power to disallow fee amendments that might unfairly pass costs to Industry Members.

¹⁵⁸ See note 113, *supra*, and referring text.

¹⁵⁹ The Commission believes the Participants' views on their potential regulatory immunity with

face significant costs, both direct and indirect, that would result from a data breach. The potential reputational consequences of a data breach would likely be severe and such a breach is likely to draw significant negative publicity, public scrutiny, and attention from regulatory and other government entities. Further, while contractual limitation of liability reduces the risk of exposure, it does not prevent enforcement actions from the Commission or litigation by parties other than Industry Members. In addition, any breach would likely cause a significant disruption to Participants' own operations¹⁶⁰ and some breach threats are not about compromising data but are indeed designed to disrupt operations;¹⁶¹ Participants are thus still incentivized to create security measures that mitigate the risk of such breaches, which likely help mitigate the risk of compromised data that could directly affect Industry Members. However, the Commission believes that decreasing the risk of exposure that Participants face through the Proposed Amendment will likely on balance disincentivize the Participants from investing in data security, particularly if the proposed amendments increase the scope of immunity that might be expected beyond regulatory immunity.¹⁶²

The Commission believes that taking measures that may prevent a data breach is more efficient than remediating the consequences of a data breach after it has occurred.¹⁶³ Consequently, measures that incentivize appropriate security measures are likely to increase efficiency while measures that potentially disincentivize Participants from securing CAT Data may reduce efficiency.

As noted above, several commenters express concern that shifting liability through the proposed Limitation of Liability Provisions would reduce the incentives of Participants to develop robust data security and risk mitigation mechanisms, and may even incentivize

the Participants to de-prioritize data security.¹⁶⁴ The Commission believes, however, that the degree to which the proposed amendment would disincentivize the Participants from appropriate security measures is dependent upon the Participants' belief in the applicability of regulatory immunity to the collection and permitted uses of CAT Data in the absence of the proposed amendment. The Commission believes that uncertainty regarding liability in case of a CAT data breach thus serves as an incentive for the Participants to invest in data security to the extent that Participants believe a court might not uphold their regulatory immunity or it would be judged not to apply in a given case that was before the courts. If the Participants believe that regulatory immunity is likely to apply, the proposed amendments would serve to reduce their risk of incurring costs of litigation by reducing the likelihood of litigation by Industry Members.

Some commenters addressed the scope of the limitation of liability, considering whether Participants might be shielded from liability in commercial use of CAT Data,¹⁶⁵ even though such use is prohibited by the CAT NMS Plan.¹⁶⁶ Another commenter focused on the scope of the immunity more generally as it would appear to exceed the bounds of conventional regulatory immunity.¹⁶⁷ One commenter characterized the economic structure as creating a "moral hazard" and stated that permitting litigation against Participants and their representatives when they are acting outside their regulatory capacity is "crucial" and would give the Participants very strong financial incentives to invest heavily to prevent or minimize the likelihood of such failures.¹⁶⁸

To the extent that the scope of limitation of liability in the Proposed Amendment exceeds what might be expected from the doctrine of regulatory immunity, an expansion of the scope of activities that could be shielded from liability would potentially further

disincentivize Participants from activities that promote CAT data security even if regulatory immunity applies.

The Commission also recognizes that the Proposed Amendment may reduce the risk of litigation in the event of a breach by resolving the existing uncertainty about whether the Participants could be liable; in other words, if Industry Members know they cannot recover due to the limitation of liability, regardless of the applicability of regulatory immunity, they may be less likely to sue over a breach. Such litigation would impose costs, both direct and indirect,¹⁶⁹ on the Participants to defend themselves even if they would ultimately prevail due to regulatory immunity and those direct costs might be passed on to Industry Members and ultimately investors. The Proposed Amendment would reduce the likelihood of litigation and thus might avoid costs associated with litigation that investors would unnecessarily bear, which could improve efficiency. Additional insurance costs to Industry Members related to liability risks from the Proposed Amendment are discussed below.

While both the CRA Paper and the Lewis Paper frame their analyses from a perspective of potential litigation, the Commission notes that not all potential data breaches are amenable to litigation. The Commission believes that a data breach could go undetected, particularly if such a breach were perpetrated by authorized users of the CAT System such that detection of the breach relied primarily on the Participants' screening of their employees and contractors before providing access to CAT Data and then the monitoring of their use of CAT Data when they became authorized users.¹⁷⁰ Such a breach could impose significant costs on Industry Members if their intellectual property (such as proprietary trading strategies) were revealed to competitors or bad actors. Consequently, the Commission believes that reducing the Participants' existing incentives to properly invest in data security activities might disincentivize

regard to CAT data collection and use is immaterial to this second set of incentives because these consequences of a data breach could occur regardless of whether there could or would be litigation as a result of that breach.

¹⁶⁰ A breach of CAT data could occur in a Participant's own analytic or operational environment.

¹⁶¹ See, e.g., Raphael Satter, *Up to 1,500 businesses affected by ransomware attack, U.S. firm's CEO says*, Reuters (July 6, 2021), available at <https://www.reuters.com/technology/hackers-demand-70-million-liberate-data-held-by-companies-hit-mass-cyberattack-2021-07-05/>.

¹⁶² See Sections V.B and V.C, *supra*.

¹⁶³ See, e.g., Securities Exchange Act Release No. 89632 (Aug. 21, 2020), 85 FR 65990, 66091 (Oct. 16, 2020) (proposing amendments to the CAT Plan to enhance data security).

¹⁶⁴ See, e.g., Lewis Paper at 5–9, 14; SIFMA Letter at 7, 9; LPL Financial Letter at 1; Raymond James Letter at 2; FIA PTG Letter at 2; Virtu Letter at 3; ASA Letter at 2; Fidelity Letter at 2; Citi Letter at 2.

¹⁶⁵ See, e.g., SIFMA Letter at 8; LPL Financial Letter at 1; FIA PTG Letter at 2; Raymond James Letter at 2.

¹⁶⁶ See, e.g., CAT NMS Plan Sections 6.5(f)(i)(A); 6.5(g).

¹⁶⁷ See Citadel Letter at 5.

¹⁶⁸ See Citi Letter at 2. In response, the CRA Response argues that the structure might not be considered a classic "moral hazard" due to Industry Members' ability to monitor and influence CAT cyber security. See CRA Response at 10–11.

¹⁶⁹ Indirect costs would include opportunity costs of time and effort spent dealing with litigation. See, e.g., Notice, *supra* note 5, 85 FR at 617–618; Response Letter at 8–9.

¹⁷⁰ Several commenters discussed arguments in the CRA Paper and Lewis Paper regarding ex-ante regulation versus ex-post litigation. See Citadel Letter at 1–2, 7; Lewis Paper at 7–9. An undetected breach cannot be addressed through litigation, but might be prevented by ex-ante regulation or the proper alignment of incentives in lieu of regulation. The Commission considers screening of potential users of CAT Data and monitoring their activities with CAT Data to be security activities that would be affected by Participant incentives to prevent data breaches.

individual Participants from appropriately investing in the screening and monitoring of their own employees and contractors that will access CAT Data. This might reduce efficiency by increasing the likelihood of a breach either detected or undetected.

In addition, the Proposed Amendment might improve efficiency by promoting the optimal level of usage of CAT Data.¹⁷¹ Specifically, if the Participants believe their regulatory immunity may not be recognized in litigation in the wake of a data breach, they may be incentivized to minimize their use of CAT Data to minimize opportunities for a data breach, particularly one involving their own employees or contractors. However, the Proposed Amendment might facilitate increased use levels of CAT Data by Participants by reducing the risk of exposure to litigation. Consequently, the Commission believes that the Proposed Amendment might prevent inefficiencies related to underuse of CAT Data by regulators. By contrast, to the degree that disapproval of the Proposed Amendment renders regulators more risk averse in using CAT Data to meet their regulatory obligations than they would be if the Proposed Amendment were approved, disapproval may reduce use of CAT Data by regulators. Further effects on efficiency depend upon the use of insurance by Participants and Industry Members. The Lewis Paper and the CRA Paper analyze the potential for the use of insurance by Participants and Industry Members to manage the financial risks of a potential data breach.¹⁷² Through the CRA Paper, the Participants argue that adopting the Proposed Amendment would avoid inefficiencies such as over investment in insurance beyond what would be optimal.¹⁷³ The CRA Paper argues that this inefficiency would result in unnecessary costs being passed to investors without a corresponding societal benefit.¹⁷⁴ The Lewis Paper argues that shifting the financial risks of a CAT data breach to Industry Members by limiting liability for Participants would cause them to insure against the financial consequences of a CAT data breach, which would be inefficient because Industry Members cannot give an insurer access to the CAT System to monitor or assess the security of the system. Consequently, according to the Lewis Paper, insurance purchased by

Industry Members to cover the risk would be more expensive, and investors would ultimately bear this increased expense.¹⁷⁵ Also, policies obtained by Industry Members would necessarily overlap, further increasing the cost of such insurance.¹⁷⁶ Other commenters supported the position that the Participants can more efficiently obtain cyber insurance.¹⁷⁷

The Commission agrees that the Participants are better positioned to insure against a breach both due to their ability to provide access and monitoring of the CAT System to an insurer, and because if Industry Members were to obtain insurance that would apply to a CAT data breach, such policies would overlap because the same breach event would likely impact multiple Industry Members and many investors whose data might be exposed in a breach are customers of multiple Industry Members. However, as noted by some commenters, the doctrine of regulatory immunity may already shift significant breach risk to Industry Members,¹⁷⁸ and the Participants state that Industry Members may already shift some of their own risk of data breaches to their own customers with their own limitation of liability language in customer agreements.¹⁷⁹ Further, as discussed above, insurance is unlikely to provide a remedy in case of breaches that go undetected. However, the Commission recognizes that if the doctrine of regulatory immunity does not apply, the Proposed Amendment would shift the financial risks of a breach to Industry Members. The Commission believes that investors are likely to bear the costs of providing security to the CAT System as well as any costs of a breach of CAT Data. However, the Commission recognizes that inefficiencies in providing security to CAT are likely to increase the costs that investors bear.

The Commission believes that, even if the Proposed Amendment were approved, inefficiencies in the scope and maintenance of Industry Member insurance policies against a CAT data breach are likely to be minor for two reasons. First, Industry Members that carry customer accounts already face risks related to breach of customer information. The Commission believes these Industry Members actively manage the security of their environments to prevent a breach of this

data within their systems and acknowledges that they cannot continue to safeguard this data once this data is reported to CAT. However, as noted by commenters, Industry Members also typically indemnify themselves with agreements that limit their liability in the case of a data breach and thus would be unlikely to increase their insurance coverage if the proposed amendments were approved. Second, any additional insurance burdens would likely to be negligible for Industry Members that carry no customer accounts because they do not risk litigation from customers. However to the degree that Industry Members overall would increase cyber insurance to offset this risk if the Proposed Amendment is approved, the cost of such insurance would likely to be higher than it would be if the risk were borne by Participants because Industry Members cannot facilitate the monitoring of an insurer and the policies Industry Members would purchase would necessarily be overlapping policies because investors often have accounts with multiple Industry Members and a single data breach might expose data from multiple Industry Members. Those inflated costs would ultimately be passed to investors, and the security improvements that might be facilitated by the monitoring of an insurer contracted by the Participants would be unrealized.

B. Competition

The Commission believes that the Proposed Amendment might have negative effects upon competition, but believes these effects would be partially mitigated. In their filing, the Participants state they do not believe the Proposed Amendment will have any impact on competition.¹⁸⁰ However, the Commission believes that the Proposed Amendment could have negative effects on the competitive positions of some Industry Members relative to other Industry Members. Industry Members have diverse business models; some of these models employ proprietary trading strategies that might be revealed in the wake of a data breach. If such proprietary strategies were revealed, Industry Members that employed such strategies might experience loss of intellectual property that could damage their competitive positions relative to their peers. The Commission further acknowledges that a data breach could harm an Industry Member's reputation and damage its competitive position within the markets in which it competes, particularly if customer data were released from some but not all

¹⁷¹ See CAT NMS Plan Approval Order, *supra* note 1, at 84833–40.

¹⁷² See Lewis Paper at 11–14; Notice, *supra* note 5, at 618–620.

¹⁷³ See Notice, *supra* note 5, at 617–18.

¹⁷⁴ See Notice, *supra* note 5, at 617–18.

¹⁷⁵ See Lewis Paper at 11–14.

¹⁷⁶ See Lewis Paper at 14.

¹⁷⁷ See SIFMA Letter at 8–9; LPL Financial Letter at 2; FIA PTG Letter at 2; Raymond James Letter at 2; Virtu Letter at 3–4.

¹⁷⁸ See Section IV.C.1, *supra*.

¹⁷⁹ See Response Letter at 10.

¹⁸⁰ See Notice, *supra* note 5, at 597.

competitors within those markets. The Commission acknowledges that robust investment in cyber security does not guarantee breaches will not occur. The likelihood of a data breach happening however, increases if Participants reduce potential additional investment in CAT data security including additional investment in cyber insurance coverage (should such coverage become available) or additional investment in the screening and monitoring of employees and contractors that have access to CAT Data. But the assurance of limited liability provided by the Proposed Amendment could disincentivize such actions. The Commission believes that Participants would remain incentivized to invest in CAT data security to some extent, even if the Proposed Amendment is approved because of the additional incentives discussed above, such as reputational damage, which would remain unaffected by the Proposed Amendment.¹⁸¹

The Commission further believes there might be additional competitive effects of the Proposed Amendment in the market for trading services. The Commission recognizes that Industry Members are not just the customers and members of the Participants, but are sometimes competitors of the Participants. Exchanges (all of which are Participants) compete in the market for trading services with off-exchange venues such as alternative trading systems (all of which are operated by Industry Members) and Industry Members that provide liquidity to orders off-exchange.¹⁸² Consequently, if the Proposed Amendment were to shift any of the expense of insuring against the risk of a CAT data breach from Participants to Industry Members, and if such expenses were more efficiently borne by Participants as discussed previously, the additional marginal costs incurred by Industry Members could disadvantage them in this competition to provide trading services. However, the Commission believes that this effect would be partially mitigated because, as discussed previously, that even under the Proposed Amendment, the Participants would remain incentivized to invest in CAT data security, and that Industry Members' need to invest in additional insurance would be mitigated by their own use of limitation of liability agreements with their own customers.¹⁸³

C. Capital Formation

The Commission believes that the Proposed Amendment might have negative effects on capital formation in markets in which Industry Members compete, but believes these effects would be partially mitigated.

The Participants argue that adopting the proposed amendment would avoid inefficiencies by avoiding the increased costs that would otherwise arise,¹⁸⁴ namely over investment in cyber security and insurance beyond what would be optimal, and underinvestment in adoption of policies or technologies that decrease costs or increase efficiencies as described in the CRA Paper. The Participants argue that avoiding these issues, by limiting liability, would promote capital formation in the U.S. securities markets. While the Commission acknowledges that an inappropriate level of risk-aversion might result in these effects, if the Participants believe, as asserted in their filing, that they have regulatory immunity, the Commission believes these effects would be small because the potential shift in liability from the proposed amendments would be far less significant than anticipated in the CRA Paper.

It is possible that capital formation could be negatively impacted by an inefficient insurance burden on Industry Members as described in the Lewis Paper.¹⁸⁵ However, even in cases in which Participants' regulatory immunity would not apply, the Commission does not believe the Proposed Amendment would significantly increase Industry Members' insurance burden because, as discussed previously, many Industry Members have agreements limiting their liability with their own customers, and not all Industry Members have customers that might initiate litigation.¹⁸⁶

The Commission recognizes, however, that the risk of a data breach can impact capital formation through routes other than inefficient insurance costs and underinvestment. If Industry Members believe that the proposed amendment would significantly reduce Participants' incentives to invest in CAT security, Industry Members may be less incentivized to invest in intellectual property that could be compromised by a data breach, potentially reducing capital formation in liquidity provision on exchanges or in proprietary trading activities. The Commission believes this risk is partially mitigated because the

Participants are still incentivized to secure CAT Data by other incentives that are not affected by the proposed amendment.¹⁸⁷

VI. Conclusion

For the reasons set forth above, the Commission does not find, pursuant to Section 11A of the Exchange Act, and Rule 608(b)(2) thereunder, that the Proposed Amendment is consistent with the requirements of the Exchange Act and the rules and regulations thereunder applicable to an NMS plan amendment.

It is therefore ordered, pursuant to Section 11A of the Exchange Act, and Rule 608(b)(2) thereunder, that the Proposed Amendment (File No. 4-698) be, and hereby is, disapproved.

By the Commission.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021-24035 Filed 11-3-21; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 34411]

Notice of Applications for Deregistration Under Section 8(f) of the Investment Company Act of 1940

October 29, 2021.

The following is a notice of applications for deregistration under section 8(f) of the Investment Company Act of 1940 for the month of October 2021. A copy of each application may be obtained via the Commission's website by searching for the file number, or for an applicant using the Company name box, at <http://www.sec.gov/search/search.htm> or by calling (202) 551-8090. An order granting each application will be issued unless the SEC orders a hearing. Interested persons may request a hearing on any application by emailing the SEC's Secretary at Secretarys-Office@sec.gov and serving the relevant applicant with a copy of the request by email, if an email address is listed for the relevant applicant below, or personally or by mail, if a physical address is listed for the relevant applicant below. Hearing requests should be received by the SEC by 5:30 p.m. on November 23, 2021, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to Rule 0-5 under the Act, hearing requests should state the nature

¹⁸¹ See Section VI.A., *supra*.

¹⁸² See CAT Plan Approval Order, *supra* note 1, at 84882-89.

¹⁸³ See Section VI.A., *supra*.

¹⁸⁴ See Notice, *supra* note 5, at 617-18.

¹⁸⁵ See Lewis Paper at 11-14.

¹⁸⁶ See Section VI.A., *supra*.

¹⁸⁷ See Section VI.A., *supra*.

of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary at *Secretaries-Office@sec.gov*.

ADDRESSES: The Commission: *Secretaries-Office@sec.gov*.

FOR FURTHER INFORMATION CONTACT: Shawn Davis, Assistant Director, at (202) 551-6413 or Chief Counsel's Office at (202) 551-6821; SEC, Division of Investment Management, Chief Counsel's Office, 100 F Street NE, Washington, DC 20549-8010.

Cohen & Steers Global Income Builder, Inc. [File No. 811-22057]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. The applicant has transferred its assets to Cohen & Steers Infrastructure Fund, Inc., and on December 12, 2019 made a final distribution to its shareholders based on net asset value. Expenses of \$387,207 incurred in connection with the reorganization were paid by the applicant and the acquiring fund.

Filing Dates: The application was filed on March 12, 2021, and amended on July 30, 2021, and October 14, 2021.

Applicant's Address: *FundLegalGroup@cohenandsteers.com*.

State Farm Associates' Funds Trust [File No. 811-1519]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. The applicant has transferred its assets to Advisers Investment Trust, and on August 23, 2021 made a final distribution to its shareholders based on net asset value. Expenses of \$912,500 incurred in connection with the reorganization were paid by the applicant's investment adviser.

Filing Dates: The application was filed on September 21, 2021.

Applicant's Address: *david.moore.ct95@statefarm.com*.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

J. Matthew DeLesDernier,
Assistant Secretary.

[FR Doc. 2021-24000 Filed 11-3-21; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-93471; File Nos. SR-MIAX-2021-28, SR-EMERALD-2021-21]

Self-Regulatory Organizations; Miami International Securities Exchange, LLC and MIAX Emerald, LLC; Notice of Withdrawal of Proposed Rule Changes To Establish Fees for the Exchanges' cToM Market Data Products

October 29, 2021.

On June 30, 2021, Miami International Securities Exchange, LLC ("MIAX") and MIAX Emerald, LLC ("MIAX Emerald") (collectively, the "Exchanges") each filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")¹ and Rule 19b-4 thereunder,² a proposed rule change to establish fees for, respectively, the MIAX Complex Top of Market ("cToM") and the MIAX Emerald cToM market data products.

The proposed rule changes were immediately effective upon filing with the Commission pursuant to Section 19(b)(3)(A) of the Act.³ The proposed rule changes were published for comment in the **Federal Register** on July 15, 2021.⁴ On August 27, 2021, the Commission temporarily suspended the proposed rule changes and instituted proceedings under Section 19(b)(2)(B) of the Act⁵ to determine whether to approve or disapprove the proposed rule changes.⁶ On September 30, 2021, the Exchanges withdrew the proposed rule changes (SR-MIAX-2021-28, SR-EMERALD-2021-21).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁷

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021-24017 Filed 11-3-21; 8:45 am]

BILLING CODE 8011-01-P

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ 15 U.S.C. 78s(b)(3)(A). A proposed rule change may take effect upon filing with the Commission if it is designated by the exchange as "establishing or changing a due, fee, or other charge imposed by the self-regulatory organization on any person, whether or not the person is a member of the self-regulatory organization." 15 U.S.C. 78s(b)(3)(A)(ii).

⁴ See Securities Exchange Act Release Nos. 92359 (July 9, 2021), 86 FR 37393 (SR-MIAX-2021-28); and 92358 (July 9, 2021), 86 FR 37361 (SR-EMERALD-2021-21).

⁵ 15 U.S.C. 78s(b)(2)(B).

⁶ See Securities Exchange Act Release No. 92789, 86 FR 49364 (September 2, 2021).

⁷ 17 CFR 200.30-3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-93469; File No. SR-BX-2021-049]

Self-Regulatory Organizations; Nasdaq BX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Equity 4, Rule 4703

October 29, 2021.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on October 19, 2021, Nasdaq BX, Inc. ("BX" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Equity 4, Rule 4703,³ in light of planned changes to the System, as described further below. The text of the proposed rule change is available on the Exchange's website at <https://listingcenter.nasdaq.com/rulebook/bx/rules>, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ References herein to BX Rules in the 4000 Series shall mean Rules in BX Equity 4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Presently, the Exchange is making functional enhancements and improvements to specific Order Types⁴ and Order Attributes⁵ that are currently only available via the RASH Order entry protocol.⁶ Specifically, the Exchange will be upgrading the logic and implementation of these Order Types and Order Attributes so that the features are more streamlined across the Exchange Systems and order entry protocols, and will enable the Exchange to process these Orders more quickly and efficiently. Additionally, this System upgrade will pave the way for the Exchange to enhance the OUCH Order entry protocol⁷ so that Participants may enter such Order Types and Order Attributes via OUCH, in addition to the RASH Order entry protocols.⁸ The Exchange plans to implement its enhancement of the OUCH protocol sequentially, by Order Type and Order Attribute.⁹

⁴ An "Order Type" is a standardized set of instructions associated with an Order that define how it will behave with respect to pricing, execution, and/or posting to the Exchange Book when submitted to Exchange. See Equity 1, Section 1(a)(11).

⁵ An "Order Attribute" is a further set of variable instructions that may be associated with an Order to further define how it will behave with respect to pricing, execution, and/or posting to the Exchange Book when submitted to Exchange. See *id.*

⁶ The RASH (Routing and Special Handling) Order entry protocol is a proprietary protocol that allows members to enter Orders, cancel existing Orders and receive executions. RASH allows participants to use advanced functionality, including discretion, random reserve, pegging and routing. See http://nasdaqtrader.com/content/technicalsupport/specifications/TradingProducts/rash_sb.pdf.

⁷ The OUCH Order entry protocol is an Exchange proprietary protocol that allows subscribers to quickly enter orders into the System and receive executions. OUCH accepts limit Orders from members, and if there are matching Orders, they will execute. Non-matching Orders are added to the Limit Order Book, a database of available limit Orders, where they are matched in price-time priority. OUCH only provides a method for members to send Orders and receive status updates on those Orders. See <https://www.nasdaqtrader.com/Trader.aspx?id=OUCH>.

⁸ The Exchange designed the OUCH protocol to enable members to enter Orders quickly into the System. As such, the Exchange developed OUCH with simplicity in mind, and it therefore lacks more complex order handling capabilities. By contrast, the Exchange specifically designed RASH to support advanced functionality, including discretion, random reserve, pegging and routing. Once the System upgrades occur, then the Exchange intends to propose further changes to its Rules to permit participants to utilize OUCH, in addition to RASH, to enter order types that require advanced functionality.

⁹ The Exchange notes that its sister exchange, the Nasdaq Stock Market, LLC, has filed an identical

To support and prepare for these upgrades and enhancements, the Exchange recently submitted three rule filings to the Commission that amended its rules pertaining to, among other things, Market Maker Peg Orders, Orders with Reserve Size, and Orders with Pegging and Trade Now Attributes.¹⁰ The Exchange now proposes to further amend its Rules governing the Discretion Order Attribute, at Rule 4703(g), so that it aligns with how the System, once upgraded, will handle these Orders with Discretion going forward.

As set forth in Rule 4703(g), Discretion is an Order Attribute under which an Order has a non-displayed discretionary price range within which the entering Participant is willing to trade. Presently, the Rule provides that the System will process Discretionary Orders, upon entry, by generating a Non-Displayed Order with a Time-in-Force of Immediate-or-Cancel (a "Discretionary IOC") that will attempt to access liquidity available within the discretionary price range. The System will not permit the Discretionary IOC to execute, however, if the price of the execution would trade through a Protected Quotation. If more than one Order with Discretion satisfies conditions that would cause the generation of a Discretionary IOC simultaneously, the order in which such Discretionary IOCs will be presented for execution is random, based on the respective processing time for each such Order. Whenever a Discretionary IOC is generated, the underlying Order with Discretion will be withheld or removed from the Exchange's Book and will then be routed and/or placed on the Exchange's Book if the Discretionary IOC does not exhaust the full size of the underlying Order with Discretion, with its price determined by the underlying Order Type and Order Attributes selected by the Participant. In addition to prescribing a procedure for handling Discretionary Orders generally, the existing Rule also describes special procedures for handling Discretionary Orders with various types of Routing Attributes and with pegged discretionary price ranges.

proposal, Securities Exchange Act Release No. 34-93245 (October 4, 2021), 86 FR 56302 (October 8, 2021) (SR-NASDAQ-2021-075); and Nasdaq PHLX, LLC plans to do the same concurrent with this filing.

¹⁰ See Securities Exchange Act Release No. 34-92409 (July 14, 2021), 86 FR 38366 (July 20, 2021) (SR-BX-2021-030); Securities Exchange Act Release No. 34-91334 (March 16, 2021), 86 FR 15277 (March 22, 2021) (SR-BX-2021-005); Securities Exchange Act Release No. 34-90607 (December 8, 2020), 85 FR 80842 (December 14, 2020) (SR-BX-2020-034).

The Exchange proposes to amend the process by which it processes Discretionary Orders in several respects. First, the Exchange proposes to clarify existing text which states that "[a] Participant may also specify a limit price beyond which the discretionary price range does not extend." The Exchange intended for this clause to address the specific scenario where a Participant enters a Discretionary Order with a Discretionary Pegging Attribute, but the existing text is not explicit in this regard and thus is amenable to confusion. The Exchange proposes to restate this provision as follows to make its intention explicit: "[a] Participant may also specify a limit on the discretionary price range of an Order that is entered with a Discretionary Pegging Attribute," and then further clarify the outcome of setting such a limit by stating "beyond which the discretionary pegged price may not extend."¹¹ The Exchange notes that it uses the word "may" in this provision rather than "shall" because for Discretionary Orders with Pegging Attributes, the Rules specify the discretionary range applicable to those Orders; setting a limit on how far that range is allowed to extend is optional.

As a further organizational matter, the Exchange proposes to consolidate the portion of the Rule that describes the general procedure for handling Discretionary Orders with the portion that described the process for handling Discretionary Orders without a Routing Attribute assigned to them. Because non-routed orders conform to the general procedure, it is redundant to restate the process.

Second, as to the substance of the general Discretionary Order handling procedures, the Exchange proposes the following changes. Rather than generate a Discretionary IOC immediately upon Order entry (regardless of available liquidity within the discretionary price range) and then post the unexecuted portion of the Discretionary Order on the Exchange's Book, the Exchange proposes instead to first, upon entry, execute the Discretionary Order against any previously posted Orders on the Exchange Book that are priced equal to or better than the limit price of the Discretionary Order. If no such Order exists with which the Discretionary

¹¹ For example, a displayed Order to buy might have a limit price of \$11.00 and a discretionary price range pegged to the Best Bid with a discretionary limit of \$11.05. If the NBB is \$11.02 at the time of entry, the order will be displayed at \$11.00 with a discretionary price range up to \$11.02. If the NBB later become \$11.06, the Order will still be displayed at \$11.00 and its discretionary price range will be capped at \$11.05.

Order may fully execute upon entry, then the Exchange will post the Discretionary Order to the Exchange's Book in accordance with the parameters that apply to the underlying Order Type. In such case, the Exchange will generate a Discretionary IOC, with a price equal to the highest price for an Order to buy (lowest price for an Order to sell) within the discretionary price range and a size equal to the order available for execution, if and when the System determines that liquidity within the discretionary price range is available for execution. The Exchange will then execute the Discretionary IOC (provided that doing so would not trade-through a Protected Quotation). The Exchange proposes this change to increase the efficiency with which the Exchange processes Discretionary Orders. The Exchange intended for the existing process to enable Discretionary Orders to execute immediately within the discretionary price range upon entry, but in practice, the Exchange observes that they rarely do so. Attempts to locate available liquidity within the discretionary range immediately upon entry delay Discretionary Orders from entering the priority queue on the Exchange Book, resulting in an opportunity cost when no such liquidity is located. The proposed rule change will reorient the order handling process for Discretionary Orders so that it no longer sacrifices potential queue priority for attempts at possible immediate executions within the discretionary price range. Given that immediate executions of Discretionary Orders within the discretionary price range rarely occur, the Exchange does not believe that this change will have any material adverse impact on the performance of such Orders. Moreover, the Exchange will still allow for Discretionary Orders to attempt to execute against available liquidity immediately upon entry if contra-side liquidity, priced equal to or better than the limit price of the Discretionary Order, is resting on the Book at that time. And, if participants select a Time-in-Force of Immediate-or-Cancel for such Orders, then the orders will attempt to execute against available liquidity within the discretionary price range, which is unchanged from current functionality.

As noted above, whereas now, the Exchange generates a Discretionary IOC that is equal to the size of the Discretionary Order, and then posts shares to the Book that remain unexecuted after the Exchange executes the Discretionary IOC against available liquidity in the discretionary price

range, the Exchange instead proposes to generate a Discretionary IOC that will be equal to the size of the available liquidity within the discretionary range, with any residual shares of the Discretionary Order remaining on the Book and retaining their existing priority. If the Discretionary IOC is not fully executed,¹² the posted portion of the Discretionary Order will be reentered on the Exchange Book as a new Discretionary Order with a new timestamp and with an increased size to include the unexecuted portions of the Discretionary IOC. The Exchange believes that the proposed rule change will benefit participants by enabling their Discretionary Orders to remain executable against new incoming liquidity when available liquidity within the discretionary price range is smaller than the full size of the Discretionary Order (provided that Participants have not specified a minimum quantity for execution).

The Exchange proposes to move existing rule text that governs the situations where more than one Order with Discretion satisfies conditions that would cause the generation of a Discretionary IOC simultaneously. Whereas now, in all such situations, the order in which such Discretionary IOCs are presented for execution is random, based on the respective processing time for each such Order; going forward, the system will present Discretionary IOCs associated with Discretionary Orders without Routing differently as it gains responsibility for handling such Orders from RASH. That is, the system will present multiple Discretionary IOCs associated with such Orders for execution in price-time priority, as is specified in Rule 4757(a). The price by which the Orders will be prioritized for execution refers to the price of the Discretionary IOCs that are generated, meaning the highest price for the Order with Discretion to buy (lowest price for the Order with Discretion to sell) within the discretionary price range. This change will not affect Discretionary Orders with Routing, when Discretionary IOCs are generated for routing, which will continue to be handled by RASH under the existing random presentment procedures.

The Exchange proposes to add to the Rule the following example to illustrate the new procedures. If a Participant enters a Price to Display Order to buy 500 shares at \$11 with a discretionary price range of up to \$11.03, then upon

entry, the System will first execute the Order against any orders resting on the Exchange Book that are priced equal to or better than the limit price of the Discretionary Order. Assuming that no such resting order exists, the System will post the full size of the Price to Display Order to the Exchange Book in accordance with its parameters. If there is an Order on the Exchange Book to sell 200 shares priced at \$11.03, the System will generate a Discretionary IOC to buy priced at \$11.03 to execute against the Order on the Exchange Book, if an execution at \$11.03 would not trade through a Protected Quotation; the remaining 300 shares of the original Order with Discretion will remain posted on the Exchange Book.¹³

With respect to procedures for processing Discretionary Orders with Routing Attributes assigned to them, the Exchange proposes to reorganize and consolidate the procedures, as well as to eliminate obsolete and duplicative text, and to improve readability.

Specifically, the Exchange proposes to largely delete bulleted text that presently describes distinct procedures for handling Discretionary Orders with passive and reactive routing strategies, as well as for handling Discretionary Orders with Routing Attributes depending upon whether the discretionary price range of the Order is pegged. The Exchange proposes to eliminate certain existing text that describes order handling procedures for Discretionary Orders with passive and reactive routing strategies after being posted because such procedures do not differ from the general procedures for handling Discretionary Orders with respect to available liquidity on the Exchange Book within the discretionary price range.¹⁴ As to Discretionary Orders with reactive routing strategies, the Exchange believes that it is sufficient to state, going forward, that if a Discretionary IOC associated with such an Order does not exhaust the full size of the Discretionary Order, then the

¹³ The Exchange also proposes to move and reorganize, but not substantively modify, certain text within Rule 4703(g) to eliminate duplication and improve its readability.

¹⁴ The Exchange proposes to retain the concept in the existing rule that whenever it generates a Discretionary IOC, the underlying Order with Discretion will be withheld or removed from the Exchange's Book and will then be routed and/or placed on the Exchange's Book if the Discretionary IOC does not exhaust the full size of the underlying Order with Discretion, with its price determined by the underlying Order Type and Order Attributes selected by the Participant. However, rather than applying this concept to all Discretionary Orders going forward, the proposal will apply it only to Discretionary Orders with Routing Attributes, as this is the context in which the concept applies, in practice.

¹² A Discretionary IOC may not execute fully in a race condition where an incoming order executes against all or a portion of the available liquidity within the discretionary price range before the Discretionary IOC is able to do so.

Exchange will generate and route additional Discretionary IOC orders in response to new quotations within the discretionary price range according to the routing strategy assigned to the Order. Moreover, the Exchange proposes to retain language in the existing rule which states that, if a Discretionary Order uses a passive routing strategy, the System will not generate additional Discretionary IOC orders in response to new away market quotations within the discretionary price range unless the Order is updated in a manner that causes it to receive a new timestamp, in which case the Order will behave in the same manner as a newly entered Discretionary Order.

Moreover, the Exchange proposes to delete existing Rule text that describes how the Exchange handles Discretionary Orders with Routing Attributes in scenarios where such Orders do and do not have pegged discretionary price ranges associated with them. The text presently states that where a Discretionary IOC associated with such an Order does not exhaust the full size of the Order, the Exchange will post the remaining size of the Order to the Exchange Book in accordance with the parameters that apply to the underlying Order Type. With respect to Discretionary Orders with reactive routing strategies, the Exchange will examine whether there is an order on the Exchange Book or an accessible quotation at another trading venue that is within the discretionary price range and against which the Discretionary Order could execute. When the Exchange currently examines the Exchange Book in the scenario where the Discretionary Order with reactive routing has a pegged discretionary price range, it examines only displayed orders on the Exchange Book for this purpose, whereas if the Discretionary Order with Routing has no pegged discretionary price range, the Exchange examines all orders on its Book, including non-displayed orders. This distinction in order handling procedures is a legacy of the existing limitations of the RASH protocol that will no longer be applicable after the Exchange migrates responsibility from RASH to the System for handling Discretionary Orders. That is, going forward, the System will be capable of and will examine the Exchange Book for both displayed and non-displayed orders in the discretionary price range against which to execute Discretionary Orders with Routing, regardless of whether the discretionary price range of such Orders is pegged.

In the new proposed paragraph that governs Discretionary Orders with

Routing, the Exchange also proposes to amend existing text concerning the price and size at which the Exchange will generate a Discretionary IOC when, before routing, it determines that there is liquidity available on the Exchange Book within the discretionary price range with which the Discretionary Orders may interact.¹⁵ Whereas existing rule text states that the Exchange will generate a Discretionary IOC in this instance that matches the price and size of the Order on the Exchange Book, the proposed rule text states that the Exchange will generate a Discretionary IOC equal to the highest price for the Order with Discretion to buy (lowest price for the Order with Discretion to sell) within the discretionary price range and a size equal to the applicable size of the available liquidity on the Exchange Book.

Additionally in that same paragraph, the Exchange proposes to change existing language that governs the generation of a Discretionary IOC in response to accessible quotations within the discretionary price range at away market centers. The existing rule text states that the Exchange will generate a Discretionary IOC in this instance that matches the price and size of the away market quotation within the discretionary price range. The proposed rule, by contrast, states that the Exchange will generate one or more Discretionary IOCs that will match the price of the away market quotation. The size of the Discretionary IOC(s) generated in this instance will be determined by the router to maximize execution opportunities, consistent with existing routing strategies.

Last, as explained above, the Exchange proposes to move the following existing text to the new consolidated paragraph governing procedures for handling Discretionary Orders with Routing. The text clarifies that for these Orders (as opposed to Discretionary Orders without Routing), the existing practice of randomly presenting for execution simultaneously generated Discretionary IOCs for routing is still applicable; because responsibility for this functionality is still being managed by RASH, it will not be affected by the present system changes:

Furthermore, if a new quotation satisfies conditions that would cause the simultaneous generation of a Discretionary IOC for more than one Order with Discretion that have been assigned a Routing Order Attribute, the order in which such Discretionary IOCs are presented for

execution is random, based on the respective processing time for each such Order.

The Exchange intends to implement the foregoing changes during the Fourth Quarter of 2021. The Exchange will issue an Equity Trader Alert at least 7 days in advance of implementing the changes.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,¹⁶ in general, and furthers the objectives of Section 6(b)(5) of the Act,¹⁷ in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest.

The Exchange believes that its proposed amendments to the Discretionary Order Attribute, at Rule 4703(g), are consistent with the Act. The Exchange believes that its proposal to revise its process for handling Discretionary Orders so that they post to the Exchange Book, upon entry after checking for available interest at or better than their limit price, rather than attempt to execute against available liquidity within the discretionary price range immediately upon entry, will benefit Participants and investors because such immediate attempts at execution within the discretionary price range rarely succeed and typically result only in Discretionary Orders posting to the Book later than they would otherwise, and thus resulting in potentially lower queue priority. The proposed amendments will provide Participants with an opportunity to first secure queue priority by posting to the Book upon entry (after checking for available interest at or better than their limit price), and only generate a Discretionary IOC if and when the System later determines that liquidity within the discretionary price range is available for execution. The Exchange notes that it will still allow for Discretionary Orders to attempt to execute against available liquidity within the discretionary price range immediately upon entry if Participants select a Time-in-Force of Immediate-or-Cancel for such Orders.

Additionally, the proposal to generate Discretionary IOCs that equal the size of available liquidity within the discretionary range, rather than the full size of Discretionary Orders, will benefit participants by enabling their Discretionary Orders to maintain their

¹⁵ The Exchange notes that certain routing strategies, such as Directed Orders, do not check the Exchange system first before routing to other market centers.

¹⁶ 15 U.S.C. 78f(b).

¹⁷ 15 U.S.C. 78f(b)(5).

queue priority on the Exchange Book when available liquidity within the discretionary price range is smaller than the full size of the Discretionary Order.

The Exchange believes that it is consistent with the Act to amend the Rule to state that if the Discretionary IOC is not fully executed, the posted portion of the Discretionary Order will be reentered on the Exchange Book as a new Discretionary Order with a new timestamp and with an increased size to include the unexecuted portions of the Discretionary IOC. The Exchange believes that the proposed rule change will benefit participants by enabling their Discretionary Orders to remain executable against new incoming liquidity when available liquidity within the discretionary price range is smaller than the full size of the Discretionary Order (provided that Participants have not specified a minimum quantity for execution).

Furthermore, it is consistent with the Act to reorganize, consolidate, and otherwise amend the provisions of the existing Rule that describe procedures for handling Discretionary Orders with Routing Attributes, passive and reactive routing strategies, and pegged and non-pegged discretionary price ranges. The proposed changes will improve the clarity and readability of the Rule by eliminating unnecessary and duplicative text. It will also reflect an upgrade in the ability of the Exchange to examine its Book for both displayed and non-displayed orders against which a Discretionary Order with Routing and a pegged discretionary price range may execute (with such upgrade occurring as a product of responsibility for Discretionary Order handling migration from RASH to the Exchange's matching System). It also is consistent with the Act to clarify that for Discretionary Orders with Routing Attributes, the existing practice of randomly presenting for execution simultaneously generated Discretionary IOCs for routing still applies.

Likewise, it is consistent with the Act to modify the price at which the Exchange will generate Discretionary IOCs when, before routing a Discretionary Order with Routing, the Exchange determines that there is liquidity available on the Exchange Book within the discretionary price range with which the Discretionary Orders may interact. The current practice of generating a Discretionary IOC with a price equal to the price of the Order on the Exchange Book does not maximize the potential for executions, whereas, generating a Discretionary IOC with a price equal to the highest price for an Order to buy

(lowest price for an Order to sell) within the discretionary price range allows the Discretionary IOC to access additional liquidity at a more aggressive price in the event of a race condition where the liquidity with which the Order with Discretion is reacting is removed before the Discretionary IOC is able to execute against it.

Finally, it is consistent with the Act to amend existing rule text to state that when the Exchange generates a Discretionary IOC to attempt to execute accessible liquidity within the discretionary price range at another market center, the Exchange will generate a Discretionary IOC that will match the price of the away market quotation, but the size will be determined by the router to maximize execution opportunities, consistent with existing routing strategies. The current rule, as written, does not contemplate the scenario where the remaining size of the Order with Routing is less than the size of the away market quotation; in which case a smaller order must be routed to the quoting market, comprising the full size of the Order with Routing. The new rule text allows for this behavior, and so more clearly communicates the operation of the System to Participants. Furthermore, additional non-displayed liquidity may exist on the quoting market in excess of the displayed size of the quote. It benefits the Participant to maximize execution opportunities for their orders, so the new rule text allows the router to send orders that are larger than the size of the away market quotation. Because an Order assigned both Discretion and Routing Order Attributes is withheld or removed from the Exchange Book whenever a Discretionary IOC is generated for routing, thereby yielding priority on the Exchange Book, there are no opportunity costs to routing additional shares in excess of the displayed quote.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that its proposed rule changes will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. As a general principle, the proposed changes are reflective of the significant competition among Exchanges and non-exchange venues for order flow. In this regard, proposed changes that facilitate enhancements to the Exchange's System and order entry protocols as well as those that amend and clarify the Exchange's Rules regarding its Order Attributes, are pro-competitive because they bolster the efficiency, integrity, and

overall attractiveness of the Exchange in an absolute sense and relative to its peers.

Moreover, none of the proposed changes will unduly burden intra-market competition among various Exchange participants. The Exchange's proposal to revise its processes for handling Discretionary Orders upon entry does have the potential to improve the relative queue positions of Discretionary Orders on the Exchange's Book, but these changes are warranted because existing processes are inefficient and result in opportunity costs to users of Discretionary Orders. Indeed, participants potentially lose queue priority when the System delays posting their Discretionary Orders to the Book only after making attempts to execute those Orders against liquidity within its discretionary price range immediately upon entry. Similarly, participants potentially lose queue priority whenever available liquidity within the discretionary price range is less than the size of a Discretionary Order, and the System processes residual shares by posting them to the Book with new timestamps.

Furthermore, routing orders to away markets for only the displayed size of their quotes unnecessarily limits the opportunity for execution against non-displayed liquidity, while restricting the price of a Discretionary IOC to the price of an available order on the Exchange Book (as opposed to assigning the most aggressive price allowed within the discretionary range) limits opportunities for execution when race conditions cause the original order that the Discretionary IOC was created to execute against to no longer be available by the time the Discretionary IOC is received by the System. The proposed changes have the potential to increase execution opportunities, but these changes are warranted because they will equally benefit all Exchange participants utilizing the Discretion Attribute by making the processes more efficient.

Likewise, there will be no adverse competitive impact from the Exchange's proposal to examine both displayed and non-displayed orders in the Exchange Book (as opposed to only displayed orders, in current practice) in the scenario where the Discretionary Order with reactive routing has a pegged discretionary price range. As explained above, existing handling procedures in this scenario is a legacy of the limitations of the RASH protocol, which will no longer be applicable after the Exchange migrates responsibility from RASH to the System for handling Discretionary Orders.

For similar reasons, there will be no adverse competitive impact associated with the Exchange's proposal to present Discretionary IOCs associated with Discretionary Orders without Routing in price-time priority, rather than in random order, as is currently the case and as will remain the case for Discretionary IOCs associated with Discretionary Orders with Routing. Whereas RASH is unable to present Discretionary IOCs in time-price [sic] priority, the Exchange's system will be capable of doing so, and thus it will do so when it assumes responsibility for handling Discretionary Orders without routing. Insofar as RASH will continue to handle Discretionary Orders with Routing, existing randomized processes for presenting Discretionary IOCs associated with those Orders for routing will continue to apply.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act¹⁸ and Rule 19b-4(f)(6) thereunder.¹⁹

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

¹⁸ 15 U.S.C. 78s(b)(3)(A).

¹⁹ 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-BX-2021-049 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to File Number SR-BX-2021-049. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street, NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-BX-2021-049 and should be submitted on or before November 26, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁰

J. Matthew DeLesDernier,

Assistant Secretary.

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-93464; File No. SR-Phlx-2021-65]

Self-Regulatory Organizations; Nasdaq PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change to Extend the Exchange's Nonstandard Expirations Pilot Program

October 29, 2021.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on October 28, 2021, Nasdaq PHLX LLC ("Phlx" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to extend the pilot period for the Exchange's nonstandard expirations pilot program, currently set to expire on November 4, 2021.

The Exchange also proposes a technical amendment to Options 4, Section 5, Series of Options Contracts Open for Trading.

The text of the proposed rule change is available on the Exchange's website at <https://listingcenter.nasdaq.com/rulebook/phlx/rules>, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the

²⁰ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

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

On December 15, 2017, the Commission approved a rule change for the listing and trading on the Exchange, on a twelve month pilot basis, of p.m.-settled options on broad-based indexes with nonstandard expirations dates ("Program").³ The Program permits both Weekly Expirations and End of Month ("EOM") expirations similar to those of the a.m.-settled broad-based index options, except that the exercise settlement value of the options subject to the pilot are based on the index value derived from the closing prices of component stocks. This pilot was extended various times and is currently extended through November 4, 2021.⁴

Pursuant to Phlx Options 4A, Section 12(b)(5)(A) the Exchange may open for trading Weekly Expirations on any broad-based index eligible for standard options trading to expire on any Monday, Wednesday, or Friday (other than the third Friday-of-the-month or days that coincide with an EOM expiration). Weekly Expirations are subject to all provisions of Options 4A, Section 12 and are treated the same as options on the same underlying index that expire on the third Friday of the expiration month. Unlike the standard monthly options, however, Weekly Expirations are p.m.-settled.

Similarly, pursuant to Options 4A, Section 12(b)(5)(B) the Exchange may open for trading EOM expirations on any broad-based index eligible for standard options trading to expire on the last trading day of the month. EOM

expirations are subject to all provisions of Options 4A, Section 12 and treated the same as options on the same underlying index that expire on the third Friday of the expiration month. However, the EOM expirations are p.m.-settled.

The Exchange now proposes to amend Options 4A, Section 12(b)(5)(C) so that the duration of the Program for these nonstandard expirations will be through May 4, 2022. The Exchange continues to have sufficient systems capacity to handle p.m.-settled options on broad-based indexes with nonstandard expirations dates and has not encountered any issues or adverse market effects as a result of listing them. Additionally, there is continued investor interest in these products. The Exchange will continue to make public on its website any data and analysis it submits to the Commission under the Program.

The Exchange will be submitting a rule change to request that the pilot program become permanent. In lieu of submitting any additional annual reports, the Exchange would provide additional information requested by the Commission in connection with the permanency rule change for this Program. The Exchange would continue to provide the Commission with ongoing data unless and until the Program is made permanent or discontinued.

The Exchange believes that the proposed extension of the Program will not have an adverse impact on capacity.

Technical Amendment

The Exchange proposes a technical amendment to Options 4, Section 5, Series of Options Contracts Open for Trading. Specifically, the Exchange proposes to amend the second sentence of Supplementary Material .03 to Options 4, Section 5, related to the Short Term Options Series Program, which states, "The Exchange may have no more than a total of five Short Term Option Expiration Dates, not including any Monday or Wednesday SPY Expirations as provided below." The Exchange proposes to amend the sentence to instead provide, "The Exchange may have no more than a total of five Short Term Option Expiration Dates, not including any Monday or Wednesday SPY, QQQ and IWM Expirations as provided below." The Exchange previously filed to permit Monday and Wednesday expirations for options listed pursuant to the Short Term Options Program on the Invesco QQQ TrustSM Series ETF Trust

("QQQ"),⁵ and recently filed and was approved to permit Monday and Wednesday expirations for options listed pursuant to the Short Term Options Program on the iShares Russell 2000 ETF ("IWM").⁶ The Exchange inadvertently omitted the references to "QQQ" and "IWM" in the rule text for those filings. At this time, the Exchange proposes to add "QQQ and IWM" to the rule text within Supplementary Material .03 to Options 4, Section 5 for clarity. This amendment is non-substantive as it proposes to make clear that Monday and Wednesday expirations are not included in determining the maximum number of Short Term Option Expiration Dates that may be listed on the Exchange. Short Term Options Series expire, by definition, on Friday. To avoid any confusion, the proposed amendment makes clear which Monday and Wednesday expirations are specifically being excluded by the Exchange.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,⁷ in general, and furthers the objectives of Section 6(b)(5) of the Act,⁸ in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest. The Exchange believes the proposed rule change will protect investors and the public interest by providing the Exchange, the Commission and investors the benefit of additional time to analyze nonstandard expiration options. In particular, the Exchange believes that the Program has been successful to date. The Exchange has not encountered any problems with the Program. By extending the Program, investors may continue to benefit from a wider array of investment opportunities. Additionally, both the Exchange and the Commission may continue to monitor the potential for adverse market effects of p.m.-settlement on the market, including the

³ See Securities Exchange Act Release No. 82341 (December 15, 2017), 82 FR 60651 (December 21, 2017) (approving SR-Phlx-2017-79) (Order Approving a Proposed Rule Change, as Modified by Amendment No. 1 and Granting Accelerated Approval of Amendment No. 2, of a Proposed Rule Change To Establish a Nonstandard Expirations Pilot Program).

⁴ See Securities Exchange Act Release Nos. 84835 (December 17, 2018), 83 FR 65773 (December 21, 2018) (SR-Phlx-2018-80); 85669 (April 17, 2019), 84 FR 16913 (April 23, 2019) (SR-Phlx-2019-13); 87381 (October 22, 2019), 84 FR 57788 (October 28, 2019) (SR-Phlx-2019-43); 88684 (April 17, 2020), 85 FR 22781 (April 23, 2020) (SR-Phlx-2020-24); 90256 (October 22, 2020), 85 FR 68393 (October 28, 2020) (SR-Phlx-2020-48); and 91484 (April 6, 2021), 86 FR 19050 (April 12, 2021) (SR-Phlx-2021-21).

⁵ See Securities Exchange Act Release No. 91614 (April 20, 2021), 86 FR 22082 (April 26, 2021) (SR-Phlx-2021-10) (Order Approving a Proposed Rule Change To Permit Monday and Wednesday Expirations for Options Listed Pursuant to the Short Term Options Program on the Invesco QQQ TrustSM Series ETF Trust).

⁶ See Securities Exchange Act Release No. 93157 (September 28, 2021), 86 FR 54749 (October 4, 2021) (SR-PHLX-2021-43) (Order Approving a Proposed Rule Change To Permit Monday and Wednesday Expirations for Options Listed Pursuant to the Short Term Options Program on the iShares Russell 2000 ETF (IWM)).

⁷ 15 U.S.C. 78f(b).

⁸ 15 U.S.C. 78f(b)(5).

underlying cash equities market, at the expiration of these options.

Technical Amendment

The Exchange's proposal to amend Supplementary Material .03 to Options 4, Section 5, related to the Short Term Options Series Program, to add rule text related to Monday and Wednesday expirations for options listed pursuant to the Short Term Options Program on QQQ and IWM, which was inadvertently omitted, is consistent with the Act. Adding references to "QQQ" and "IWM" within the second sentence of Supplementary Material .03 to Options 4, Section 5 will bring greater clarity to the Exchange's rules by explicitly stating which Monday and Wednesday expirations are specifically being excluded by the Exchange. This amendment is non-substantive and is intended to promote clarity and avoid investor confusion.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. Options with nonstandard expirations would be available for trading to all market participants.

Technical Amendment

The Exchange's proposal to amend Supplementary Material .03 to Options 4, Section 5, related to the Short Term Options Series Program, to add rule text related to Monday and Wednesday expirations for options listed pursuant to the Short Term Options Program on QQQ and IWM, which was inadvertently omitted, does not impose an undue burden on competition as adding references to "QQQ" and "IWM" within the second sentence of Supplementary Material .03 to Options 4, Section 5 will bring greater clarity to the Exchange's rules by explicitly stating which Monday and Wednesday expirations are specifically being excluded by the Exchange. This amendment is non-substantive and is intended to promote clarity and avoid investor confusion.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act⁹ and subparagraph (f)(6) of Rule 19b-4 thereunder.¹⁰

A proposed rule change filed pursuant to Rule 19b-4(f)(6) under the Act¹¹ normally does not become operative for 30 days after the date of its filing. However, Rule 19b-4(f)(6)(iii)¹² permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that it may immediately extend the Program prior to the current expiration date so that the pilot may continue uninterrupted. In addition, the Exchange states the non-substantive technical amendment to Supplementary Material .03 to Options 4, Section 5, will promote clarity and avoid investor confusion. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest as it will allow the Program to continue uninterrupted, thereby avoiding investor confusion that could result from a temporary interruption in the Program, and will allow the Exchange to immediately update its rules to reflect the technical amendment. Accordingly, the Commission hereby waives the operative delay and designates the proposed rule change operative upon filing.¹³

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if

⁹ 15 U.S.C. 78s(b)(3)(A).

¹⁰ 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

¹¹ 17 CFR 240.19b-4(f)(6).

¹² 17 CFR 240.19b-4(f)(6)(iii).

¹³ For purposes only of waiving the 30-day operative delay, the Commission also has considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-Phlx-2021-65 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.
- All submissions should refer to File Number SR-Phlx-2021-65. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish

to make available publicly. All submissions should refer to File Number SR–Phlx–2021–65, and should be submitted on or before November 26, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁴

J. Matthew DeLesDernier,
Assistant Secretary.

[FR Doc. 2021–24013 Filed 11–3–21; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93466; File No. SR–NYSEArca–2021–68]

Self-Regulatory Organizations; NYSE Arca, Inc.; Order Instituting Proceedings to Determine Whether to Approve or Disapprove a Proposed Rule Change to Adopt New Exchange Rule 6.91P–O

October 29, 2021.

I. Introduction

On July 23, 2021, NYSE Arca, Inc. (“NYSE Arca” or the “Exchange”) filed with the Securities and Exchange Commission (the “Commission”), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”) ¹ and Rule 19b–4 thereunder, ² a proposed rule change to adopt new Exchange Rule 6.91P–O to govern the trading of Electronic Complex Orders (“Electronic Complex Orders” or “ECOs”) on the Exchange’s Pillar trading platform and to make conforming amendments to Exchange Rule 6.47A–O. ³ The proposed rule change was published for comment in the **Federal Register** on August 4, 2021. ⁴ On September 20, 2021, pursuant to Section 19(b)(2) of the Act, ⁵ the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to approve or disapprove the proposed rule change. ⁶

The Commission has received no comments regarding the proposed rule change. This order institutes proceedings pursuant to Section 19(b)(2)(B) of the Act ⁷ to determine whether to approve or disapprove the proposed rule change.

II. Description of the Proposal

Background

As described more fully in the Notice, the Exchange plans to transition its options trading platform to its Pillar technology platform. The cash equity markets of the Exchange and its national securities exchange affiliates are currently operating on Pillar. ⁸ For the transition, the Exchange proposes to use the same Pillar technology already in operation for its cash equity market, thereby allowing the Exchange to offer common trading functions and common specifications for connecting to its cash equity and equity options markets. The Exchange plans to roll out the new technology platform over a period of time based on a range of symbols.

The Exchange has filed a proposal (the “Single-Leg Pillar Filing”) to add new rules describing how single-leg options will trade on the Exchange once Pillar is implemented. ⁹ The current proposal describes how ECOs will trade on the Exchange once Pillar is implemented. As the Exchange transitions to Pillar, certain rules will continue to be applicable to symbols trading on the current trading platform, but will not be applicable to symbols that have transitioned to trading on Pillar. ¹⁰ Proposed Exchange Rule 6.91P–O, which will govern the trading of Electronic Complex Orders in options symbols that have migrated to the Pillar

2021). The Commission designated November 8, 2021, as the date by which the Commission shall approve or disapprove, or institute proceedings to determine whether to approve or disapprove, the proposed rule change.

⁷ 15 U.S.C. 78s(b)(2)(B).

⁸ The Exchange’s national securities exchange affiliates are the New York Stock Exchange LLC (“NYSE”), NYSE American LLC (“NYSE American”), NYSE National, Inc. (“NYSE National”), and NYSE Chicago, Inc. (“NYSE Chicago”).

⁹ See Securities Exchange Act Release Nos. 92304 (June 30, 2021), 86 FR 36440 (July 9, 2021) (notice of filing of File No. SR–NYSEArca–2021–47). The Commission extended the time for Commission action on the Single-Leg Pillar Filing and instituted proceedings to determine whether to approve or disapprove that proposal. See Securities Exchange Act Release Nos. 92696 (August 18, 2021), 86 FR 47350 (August 24, 2021) (extending the time for Commission action on the Single-Leg Pillar Filing); and 93193 (September 29, 2021), 86 FR 55926 (October 7, 2021) (order instituting proceedings to determine whether to approve or disapprove the Single-Leg Pillar Filing).

¹⁰ The Exchange will announce by Trader Update when symbols are trading on the Pillar trading platform.

platform, will have the same number as the current Electronic Complex Order Trading rule, but with the modifier “P” appended to the rule number. Current Exchange Rule 6.91–O will remain unchanged and continue to apply to any trading in symbols on the current system. The proposed rule will use terminology that is based on Exchange Rule 7–E and will introduce new functionality for Electronic Complex Order trading. The Exchange intends to transition ECO trading on Pillar at the same time it transitions single-leg trading to Pillar.

Proposed Exchange Rule 6.91P–O: Electronic Complex Order Trading

Exchange Rule 6.91–O describes how the Exchange currently processes ECOs submitted to the Exchange. The Exchange proposes new Exchange Rule 6.91P–O to describe the processing of ECOs after the transition to Pillar.

Definitions. Proposed Exchange Rule 6.91P–O(a) defines terms that will apply to the trading of ECOs on Pillar, including the following:

- “ECO Order Instruction” will mean a request to cancel, cancel and replace, or modify an ECO; ¹¹
- “leg” or “leg market” will mean each of the component option series that comprise an ECO; ¹²
- “Complex NBBO” will mean the derived national best bid and derived national best offer for a complex strategy calculated using the NBB and NBO for each component leg of a complex strategy; ¹³
- “Complex strategy” will mean a particular combination of leg components and their ratios to one another. New complex strategies can be created when the Exchange receives a request to create a new complex strategy or an ECO with a new complex strategy; ¹⁴
- “DBBO” will mean the derived best bid (“DBB”) and derived best offer (“DBO”) for a complex strategy calculated using the Exchange BBO ¹⁵ for each leg (or the Away Market NBBO ¹⁶ for a leg if there is no Exchange

¹¹ See proposed Exchange Rule 6.91P–O(a)(2).

¹² See proposed Exchange Rule 6.91P–O(a)(3).

¹³ See proposed Exchange Rule 6.91P–O(a)(4).

¹⁴ See proposed Exchange Rule 6.91P–O(a)(5).

¹⁵ The term BBO when used with respect to options traded on the Exchange will mean “the best displayed bid or best displayed offer on the Exchange.” See Single-Leg Pillar Filing, proposed Exchange Rule 1.1.

¹⁶ In the Single-Leg Pillar Filing, the Exchange proposes that the term “Away Market NBBO” will refer to a calculation of the NBBO that excludes the Exchange’s BBO. See Single-Leg Pillar Filing (defining Away Market NBBO in proposed Exchange Rule 1.1).

¹⁴ 17 CFR 200.30–3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

³ The proposal defines an Electronic Complex Order or ECO as “a Complex Order as defined in Rule 6.62P–O(f) or a Stock/Option Order or Stock/Complex Order as defined in Rule 6.62P–O(h)(6)(A), (B), respectively, that is submitted electronically to the Exchange.” See proposed Exchange Rule 6.91P–O(a)(1).

⁴ Securities Exchange Act Release No. 92563 (August 4, 2021), 86 FR 43704 (August 10, 2021) (File No. SR–NYSEArca–2021–68) (“Notice”).

⁵ 15 U.S.C. 78s(b)(2).

⁶ See Securities Exchange Act Release No. 93057 (September 20, 2021), 86 FR 53128 (September 24,

BBO), provided that the bid (offer) price used to calculate the DBBO will never be lower (higher) than the greater of \$0.05 or 5% below (above) the Away Market NBB (NBO).¹⁷ The DBBO will be updated as the Exchange's calculation of the Exchange BBO or Away Market NBBO, as applicable, is updated.¹⁸ If there is no Exchange BB (BO) or Away Market NBB (NBO) for a leg, the bid (offer) price used to calculate the DBBO will be the offer (bid) price for that leg minus (plus) "one collar value," which is (i) \$0.25 where the best offer (bid) is priced \$1.00 or lower; or (ii) the lower of \$2.50 or 25% where the best offer (bid) is priced above \$1.00, provided that if the best offer is equal to or less than one collar value, the best bid price used to calculate the DBBO for that leg will be \$0.01;¹⁹

- "Complex Order Auction" or "COA" will mean an auction of an ECO as set forth in proposed Exchange Rule 6.91P-O(f);²⁰

- "COA Order" will mean an ECO that is designated by the OTP Holder as eligible to initiate a COA;²¹

- "Request for Response" or "RFR" will mean a message disseminated to the Exchange's proprietary complex data feed announcing that the Exchange has received a COA Order and that a COA has begun. Each RFR message will identify the component series, the price, and the size and side of the market of the COA Order;²²

- "RFR Response" will mean any ECO received during the Response Time Interval that is in the same complex strategy, on the opposite side of the market of the COA Order that initiated the COA and marketable against the COA Order.²³ The Exchange will consider any ECOs received during the Response Time Interval (defined below) that are marketable against the COA Order as an RFR Response; and

- "Response Time Interval" will mean the period of time during which RFR Responses for a COA may be entered. The Exchange will determine and announce by Trader Update the length of the Response Time Interval. The duration of the Response Time Interval will not be less than 100 milliseconds and will not exceed one second.²⁴

Types of ECOs. Under the proposal, ECOs may be entered as Limit Orders or Limit Orders designated as Complex Only Orders.²⁵ An ECO designated as a Complex Only Order will trade only with ECOs and will not trade with the leg markets.²⁶ If there is displayed Customer interest on all legs of the Complex Only Order, it will not trade below (above) one penny (\$0.01) times the smallest leg ratio inside the DBB (DBO) containing Customer interest.²⁷ Complex Only Orders are based in part on existing functionality for PNP Plus orders, which may trade only with other Electronic Complex Orders.²⁸ ECOs may be designated with a time-in-force of Day, IOC, FOK, or GTC, as those terms are defined in proposed Exchange Rule 6.62P-O(b), or GTX.²⁹

Priority and Pricing of ECOs. Proposed Exchange Rule 6.91P-O(c) describes how ECOs will be prioritized and priced on Pillar. Under the proposal, an ECO received by the Exchange that is not executed immediately (or cancelled) will be ranked in the Consolidated Book according to price-time priority based on the total net price and the time of entry of the order.³⁰ When trading with the leg markets, an ECO must trade at or within the greater of \$0.05 or 5% higher (lower) than the Away Market NBO (NBB).³¹ An ECO will trade at the prices of the leg markets.³² For example, if there is sell interest in a leg market at \$1.00, and a leg of an ECO to buy could trade up to \$1.05, the ECO would trade with the leg market at \$1.00. When trading with another ECO, an ECO must trade at a price at or within the DBBO and no leg of an ECO may trade at a price of zero.³³ An ECO may trade without consideration of prices of the same complex strategy available on other exchanges.³⁴ In addition, an ECO

may trade in \$0.01 increments regardless of the MPV otherwise applicable to any leg of the complex strategy.³⁵

Execution of ECOs at the Open (or Reopening after a Trading Halt). With the transition to Pillar, the Exchange proposes new functionality regarding the ECO Opening Auction Process on the Exchange, which will apply to both to openings and reopenings following a trading halt. Under the proposed rules, the Exchange will initiate an ECO Opening Auction Process for a complex strategy only if all legs of the complex strategy have opened or reopened for trading.³⁶ A complex strategy will not be opened if: (A) Any leg of the complex strategy has no BO or NBO; (B) the bid and offer prices used to calculate the DBBO for the complex strategy are locking or crossing; or (C) all legs of the complex strategy include displayed Customer interest and the width of the DBBO is less than or equal to one penny (\$0.01) times the smallest leg ratio.³⁷ Any ECOs in a complex strategy with prices that lock or cross one another will be eligible to trade in the ECO Opening Auction Process.³⁸ An ECO received during a pre-open state will not participate in the Auction Process for the leg markets pursuant to proposed Exchange Rule 6.64P-O.³⁹ A complex strategy created intra-day when all leg markets are open will not be subject to an ECO Opening Auction Process and instead will trade pursuant to proposed Exchange Rule 6.91P-O(e) regarding the handling of ECOs during Core Trading Hours.⁴⁰ The ECO Opening Auction Process will be used to reopen trading in ECOs after a trading halt.⁴¹

Proposed Exchange Rule 6.91P-O(d)(3) describes the ECO Opening Auction Process. Under the proposed rule, locking and crossing ECOs in a complex strategy will trade at the ECO Auction Price.⁴² The ECO Auction Price will be the price at which the maximum volume of ECOs can be traded in an ECO Opening Auction, subject to the proposed ECO Auction Collar.⁴³ If there

²⁵ See proposed Exchange Rule 6.91P-O(b)(1).

²⁶ See proposed Exchange Rule 6.91P-O(b)(1)(A).

²⁷ See *id.*

²⁸ See Exchange Rule 6.62-O(y) (describing PNP Plus orders as ECOs that may only trade with other ECOs, but which will continuously be repriced if locking or crossing the Complex BBO).

²⁹ See proposed Exchange Rule 6.91P-O(b)(2). Proposed Exchange Rule 6.91P-O(b) is included in the Single-Leg Pillar Filing. An ECO designated as GTX ("ECO GTX Order") will not be displayed, may be entered only during the Response Time Interval of a COA, must be on the opposite side of the COA Order, and must specify the price, size, and side of the market. ECO GTX Orders may be modified or cancelled during the Response Time Interval and any remaining size that does not trade with the COA Order will be cancelled at the end of the COA. See proposed Exchange Rule 6.91P-O(b)(2)(B).

³⁰ See proposed Exchange Rule 6.91P-O(c).

³¹ See proposed Exchange Rule 6.91P-O(c)(1)(A).

³² See proposed Exchange Rule 6.91P-O(c)(1)(B).

³³ See Proposed Exchange Rule 6.91P-O(c)(2).

³⁴ See Proposed Exchange Rule 6.91P-O(c)(3).

³⁵ See Proposed Exchange Rule 6.91P-O(c)(4).

³⁶ See proposed Exchange Rule 6.91P-O(d)(1).

³⁷ See proposed Exchange Rule 6.91P-O(d)(1)(A)-(C).

³⁸ See proposed Exchange Rule 6.91P-O(d)(2).

³⁹ See proposed Exchange Rule 6.91P-O(d)(2)(A).

⁴⁰ See proposed Exchange Rule 6.91P-O(d)(2)(B).

⁴¹ See proposed Exchange Rule 6.91P-O(d)(2)(C).

⁴² See proposed Exchange Rule 6.91P-O(d)(3)(B)(ii).

⁴³ See proposed Exchange Rule 6.91P-O(d)(3)(B). The upper (lower) price of an ECO Auction Collar for a complex strategy would be the DBO (DBB); provided, however, that if there is displayed Customer interest on all legs of a complex strategy, the upper (lower) price of an ECO Auction Collar will be one penny (\$0.01) times the smallest leg

¹⁷ See proposed Exchange Rule 6.91P-O(a)(6).

¹⁸ See *id.*

¹⁹ See proposed Exchange Rule 6.91P-O(a)(6)(A).

²⁰ See proposed Exchange Rule 6.91P-O(a)(7).

²¹ See proposed Exchange Rule 6.91P-O(a)(7)(A).

²² See proposed Exchange Rule 6.91P-O(a)(7)(B).

²³ See proposed Exchange Rule 6.91P-O(a)(7)(C).

The term "marketable" is defined in proposed Exchange Rule 1.1 of the Single-Leg Pillar Filing.

²⁴ See proposed Exchange Rule 6.91P-O(a)(7)(D).

are no locking or crossing ECOs in a complex strategy at or within the ECO Auction Collars, the Exchange will open the complex strategy without a trade.⁴⁴ An ECO to buy (sell) with a limit price at or above (below) the upper (lower) ECO Auction Collar will be included in the ECO Auction Price calculation at the price of the upper (lower) ECO Auction Collar, but ranked for participation in the ECO Opening (or Reopening) Auction Process in price-time priority based on its limit price.⁴⁵

The Exchange proposes to apply existing Pillar auction functionality regarding the processing of ECOs received during the period when an ECO Opening Auction Process is ongoing. Under the proposal, new ECOs and ECO Order Instructions⁴⁶ that the Exchange receives when the Exchange is conducting the ECO Opening Auction Process for a complex strategy will be accepted but will not be processed until after the conclusion of the process.⁴⁷ An ECO Order Instruction received during the ECO Opening Auction Process will not be processed until after this process concludes if it relates to an ECO that was received before the process begins and any subsequent ECO Order Instructions relating to the ECO will be rejected.⁴⁸ An ECO Order Instruction received during the ECO Opening Auction Process will be processed on arrival if it relates to an order that was received during the opening process.⁴⁹

After the ECO Opening Auction, ECOs will be subject to the ECO Price Protection in proposed Exchange Rule 6.91P–O(g)(2). An ECO received before the complex strategy was opened that did not trade in whole in the ECO Opening Auction Process and that is locking or crossing other ECOs or leg markets in the Consolidated Book will trade pursuant to proposed Exchange

ratio inside the DBO (DBB) containing Customer interest. See proposed Exchange Rule 6.91P–O(d)(3)(A). If there is more than one price at which the maximum volume of ECOs can be traded within the ECO Auction Collar, the ECO Auction Price will be the price closest to the midpoint of the ECO Auction Collar, or, if the midpoint falls within such prices, the ECO Auction Price will be the midpoint, provided that the ECO Auction Price would not be lower (higher) than the highest (lowest) price of an ECO to buy (sell) that is eligible to trade in the ECO Opening Auction Process. If the ECO Auction Price would be a sub-penny price, it will be rounded to the nearest whole penny. See proposed Exchange Rule 6.91P–O(d)(3)(B).

⁴⁴ See proposed Exchange Rule 6.91P–O(d)(3)(B)(ii).

⁴⁵ See proposed Exchange Rule 6.91P–O(d)(3)(B)(i).

⁴⁶ An “ECO Order Instruction” is “a request to cancel, cancel and replace, or modify an ECO.” See proposed Exchange Rule 6.91P–O(a)(2).

⁴⁷ See proposed Exchange Rule 6.91P–O(d)(4).

⁴⁸ See proposed Exchange Rule 6.91P–O(d)(4)(A).

⁴⁹ See proposed Exchange Rule 6.91P–O(d)(4)(B).

Rule 6.91P–O(e).⁵⁰ Any ECO received during the ECO Opening Auction Process will be processed in time sequence relative to one another based on original entry time.⁵¹

Execution of ECOs During Core Trading Hours. Proposed Exchange Rule 6.91P–O(e) describes the processing of ECOs during Core Trading Hours. Proposed Exchange Rule 6.91P–O(e)(1)(A) provides that if, at a price, an incoming ECO would be eligible to trade with the leg markets (e.g., the order is not a Complex Only Order), the leg markets will have first priority at that price and will trade with the incoming ECO pursuant to proposed Exchange Rule 6.76AP–O before the incoming ECO will trade with contra-side ECOs resting in the Consolidated Book at that price. An ECO will not trade with orders in the leg markets designated as AON or with an MTS modifier.⁵² An ECO that is not designated as a Complex Only Order will be eligible to trade with the leg markets (in full or in a permissible ratio), provided that an ECO will be ineligible to trade with the leg markets and will be processed as a Complex Only Order if the ECO has a strategy with: (i) More than five legs; (ii) two legs and both legs are buying or both legs are selling, and both legs are calls or both legs are puts; or (iii) three or more legs and all legs are buying or all legs are selling.⁵³

Any ECO or portion thereof that does not trade immediately when it is received by the Exchange and that is designated either Day or GTC will be ranked in the Consolidated Book pursuant to proposed Exchange Rule 6.91P–O(c).⁵⁴ The Exchange will evaluate trading opportunities for a resting ECO when the leg markets comprising a complex strategy update, provided that during periods of high message volumes, the Exchange may reduce the evaluations to no less than ten times per one second.⁵⁵ ECOs that trade with the leg markets will be allocated pursuant to Exchange Rule 6.76AP–O.⁵⁶

Execution of ECOs During a COA. A COA Order received when a complex strategy is open for trading will initiate a COA only on arrival, subject to proposed Exchange Rule 6.91P–

O(f)(1).⁵⁷ A COA Order will be rejected if entered during a pre-open state or if entered during Core Trading Hours with a time-in-force of FOK or GTX.⁵⁸ Only one COA will be conducted at a time in a complex strategy.⁵⁹

To initiate a COA, the limit price of a COA Order to buy (sell) must be higher (lower) than the best-priced, same-side ECOs resting on the Consolidated Book and equal to or higher (lower) than the midpoint of the DBBO.⁶⁰ A COA Order that does not satisfy these pricing parameters will not initiate a COA and will be processed as an ECO.⁶¹ Once a COA is initiated, the Exchange will disseminate a Request for Response message, the Response Time Interval will begin, and the Exchange will accept RFR Responses, including GTX ECO Orders.⁶²

A COA Order to buy (sell) will initiate a COA at its limit price, unless its limit price locks or crosses the DBO (DBB), in which case it will initiate a COA at a price equal to one penny (\$0.01) times the smallest leg ratio inside the DBO (DBB) (the “COA initiation price”).⁶³ Prior to initiating a COA, a COA Order to buy (sell) will trade with any ECO to sell (buy) that is priced equal to or below (above) one penny (\$0.01) times the smallest leg ratio inside the DBO (DBB) (i.e., priced better than the leg markets) and any unexecuted portion of such COA Order will initiate a COA.⁶⁴ A COA Order will not be eligible to trade with the leg markets until after the COA ends.⁶⁵

A COA will end prior to the expiration of the Response Time Interval if: (A) The Exchange receives an incoming ECO or COA Order to buy (sell) in the same complex strategy that is priced higher (lower) than the initiating COA Order to buy (sell); (B) the Exchange receives an RFR Response that crosses the same-side DBBO; (C) the leg markets update causing the same-side DBBO to lock or cross (i) any RFR Response(s) or (ii) if no RFR Responses have been received, the best-priced, contra-side ECOs; or (D) the leg markets update causing the contra-side DBBO to lock or cross the COA initiation price.⁶⁶

At the conclusion of a COA, RFR Responses to sell (buy) will trade in price-time priority with a COA Order to

⁵⁰ See proposed Exchange Rule 6.91P–O(d)(5)(A).

⁵¹ See proposed Exchange Rule 6.91P–O(d)(5)(B).

⁵² See proposed Exchange Rule 6.91P–O(e)(1)(B).

See also See Single-Leg Pillar Filing (describing Minimum Trade Size or MTS Modifier in proposed Exchange Rule 6.62P–O(i)(3)(B)).

⁵³ See proposed Exchange Rule 6.91P–O(e)(1)(C).

⁵⁴ See proposed Exchange Rule 6.91P–O(e)(2).

⁵⁵ See *id.*

⁵⁶ See proposed Exchange Rule 6.91P–O(e)(3).

⁵⁷ See proposed Exchange Rule 6.91P–O(f).

⁵⁸ See *id.*

⁵⁹ See *id.*

⁶⁰ See proposed Exchange Rule 6.91P–O(f)(1).

⁶¹ See *id.*

⁶² See *id.*

⁶³ See proposed Exchange Rule 6.91P–O(f)(2).

⁶⁴ See proposed Exchange Rule 6.91P–O(f)(2)(A).

⁶⁵ See proposed Exchange Rule 6.91P–O(f)(2)(B).

⁶⁶ See proposed Exchange Rule 6.91P–O(f)(3).

buy (sell).⁶⁷ If there is displayed Customer interest on all legs of the DBB (DBO), RFR Responses to sell (buy) will not trade below (above) one penny (\$0.01) times the smallest leg ratio inside the DBB (DBO).⁶⁸ Any unexecuted balance of a COA Order (including those designated as IOC) will be eligible to trade with any contra-side interest, including the leg markets, unless the COA Order is designated or treated as a Complex Only Order.⁶⁹ Following these allocations, any unexecuted balance of a COA Order will be processed as an ECO pursuant to proposed Exchange Rule 6.91P–O(e).⁷⁰

A pattern or practice of submitting unrelated orders that cause a COA to conclude early will be deemed conduct inconsistent with just and equitable principles of trade, as will the dissemination of information related to COA Orders to third parties.⁷¹

ECO Risk Checks. With the transition to Pillar, the Exchange proposes to modify and enhance its existing risk checks for ECOs by adopting a Complex Strategy Limit, ECO Price Protection, and Complex Strategy Protections. Under the proposed Complex Strategy Limit, the Exchange will establish a limit on the maximum number of new complex strategies that may be requested to be created per MPID.⁷² When an MPID reaches the limit on the maximum number of new complex strategies, the Exchange will reject all requests to create new complex strategies from that MPID for the rest of the trading day.⁷³ Notwithstanding the established Complex Strategy Limit, the Exchange may reject a request to create a new complex strategy from any MPID whenever the Exchange determines it is necessary in the interests of a fair and orderly market.⁷⁴

Under the ECO Price Protection, an ECO to buy (sell) will be rejected or cancelled (if resting) if it is priced a Specified Threshold⁷⁵ equal to or above

(below) the Reference Price, rounded down to the nearest penny (\$0.01).⁷⁶ An ECO that arrives when a complex strategy is open for trading will be evaluated for ECO Price Protection on arrival.⁷⁷ An ECO received during a pre-open state will be evaluated for ECO Price Protection after the ECO Opening Auction Process concludes.⁷⁸ An ECO resting on the Consolidated Book before a trading halt will be reevaluated for ECO Price Protection after the ECO Opening Auction Process concludes.⁷⁹ Cross Orders and ECOs entered on the Trading Floor will not be subject to ECO Price Protection.⁸⁰ ECO Price Protection will not be applied if there is no Reference Price for an ECO.⁸¹

Under the Complex Strategy Protections, the Exchange will reject ECOs that are comprised of certain erroneously-priced complex strategies.⁸² The proposed rule states that, to protect an OTP Holder or OTP Firm that sends an ECO with the expectation that it will receive (or pay) a net premium but has priced the ECO such that the ECO sender will instead pay (or receive) a net premium, the Exchange will reject any ECO that is comprised of the following erroneously-priced complex strategies:

- “All buy” or “all sell” strategies.

An ECO for a complex strategy where all legs are to buy (sell) and it is entered at a price less than one penny (\$0.01) times the sum of the number of options in the ratio of each leg of such strategy (e.g., a complex strategy to buy (sell) two calls and buy (sell) one put with a price less than \$0.03);⁸³

- Vertical spreads. A vertical spread complex strategy consists of a leg to sell a call (put) option and a leg to buy a call

(put) option in the same option class with the same expiration but at different strike prices, as follows: (i) An ECO for a vertical spread to buy a lower (higher) strike call and sell a higher (lower) strike call and the ECO sender would receive (pay) a net premium; (ii) an ECO for a vertical spread to buy a higher (lower) strike put and sell a lower (higher) strike put and the ECO sender would receive (pay) a net premium;⁸⁴ and

- Calendar spreads. A calendar spread consists of a leg to sell a call (put) option and a leg to buy a call (put) option in the same option class at the same strike price but with different expirations, as follows: (i) An ECO for a calendar spread to buy a call leg with a shorter (longer) expiration while selling a call leg with a longer (shorter) expiration and the ECO sender would pay (receive) a net premium; (ii) an ECO for a calendar spread to buy a put leg with a shorter (longer) expiration while selling a put leg with a longer (shorter) expiration and the ECO sender would pay (receive) a net premium.⁸⁵

Rule 6.47A–O: Order Exposure Requirements—OX

The Exchange also proposes conforming, non-substantive amendments to Exchange Rule 6.47A–O, regarding order exposure, to add a cross-reference to new Exchange Pillar Rule 6.91P–O. This proposed amendment will extend the exemption from the order exposure requirements to COAs on Pillar.⁸⁶ The Exchange also proposes to modify the reference to “Complex Order Auction Process (‘COA’)” to simply “Complex Order Auction (‘COA’),” consistent with the way this concept is defined in proposed Exchange Rule 6.91P–O(a)(7).

As described more fully in the Notice, the Exchange believes that the proposal will promote clarity and transparency regarding the trading of ECOs on Pillar. The Exchange states that the proposed price-time priority model for Pillar and the pricing requirements for ECO trading are substantively the same as the Exchange’s current price-time priority model and pricing requirements. In addition, the Exchange states that the proposed ECO auction process maintains the fundamentals of an auction process that the Exchange currently uses for ECOs while enhancing the process by incorporating Pillar auction functionality that is

⁸⁴ See proposed Exchange Rule 6.92P–O(g)(3)(B).

⁸⁵ See proposed Exchange Rule 6.92P–O(g)(3)(C).

⁸⁶ See proposed Exchange Rule 6.47A–O(iii).

Consistent with the Single-Leg Pillar Filing, the Exchange also proposes to replace reference to “OX” with “the Exchange.”

otherwise by the Exchange and announced to OTP Holders and OTP Firms by Trader Update. See proposed Exchange Rule 6.91P–O(g)(2)(C).

⁷⁶ The Reference Price for calculating ECO Price Protection for an ECO to buy (sell) will be the Complex NBO (NBB), provided that, immediately following an ECO Opening Auction Process, the Reference Price will be the ECO Auction Price or, if none, the Complex NBO (NBB). There will be no Reference Price for an ECO if there is no NBBO for any leg of such ECO. For purposes of determining a Reference Price, the Exchange will not use an adjusted NBBO. See proposed Exchange Rule 6.91P–O(g)(2)(B).

⁷⁷ See proposed Exchange Rule 6.92P–O(g)(2)(A)(i).

⁷⁸ See proposed Exchange Rule 6.92P–O(g)(2)(A)(ii).

⁷⁹ See proposed Exchange Rule 6.92P–O(g)(2)(A)(iii).

⁸⁰ See proposed Exchange Rule 6.92P–O(g)(2)(A)(iv).

⁸¹ See proposed Exchange Rule 6.92P–O(g)(2)(A)(v).

⁸² See proposed Exchange Rule 6.91P–O(g)(3). Any ECO that is not rejected by the Complex Strategy Protections would still be subject to the ECO Price Protection. See proposed Exchange Rule 6.92P–O(g)(3)(D).

⁸³ See proposed Exchange Rule 6.92P–O(g)(3)(A).

⁶⁷ See proposed Exchange Rule 6.91P–O(f)(4)(A).

⁶⁸ See *id.*

⁶⁹ See proposed Exchange Rule 6.91P–O(f)(4)(B).

⁷⁰ See proposed Exchange Rule 6.91P–O(f)(4)(C).

⁷¹ See proposed Exchange Rule 6.91P–O(f)(5).

⁷² The Exchange will announce the limit on the maximum number of new complex strategies by Trader Update. See proposed Exchange Rule 6.91P–O(g)(1). In the Single-Leg Pillar Filing, the Exchange has proposed to amend define MPID to mean “the identification number(s) assigned to the orders and quotes of a single ETP Holder, OTP Holder, or OTP Firm for the execution and clearing of trades on the Exchange by that permit holder. An ETP Holder, OTP Holder, or OTP Firm may obtain multiple MPIDs and each such MPID may be associated with one or more sub-identifiers of that MPID.”

⁷³ See proposed Exchange Rule 6.91P–O(g)(1).

⁷⁴ See *id.*

⁷⁵ The Specified Threshold for calculating ECO Price Protection will be \$1.00, unless determined

currently available on the Exchange's cash equity platform. The Exchange states that the proposed ECO risk checks are similar to functionality currently available on the Exchange or on other exchanges.

III. Proceedings To Determine Whether To Approve or Disapprove SR–NYSEArca–2021–68 and Grounds for Disapproval Under Consideration

The Commission is instituting proceedings pursuant to Section 19(b)(2)(B) of the Act⁸⁷ to determine whether the proposed rule change should be approved or disapproved. Institution of such proceedings is appropriate at this time in view of the legal and policy issues raised by the proposed rule change. Institution of proceedings does not indicate that the Commission has reached any conclusions with respect to any of the issues involved. Rather, as described below, the Commission seeks and encourages interested persons to provide comments on the proposed rule change.

Pursuant to Section 19(b)(2)(B) of the Act,⁸⁸ the Commission is providing notice of the grounds for disapproval under consideration. The Commission is instituting proceedings to allow for additional analysis of the proposed rule change's consistency with Section 6(b)(5) of the Act,⁸⁹ which requires, among other things, that the rules of a national securities exchange be "designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, . . . to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest,"⁹⁰ and not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.⁹¹

IV. Procedure: Request for Written Comments

The Commission requests that interested persons provide written submissions of their data, views, and arguments with respect to the issues identified above, as well as any other concerns they may have with the proposal. In particular, the Commission invites the written views of interested persons concerning whether the proposed rule change is consistent with Section 6(b)(5) or any other provisions

of the Act, or rules and regulations thereunder. Although there do not appear to be any issues relevant to approval or disapproval that would be facilitated by an oral presentation of data, views, and arguments, the Commission will consider, pursuant to Rule 19b–4 under the Act,⁹² any request for an opportunity to make an oral presentation.⁹³

Interested persons are invited to submit written data, views, and arguments regarding whether the proposed rule change should be approved or disapproved by November 26, 2021. Any person who wishes to file a rebuttal to any other person's submission must file that rebuttal by December 9, 2021. The Commission asks that commenters address the sufficiency and merit of the Exchange's statements in support of the proposal, in addition to any other issues raised by the proposed rule change raised under 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 No. SR–NYSEArca–2021–68 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 No. SR–NYSEArca–2021–68. The 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

⁹² 17 CFR 240.19b–4.

⁹³ Section 19(b)(2) of the Act, as amended by the Securities Acts Amendments of 1975, Public Law 94–29 (June 4, 1975), grants to the Commission flexibility to determine what type of proceeding—either oral or notice and opportunity for written comments—is appropriate for consideration of a particular proposal by a self-regulatory organization. See Securities Acts Amendments of 1975, Senate Comm. on Banking, Housing & Urban Affairs, S. Rep. No. 75, 94th Cong., 1st Sess. 30 (1975).

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 No. SR–NYSEArca–2021–68 and should be submitted by November 26, 2021. Rebuttal comments should be submitted by December 9, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁹⁴

J. Matthew DeLesDernier,
Assistant Secretary.

[FR Doc. 2021–24014 Filed 11–3–21; 8:45 am]

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #17256 and #17257; California Disaster Number CA–00349]

Administrative Declaration of a Disaster for the State of California

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Administrative declaration of a disaster for the State of California dated 10/29/2021.

Incident: Brannan Island Fire.

Incident Period: 10/11/2021.

DATES: Issued on 10/29/2021.

Physical Loan Application Deadline Date: 12/28/2021.

Economic Injury (EIDL) Loan Application Deadline Date: 07/29/2022.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street, SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

⁹⁴ 17 CFR 200.30–3(a)(12); 17 CFR 200.30–3(a)(57).

⁸⁷ 15 U.S.C. 78s(b)(2)(B).

⁸⁸ *Id.*

⁸⁹ 15 U.S.C. 78f(b)(5).

⁹⁰ *Id.*

⁹¹ See *id.*

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the Administrator's disaster declaration, applications for disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Sacramento

Contiguous Counties:

California: Amador, Contra Costa, El Dorado, Placer, San Joaquin, Solano, Sutter, Yolo

The Interest Rates are:

	Percent
<i>For Physical Damage:</i>	
Homeowners with Credit Available Elsewhere	3.125
Homeowners without Credit Available Elsewhere	1.563
Businesses with Credit Available Elsewhere	5.710
Businesses without Credit Available Elsewhere	2.855
Non-Profit Organizations with Credit Available Elsewhere	2.000
Non-Profit Organizations without Credit Available Elsewhere	2.000
<i>For Economic Injury:</i>	
Businesses & Small Agricultural Cooperatives without Credit Available Elsewhere	2.855
Non-Profit Organizations without Credit Available Elsewhere	2.000

The number assigned to this disaster for physical damage is 17256 5 and for economic injury is 17257 0.

The States which received an EIDL Declaration # is California.

(Catalog of Federal Domestic Assistance Number 59008)

Isabella Guzman,
Administrator.

[FR Doc. 2021-24101 Filed 11-3-21; 8:45 am]

BILLING CODE 8026-03-P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #17258 and #17259; Connecticut Disaster Number CT-00054]

Presidential Declaration of a Major Disaster for the State of Connecticut

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for the State of Connecticut (FEMA-4629-DR), dated 10/30/2021.

Incident: Remnants of Hurricane Ida.
Incident Period: 09/01/2021 through 09/02/2021.

DATES: Issued on 10/30/2021.

Physical Loan Application Deadline Date: 12/29/2021.

Economic Injury (EIDL) Loan Application Deadline Date: 08/01/2022.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205-6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 10/30/2021, applications for disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties (Physical Damage and Economic Injury Loans): Fairfield and New London Counties, including the Mashantucket Pequot Tribal Nation and the Mohegan Tribal Nation

Contiguous Counties (Economic Injury Loans Only):

Connecticut: Hartford, Litchfield, Middlesex, New Haven, Tolland, Windham

New York: Dutchess, Putnam, Westchester

Rhode Island: Kent, Washington

The Interest Rates are:

	Percent
<i>For Physical Damage:</i>	
Homeowners with Credit Available Elsewhere	3.125
Homeowners without Credit Available Elsewhere	1.563
Businesses with Credit Available Elsewhere	5.710
Businesses without Credit Available Elsewhere	2.855
Non-Profit Organizations with Credit Available Elsewhere	2.000
Non-Profit Organizations without Credit Available Elsewhere	2.000
<i>For Economic Injury:</i>	
Businesses & Small Agricultural Cooperatives without Credit Available Elsewhere	2.855
Non-Profit Organizations without Credit Available Elsewhere	2.000

The number assigned to this disaster for physical damage is 17258 8 and for economic injury is 17259 0.

(Catalog of Federal Domestic Assistance Number 59008)

James Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2021-24104 Filed 11-3-21; 8:45 am]

BILLING CODE 8026-03-P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #17147 and #17148; New York Disaster Number NY-00208]

Presidential Declaration Amendment of a Major Disaster for the State of New York

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 5.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for the State of New York (FEMA-4615-DR), dated 09/05/2021.

Incident: Remnants of Hurricane Ida.

Incident Period: 09/01/2021 through 09/03/2021.

DATES: Issued on 10/07/2021.

Physical Loan Application Deadline Date: 12/06/2021.

Economic Injury (EIDL) Loan Application Deadline Date: 06/06/2022.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205-6734.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for the State of New York, dated 09/05/2021, is hereby amended to extend the deadline for filing applications for physical damages as a result of this disaster to 12/06/2021.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

James Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2021-24098 Filed 11-3-21; 8:45 am]

BILLING CODE 8026-03-P

**OFFICE OF THE UNITED STATES
TRADE REPRESENTATIVE**
**Reallocation of Unused Fiscal Year
2021 Tariff-Rate Quota Volume for Raw
Cane Sugar**

AGENCY: Office of the United States Trade Representative.

ACTION: Notice.

SUMMARY: The Office of the United States Trade Representative (USTR) is providing notice of country-by-country reallocations of the fiscal year (FY) 2021 in-quota quantity of the World Trade Organization (WTO) tariff-rate quota (TRQ) for imported raw cane sugar.

DATES: This notice is applicable on November 4, 2021.

FOR FURTHER INFORMATION CONTACT: Erin Nicholson, Office of Agricultural Affairs, at 202–395–9419, or Erin.H.Nicholson@ustr.eop.gov.

SUPPLEMENTARY INFORMATION: Pursuant to Additional U.S. Note 5 to Chapter 17 of the Harmonized Tariff Schedule of the United States (HTSUS), the United States maintains WTO TRQs for imports of raw cane and refined sugar.

Section 404(d)(3) of the Uruguay Round Agreements Act (19 U.S.C. 3601(d)(3)) authorizes the President to allocate the in-quota quantity of a TRQ for any agricultural product among supplying countries or customs areas. The President delegated this authority to the U.S. Trade Representative under Presidential Proclamation 6763 (60 FR 1007).

On July 9, 2020, the Secretary of Agriculture established the FY 2021 TRQ for imported raw cane sugar at the minimum amount to which the United States committed to pursuant to the WTO Uruguay Round Agreements (1,117,195 metric tons raw value (MTRV) (*conversion factor*: 1 metric ton = 1.10231125 short tons). On July 22, 2020, USTR provided notice of country-by-country allocations of the FY 2021 in-quota quantity of the WTO TRQ for imported raw cane sugar. On July 9, 2021, USTR announced that it had determined to reallocate 76,571 MTRV of the original TRQ quantity from those countries that had stated they did not plan to fill their FY 2021 allocated raw cane sugar quantities. On August 24, 2021, the Secretary of Agriculture announced an additional in-quota quantity of the WTO TRQ for raw cane sugar for the remainder of FY 2021 in the amount of 90,100 MTRV. In the same notice, the Secretary of Agriculture announced that all sugar entering the United States under the FY 2021 raw cane sugar TRQ would be permitted to enter U.S. customs territory

through October 31, 2021, a month later than the usual last entry date. On August 26, 2021, USTR provided notice of country-by-country allocations of the FY 2021 in-quota additional quantity of the WTO TRQ for imported raw cane sugar. Based on consultations with quota holders, USTR has determined to reallocate 29,440 MTRV of the overall FY 2021 raw cane sugar TRQ quantity from those countries that have stated they do not plan to fill their FY 2021 allocated raw cane sugar quantities. USTR is allocating the 29,440 MTRV to the following countries in the amounts specified below:

Country	FY 2021 raw sugar unused reallocation (MTRV)
Argentina	1,629
Australia	3,145
Belize	417
Bolivia	303
Brazil	5,494
Colombia	909
Costa Rica	568
Dominican Republic	6,668
Ecuador	417
El Salvador	985
Eswatini (Swaziland)	606
Fiji	341
Guatemala	1,819
Guyana	455
Honduras	379
India	303
Malawi	379
Mauritius	455
Mozambique	493
Nicaragua	796
Peru	1,553
South Africa	871
Zimbabwe	455

The Secretary of Agriculture also has determined that all sugar entering the United States under the FY 2021 raw sugar TRQ will be permitted to enter U.S. Customs territory through December 31, 2021, extended from the previously announced date of October 31, 2021.

These allocations are based on the countries' historical shipments to the United States. The allocations of the raw cane sugar WTO TRQ to countries that are net importers of sugar are conditioned on receipt of the appropriate verifications of origin and certificates for quota eligibility must accompany imports from any country for which an allocation has been provided.

Greta Peisch,

General Counsel, Office of the United States Trade Representative.

[FR Doc. 2021–24095 Filed 11–3–21; 8:45 am]

BILLING CODE 3390–F2–P

DEPARTMENT OF TRANSPORTATION
Federal Aviation Administration

[Docket No. FAA–2020–1051]

**Agency Information Collection
Activities: Requests for Comments;
Clearance of New Approval of
Information Collection: Unmanned
Aircraft Systems (UAS) BEYOND and
Partnership for Safety Plan (PSP)
Programs**

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval for a new information collection. The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on March 30, 2021. The collection involves data and report submissions by State, local and tribal participants in the UAS BEYOND program (BEYOND), and by industry participants in the Partnership for Safety Plan (PSP) program. BEYOND and PSP participants will also conduct qualitative, non-statistical surveys of the general public. The information to be collected will be used to inform FAA policy and decision-making regarding integrating UAS into the National Airspace System or to build FAA knowledge of best practices and lessons learned to share with UAS operators.

DATES: Written comments should be submitted by December 6, 2021.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the attention of the Desk Officer, Department of Transportation/FAA, and sent via electronic mail to oira_submission@omb.eop.gov, or faxed to (202) 395–6974, or mailed to the Office of Information and Regulatory Affairs, Office of Management and Budget, Docket Library, Room 10102, 725 17th Street NW, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Corbin Jones by email at: corbin.t.jones@faa.gov; phone: 202–641–8950.

SUPPLEMENTARY INFORMATION:

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of

information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

OMB Control Number: 2120-XXXX.

Title: *Unmanned Aircraft Systems (UAS) BEYOND and Partnership for Safety Plan (PSP).*

Form Numbers:

The data collection instruments to be used for the BEYOND and PSP programs are program specific, and will not include official form numbers. The instruments include:

- PSP Quarterly Reports
- BEYOND Semi-Annual Reports
- BEYOND Final Reports
- PSP Final Reports
- BEYOND Program Withdrawal Reports
- UAS Characteristics Reports
- UAS Monthly Operational Flight Reports
- UAS Maintenance Reports
- UAS Flight Anomaly Reports
- UAS Test Data Reports
- Legacy Societal and Economic Data Reports
- UAS Societal and Economic Data Reports
- Community Engagement Reports
- Community Engagement Tool

Type of Review: New information collection.

Background: The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on March 30, 2021 (86 FR 16653). The background and burden information within this **Federal Register** Notice has been updated to reflect feedback received from the Bureau of Transportation Statistics and internal FAA reviewers in order to clarify information pertaining to the collections and to update burden estimations based upon expectations of the programs. The data collected during the BEYOND and PSP programs is delineated as part of the Memorandum of Agreement (MOA) or Memorandum of Understanding (MOU) each participant signs with the FAA, and entered into under the authority of 49 U.S.C. 106(l) and (m).

The purpose of the BEYOND and PSP programs is for the Federal Aviation Administration (FAA) to work with state, local and tribal (SLT) governments (BEYOND) and private UAS operators (PSP) to work toward full, safe

integration of UAS into the national airspace system (NAS). There are eight SLT governments in the BEYOND program and seven industry participants in the PSP program. The programs have multiple data collections that serve different purposes to help the FAA achieve the goals.

First, there are narrative reports that will provide qualitative, non-statistical data that will inform the FAA of operational trends, highlight successes and failures and their causes, and describe challenges and lessons learned. These narrative reports are meant to inform the FAA of progress being made, to identify where there are challenges or gaps in understanding, and to help the FAA make policy and resource decisions. The data will be supplied by the eight SLT governments in the BEYOND program, and the seven industry operators in the PSP program. The collection instruments include:

- (1) PSP Quarterly Reports
- (2) BEYOND Semi-Annual Reports
- (3) BEYOND Final Reports
- (4) PSP Final Reports
- (5) BEYOND Program Withdrawal Reports

Second, there are systems and operations data submissions which will provide both quantitative and qualitative information about the program participants' aircraft, flights, corrective maintenance actions, off-nominal flight events, and UAS testing activities. The submissions are not statistical in nature but are designed to supply data that will help inform policy and standards related to UAS pilots flying their aircraft beyond their visual line of sight. The data will be supplied by the eight SLT governments in the BEYOND program, and the seven industry operators in the PSP program. The collection instruments include:

- (6) UAS Characteristics Reports
- (7) UAS Monthly Operational Flight Reports
- (8) UAS Maintenance Reports
- (9) UAS Flight Anomaly Reports
- (10) UAS Test Data Reports

Third, there are societal and economic data submissions that will provide qualitative and quantitative data regarding the potential societal and economic impacts of participant UAS operations. These are non-statistical reports that provide insight into the types of societal and economic benefits or detriments the participants' UAS operations are having on their communities and their business operations compared to non-UAS (legacy) operations. These submissions will help to inform FAA policy and decision-making toward integrating

different types of operations into the NAS, and to inform discussions with the public on the potential benefits of using UAS. The data will be supplied by the eight SLT governments in the BEYOND program, and the seven industry operators in the PSP program. The collection instruments include:

- (11) Legacy Societal and Economic Data Reports
- (12) UAS Societal and Economic Data Reports

Fourth, there is a community engagement component to the programs which includes two separate, but related, collections. One of these is the reports that will provide qualitative and quantitative data regarding the participants' community outreach activities, including the types of activities, the targeted audiences, and the types and quantity of feedback received. The reports will include any raw data collected using questionnaires or surveys. These submissions are not statistical in nature, but will provide valuable information to the FAA that will inform community engagement best practices and lessons learned which can be shared with the public. The data will be supplied by the eight SLT governments in the BEYOND program, and the seven industry operators in the PSP program. The collection instruments include:

- (13) Community Engagement Reports

The other piece of the community engagement component is the Community Engagement Tool, which will include a potential burden on the general public. The Community Engagement Tool was developed by the FAA as an optional aid for program participants that includes general and operation-specific questions related to UAS operations. The BEYOND and PSP participants may choose to use any of the pertinent sample survey questions when developing their own questionnaires to survey the general public in their communities. The tool includes questions on general knowledge of UAS and sentiments toward potential benefits or drawbacks of UAS operations. The Community Engagement Tool is intended to help the program participants develop simple questionnaires with no intended utility other than gaining insight into the general public's experience with, and opinions of, UAS operations. No statistical analysis or inference will be performed other than tabulation of responses. Results may be used to help develop lessons learned or best practices for other UAS stakeholders pertaining to community engagement activities.

(14) Community Engagement Tool
Respondents: Depending on the submission, the respondents include three groups:

1. Business or other for-profit—PSP participants only
2. State, Local or Tribal Government—BEYOND participants only

3. Individuals or Households

See the table below for details.

Frequency: The frequency depends on the report or form. See the table below for details.

Estimated Average Burden per Response: Depending on the submission, the overall estimated

average burden per response varies from 5 minutes to 80 hours. See the table below for details.

Estimated Total Annual Burden: The estimated total annual burden for all submissions is 33,756.05 hours. See the table below for a breakdown by collection instrument.

Report/form	Affected public	Frequency	Number of respondents	Total number of responses	Estimated average burden per response (hours)	Estimated total annual burden (hours)
Narrative Reports						
PSP Quarterly Reports ...	Business or other for-profit, PSP participants only	Quarterly	7.00	28.00	80.00	2,240.00
BEYOND Semi-Annual Reports.	State, Local or Tribal Government, BEYOND participants only.	Semi-Annually	8.00	16.00	80.00	1,280.00
PSP Final Reports	Business or other for-profit, PSP participants only	One-Time Submission ...	7.00	2.33	40.00	93.20
BEYOND Final Reports ..	State, Local or Tribal Government, BEYOND participants only.	One-Time Submission ...	8.00	2.67	40.00	106.80
BEYOND Program Withdrawal Reports.	State, Local or Tribal Government, BEYOND participants only.	One-Time Submission ...	8.00	2.67	40.00	106.80
Narrative Reports Sub-Totals			38.00	51.67	74.06	3,826.80
Systems and Operations Data						
UAS Monthly Operational Flight Reports.	Business or other for-profit—PSP participants only, and State, Local or Tribal Government—BEYOND participants only.	Monthly	15.00	180.00	1.00	180.00
UAS Maintenance Reports.	Business or other for-profit—PSP participants only, and State, Local or Tribal Government—BEYOND participants only.	Monthly	15.00	180.00	1.00	180.00
UAS Test Data Reports (optional).	Business or other for-profit—PSP participants only, and State, Local or Tribal Government—BEYOND participants only.	Ad hoc	15.00	15.00	0.08	1.25
UAS Anomaly Reports	Business or other for-profit—PSP participants only, and State, Local or Tribal Government—BEYOND participants only.	On Occasion—Assuming 10 annually per participant.	15.00	150.00	1.00	150.00
UAS Aircraft Characteristics Submissions.	Business or other for-profit—PSP participants only, and State, Local or Tribal Government—BEYOND participants only.	On Occasion—for each New Aircraft—Assuming average 25 annual submissions.	15.00	375.00	0.20	75.00
Systems and Operations Data Sub-Totals			75.00	900.00	0.65	586.25
Societal and Economic Data						
Legacy Societal and Economic Data Reports (PSP participants).	Business or other for-profit—PSP participants only	Quarterly	7.00	28.00	1.00	28.00
UAS Societal and Economic Data Reports (PSP participants).	Business or other for-profit—PSP participants only	Quarterly	7.00	28.00	1.00	28.00
Legacy Societal and Economic Data Reports (BEYOND participants).	State, Local or Tribal Government—BEYOND participants only.	Semi-Annually	8.00	16.00	1.00	16.00
UAS Societal and Economic Data Reports (BEYOND participants).	State, Local or Tribal Government—BEYOND participants only.	Semi-Annually	8.00	16.00	1.00	16.00
Societal and Economic Data Sub-Totals			30.00	88.00	1.00	88.00
Community Engagement						
Community Engagement Data Reports (PSP participants).	Business or other for-profit—PSP participants only	Quarterly	7.00	28.00	2.00	56.00
Community Engagement Data Reports (BEYOND participants).	State, Local or Tribal Government—BEYOND participants only.	Semi-Annually	8.00	16.00	2.00	32.00
Community Engagement Tool (optional).	Individuals or Households	On Occasion	175,005.00	175,005.00	0.17	29,167.00
Community Engagement Sub-Totals			175,020.00	175,049.00	0.17	29,255.00
Totals			175,163.00	176,088.67	0.19	33,756.05

Issued in Washington, DC, on November 1, 2021.

Corbin T. Jones,

*Acting Manager, BEYOND Program,
Unmanned Aircraft Systems Integration
Office, Federal Aviation Administration.*

[FR Doc. 2021-24083 Filed 11-3-21; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. 2021-0009]

Petition for Exemption; Summary of Petition Received; Erickson Helicopters

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

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Federal Aviation Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, FAA's exemption process. Neither publication of this notice nor the inclusion nor omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before November 24, 2021.

ADDRESSES: Send comments identified by docket number FAA-2021-0627 using any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov> and follow the online instructions for sending your comments electronically.

- *Mail:* Send comments to Docket Operations, M-30; U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W12-140, West Building Ground Floor, Washington, DC 20590-0001.

- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC 20590-0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

- *Fax:* Fax comments to Docket Operations at (202) 493-2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to

<http://www.regulations.gov>, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at <http://www.dot.gov/privacy>.

Docket: Background documents or comments received may be read at <http://www.regulations.gov> at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC 20590-0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT:

Tiffany Jackson (202-267-3796) Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Caitlin Locke,

Acting Executive Deputy Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA-2021-0627.

Petitioner: Erickson Helicopters.

Section(s) of 14 CFR Affected:

§ 141.35(d)(2) and 141.35(e).

Description of Relief Sought: The petitioner requests an exemption from 14 CFR 141.35 (d)(2) and (e) to hire a chief instructor at Erickson Helicopters. The relief requested would allow a chief instructor to administer a course of training other than those leading to the issuance of a private pilot certificate or rating, or an instrument rating or a rating with instrument privileges, without the required minimum of 1,000 hours dual instruction provided. The requested relief would also allow the designation of chief instructor for a ground school course without one year of experience as a ground school instructor at a certificated pilot school.

[FR Doc. 2021-24059 Filed 11-3-21; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket No. FRA-2010-0049]

North County Transit District's Request for Positive Train Control Safety Plan Approval and System Certification

AGENCY: Federal Railroad
Administration (FRA), U.S. Department
of Transportation (DOT).

ACTION: Notice of availability and
request for comments.

SUMMARY: This document provides the public with notice that the North County Transit District (SDNX) submitted its Positive Train Control Safety Plan (PTCSP), Version 3.0, dated September 30, 2021, to FRA's Secure Information Repository. SDNX asks FRA to approve its amendment to its PTCSP and issue a Positive Train Control System Certification as a Mixed System for SDNX's Interoperable Electronic Train Management System (I-ETMS).

DATES: FRA will consider comments received by January 3, 2022 before taking final action on the PTCSP. FRA may consider comments received after that date to the extent practicable and without delaying implementation of valuable or necessary modifications to a PTC system.

ADDRESSES:

Comments: Comments may be submitted by going to <https://www.regulations.gov> and following the online instructions for submitting comments.

Instructions: All submissions must include the agency name and the applicable docket number. The relevant PTC docket number for this host railroad is Docket No. FRA-2010-0049. For convenience, all active PTC dockets are hyperlinked on FRA's website at <https://railroads.dot.gov/train-control/ptc/ptc-annual-and-quarterly-reports>. All comments received will be posted without change to <https://www.regulations.gov>; this includes any personal information.

FOR FURTHER INFORMATION CONTACT: Mr. Gabe Neal, Staff Director, Signal, Train Control, and Crossings Division, telephone: 816-516-7168, email: Gabe.Neal@dot.gov.

SUPPLEMENTARY INFORMATION: In its PTCSP, SDNX asserts that the I-ETMS it is implementing is designed as a mixed PTC system as defined in Title 49 Code of Federal Regulations (CFR) 236.1015(e). The PTCSP describes SDNX's I-ETMS implementation and the associated I-ETMS safety processes, safety analyses, and test, validation, and verification processes used during the development of I-ETMS. The PTCSP also contains SDNX's operational and support requirements and procedures.

SDNX's PTCSP and the accompanying request for approval and system certification are available for review online at www.regulations.gov (Docket Number FRA-2010-0049) and in person at DOT's Docket Operations Facility, 1200 New Jersey Avenue SE, W12-140, Washington, DC 20590. The Docket Operations Facility is open from 9 a.m. to 5 p.m., Monday through Friday, except Federal holidays.

Interested parties are invited to comment on the PTCSP by submitting written comments or data. During its review of the PTCSP, FRA will consider any comments or data submitted. See 49 CFR 236.1011(e). However, FRA may elect not to respond to any particular comment and, under 49 CFR 236.1009(d)(3), FRA maintains the authority to approve or disapprove the PTCSP at its sole discretion. FRA does not anticipate scheduling a public hearing regarding SDNX's PTCSP because the circumstances do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment, the party should notify FRA in writing before the end of the comment period and specify the basis for their request.

Privacy Act Notice

Anyone can search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). In accordance with 49 CFR 211.3, FRA solicits comments from the public to better inform its decisions. DOT posts these comments, without edit, including any personal information the commenter provides, to <https://www.regulations.gov>, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at <https://www.transportation.gov/privacy>. See <https://www.regulations.gov/privacy-notice> for the privacy notice of www.regulations.gov. To facilitate comment tracking, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. If you wish to provide comments containing proprietary or confidential information, please contact FRA for alternate submission instructions.

Issued in Washington, DC.

Carolyn R. Hayward-Williams,

Director, Office of Railroad Systems and Technology.

[FR Doc. 2021-23997 Filed 11-3-21; 8:45 am]

BILLING CODE 4910-06-P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA-2009-0078]

Petition for Amendment of Waiver of Compliance

Under part 211 of title 49 Code of Federal Regulations (CFR), this document provides the public notice

that on October 26, 2021, the American Short Line and Regional Railroad Association (ASLRRA) petitioned the Federal Railroad Administration (FRA) to amend a waiver of compliance from certain provisions of the Federal hours of service (HOS) laws contained at 49 U.S.C. 21103(a)(4), which, in part, require a train employee to receive 48 hours off duty after initiating an on-duty period for 6 consecutive days. The relevant FRA Docket Number is FRA-2009-0078.

Specifically, ASLRRA seeks to amend its existing waiver to add five member railroads that did not participate in the original waiver, but now wish to participate. ASLRRA states the following railroads expressed a desire to participate in the waiver, and maintain at their headquarters supporting documentation of employee support, as required:

- Trans Global Solutions—Port of Beaumont;
- Trans Global Solutions—Chevron—Port Arthur, Texas;
- Trans Global Solutions—Cedar Port Industrial Park;
- Salt Lake Garfield & Western Railway; and
- Ohio River Scenic Railway.

A copy of the petition, as well as any written communications concerning the petition, is available for review online at www.regulations.gov.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment and a public hearing, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number and may be submitted at <http://www.regulations.gov>. Follow the online instructions for submitting comments.

Communications received by December 20, 2021 will be considered by FRA before final action is taken. Comments received after that date will be considered if practicable. Anyone can search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). Under 5 U.S.C. 553(c), the U.S. Department of Transportation (DOT) solicits comments

from the public to better inform its processes. DOT posts these comments, without edit, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at <https://www.transportation.gov/privacy>. See also <https://www.regulations.gov/privacy-notice> for the privacy notice of www.regulations.gov.

Issued in Washington, DC.

John Karl Alexy,

Associate Administrator for Railroad Safety Chief Safety Officer.

[FR Doc. 2021-24009 Filed 11-3-21; 8:45 am]

BILLING CODE 4910-06-P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

FEDERAL RESERVE SYSTEM

FEDERAL DEPOSIT INSURANCE CORPORATION

Agency Information Collection Activities; Submission for OMB Review; Comment Request

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: Joint notice and request for comment.

SUMMARY: In accordance with the requirements of the Paperwork Reduction Act of 1995 (PRA), the OCC, the Board, and the FDIC (the agencies) may not conduct or sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number. On July 22, 2021, the agencies, under the auspices of the Federal Financial Institutions Examination Council (FFIEC), requested public comment for 60 days on proposals to revise and extend for three years the Consolidated Reports of Condition and Income (Call Reports) (FFIEC 031, FFIEC 041, and FFIEC 051), which is currently an approved collection of information. The agencies requested comment on proposed changes to the instructions for reporting of deferred tax assets (DTAs) and to add a new item related to the standardized approach for counterparty credit risk (SA-CCR). The comment period for the notice has closed. The agencies are adding the new item related to SA-CCR as proposed.

The agencies are deferring the proposed changes to the instructions for reporting of DTAs until a future notice, which will also provide an opportunity for additional comment on the instructions. The agencies hereby give notice of their plan to submit to OMB a request to approve the revision and extension of these information collections and again invite comment on the renewal.

DATES: Comments must be submitted on or before December 6, 2021.

ADDRESSES: Interested parties are invited to submit written comments to any or all of the agencies. All comments, which should refer to the "Call Report Revisions," will be shared among the agencies.

Written comments and recommendations for the proposed information collections should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. You may find these particular information collections by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

Comments should also be sent to:

OCC: You may submit comments, which should refer to "Call Report Revisions," by any of the following methods:

- **Email:** prainfo@occ.treas.gov.
- **Mail:** Chief Counsel's Office, Office of the Comptroller of the Currency, Attention: 1557-0081, 400 7th Street SW, Suite 3E-218, Washington, DC 20219.
- **Hand Delivery/Courier:** 400 7th Street SW, Suite 3E-218, Washington, DC 20219.

Instructions: You must include "OCC" as the agency name and "1557-0081" in your comment. In general, the OCC will publish comments on www.reginfo.gov without change, including any business or personal information provided, such as name and address information, email addresses, or phone numbers. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

You may review comments and other related materials that pertain to this information collection beginning on the date of publication of the second notice for this collection by the following method:

- **Viewing Comments Electronically:** Go to www.reginfo.gov. Hover over the "Information Collection Review" tab.

Underneath the "Currently under Review" section heading, from the drop-down menu select "Department of Treasury" and then click "submit." This information collection can be located by searching by OMB control number "1557-0081." Upon finding the appropriate information collection, click on the related "ICR Reference Number." On the next screen, select "View Supporting Statement and Other Documents" and then click on the link to any comment listed at the bottom of the screen.

- For assistance navigating www.reginfo.gov, please contact the Regulatory Information Service Center at (202) 482-7340.

Board: You may submit comments, which should refer to "Call Report Revisions," by any of the following methods:

- **Agency Website:** <http://www.federalreserve.gov>. Follow the instructions for submitting comments at: <http://www.federalreserve.gov/generalinfo/foia/ProposedRegs.cfm>.

- **Email:** regs.comments@federalreserve.gov. Include "Call Report Revisions" in the subject line of the message.

- **Fax:** (202) 452-3819 or (202) 452-3102.

- **Mail:** Ann E. Misback, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW, Washington, DC 20551.

All public comments are available on the Board's website at <https://www.federalreserve.gov/apps/foia/proposedregs.aspx> as submitted, unless modified for technical reasons.

Accordingly, your comments will not be edited to remove any identifying or contact information.

FDIC: You may submit comments, which should refer to "Call Report Revisions," by any of the following methods:

- **Agency Website:** <https://www.fdic.gov/regulations/laws/federal/>. Follow the instructions for submitting comments on the FDIC's website.

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments.

- **Email:** comments@FDIC.gov. Include "Call Report Revisions" in the subject line of the message.

- **Mail:** Manuel E. Cabeza, Counsel, Attn: Comments, Room MB-3128, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.

- **Hand Delivery:** Comments may be hand delivered to the guard station at the rear of the 550 17th Street Building

(located on F Street) on business days between 7:00 a.m. and 5:00 p.m.

- **Public Inspection:** All comments received will be posted without change to <https://www.fdic.gov/regulations/laws/federal/> including any personal information provided. Paper copies of public comments may be requested from the FDIC Public Information Center by telephone at (877) 275-3342 or (703) 562-2200.

FOR FURTHER INFORMATION CONTACT: For further information about the proposed revisions to the information collections discussed in this notice, please contact any of the agency staff whose names appear below. In addition, copies of the report forms and instructions for the Call Reports can be obtained at the FFIEC's website (https://www.ffiec.gov/ffiec_report_forms.htm).

OCC: Kevin Korzeniewski, Counsel, Chief Counsel's Office, (202) 649-5490.

Board: Nuha Elmaghrabi, Federal Reserve Board Clearance Officer, (202) 452-3884, Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, 20th and C Streets NW, Washington, DC 20551. Telecommunications Device for the Deaf (TDD) users may call (202) 263-4869.

FDIC: Manuel E. Cabeza, Counsel, (202) 898-3767, Legal Division, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.

SUPPLEMENTARY INFORMATION:

I. Report Summary

The agencies propose to extend for three years, with revision, the FFIEC 031, FFIEC 041, and FFIEC 051 Call Reports.

Report Title: Consolidated Reports of Condition and Income (Call Report).

Form Number: FFIEC 031 (Consolidated Reports of Condition and Income for a Bank with Domestic and Foreign Offices), FFIEC 041 (Consolidated Reports of Condition and Income for a Bank with Domestic Offices Only), and FFIEC 051 (Consolidated Reports of Condition and Income for a Bank with Domestic Offices Only and Total Assets Less Than \$5 Billion).

Frequency of Response: Quarterly.

Affected Public: Business or other for-profit.

Type of Review: Revision and extension of currently approved collections.

OCC

OMB Control No.: 1557-0081.

Estimated Number of Respondents: 1,090 national banks and federal savings associations.

Estimated Average Burden per Response: 42.10 burden hours per quarter to file.

Estimated Total Annual Burden: 183,556 burden hours to file.

Board

OMB Control No.: 7100–0036.

Estimated Number of Respondents: 728 state member banks.

Estimated Average Burden per Response: 45.62 burden hours per quarter to file.

Estimated Total Annual Burden: 132,845 burden hours to file.

FDIC

OMB Control No.: 3064–0052.

Estimated Number of Respondents: 3,209 insured state nonmember banks and state savings associations.

Estimated Average Burden per Response: 40.13 burden hours per quarter to file.

Estimated Total Annual Burden: 515,109 burden hours to file.

The estimated average burden hours collectively reflect the estimates for the FFIEC 031, the FFIEC 041, and the FFIEC 051 reports for each agency. When the estimates are calculated by type of report across the agencies, the estimated average burden hours per quarter are 86.49 (FFIEC 031), 55.53 (FFIEC 041), and 35.38 (FFIEC 051). The changes to the FFIEC 031, FFIEC 041 and FFIEC 051 Call Report forms and instructions proposed in this notice would not have an impact on the existing burden estimates. The estimated burden per response for the quarterly filings of the Call Report is an average that varies by agency because of differences in the composition of the institutions under each agency's supervision (e.g., size distribution of institutions, types of activities in which they are engaged, and existence of foreign offices).

Type of Review: Extension and revision of currently approved collections. In addition to the proposed revisions discussed below, Call Reports are periodically updated to clarify instructional guidance and correct grammatical and typographical errors on the forms and instructions, which are published on the FFIEC website.¹ These non-substantive updates may also be commented upon.

Legal Basis and Need for Collections

The Call Report information collections are mandatory: 12 U.S.C. 161 (national banks), 12 U.S.C. 324 (state member banks), 12 U.S.C. 1817 (insured

state nonmember commercial and savings banks), and 12 U.S.C. 1464 (federal and state savings associations). At present, except for selected data items and text, these information collections are not given confidential treatment.

Banks and savings associations submit Call Report data to the agencies each quarter for the agencies' use in monitoring the condition, performance, and risk profile of individual institutions and the industry as a whole. Call Report data serve a regulatory or public policy purpose by assisting the agencies in fulfilling their shared missions of ensuring the safety and soundness of financial institutions and the financial system and protecting consumer financial rights, as well as agency-specific missions affecting national and state-chartered institutions, such as conducting monetary policy, ensuring financial stability, and administering federal deposit insurance. Call Reports are the source of the most current statistical data available for identifying areas of focus for on-site and off-site examinations. Among other purposes, the agencies use Call Report data in evaluating institutions' corporate applications, including interstate merger and acquisition applications for which the agencies are required by law to determine whether the resulting institution would control more than 10 percent of the total amount of deposits of insured depository institutions in the United States. Call Report data also are used to calculate institutions' deposit insurance assessments and national banks' and federal savings associations' semiannual assessment fees.

II. Current Actions

A. New Item for SA–CCR

On January 24, 2020, the agencies issued a final rule² (SA–CCR final rule) that amends the regulatory capital rule to implement a new approach for calculating the exposure amount for derivative contracts for purposes of calculating total risk-weighted assets (RWA), which is called SA–CCR. The final rule also incorporates SA–CCR into the determination of the exposure amount of derivatives for total leverage exposure under the supplementary leverage ratio and the cleared transaction framework under the capital rule. Banking institutions that are not advanced approaches institutions may elect to use SA–CCR to calculate standardized total RWA by notifying

their appropriate federal supervisor.³ Advanced approaches institutions are required to use SA–CCR to calculate standardized total RWA starting on January 1, 2022. Advanced approaches institutions may adopt SA–CCR prior to January 1, 2022, but must notify their appropriate federal supervisor of early adoption.⁴

On July 22, 2021, the agencies proposed to revise Schedule RC–R, Part I, Regulatory Capital Components and Ratios, on all versions of the Call Report by adding a new line item 31.b, “Standardized Approach for Counterparty Credit Risk opt-in election.”⁵ The agencies proposed to add this new item to identify institutions that have chosen to early adopt or voluntarily elect SA–CCR. This information allows for enhanced comparability of the reported derivative data and for better supervision of the implementation of the framework at these institutions. Due to the inherent complexity of adopting SA–CCR, identification of non-advanced approaches institutions that choose to voluntarily adopt SA–CCR is particularly important for their supervision.

The comment period for the July 2021 notice ended on September 20, 2021. The agencies received one comment that was generally supportive of the proposed new Call Report line item related to the SA–CCR final rule. The agencies did not receive any other comments on the proposed change and intend to add the new item for SA–CCR as proposed. The agencies made available on the FFIEC website redline changes related to SA–CCR in the forms and instructions for Schedule RC–R, Part I, Regulatory Capital Components and Ratios, and the agencies will use these same redline changes for this notice as well.

B. Instruction Revisions for DTAs

On May 10, 2021, the agencies published a proposed rule on Tax Allocation Agreements (Tax NPR) with request for comment.⁶ Consistent with the proposed requirements and discussion in the Tax NPR, the agencies proposed to revise the Call Report instructions Glossary entry for “Income Taxes” to address treatment of temporary difference deferred and operating loss and tax credit

³ 12 CFR 3.34(a)(1)(ii) (OCC); 12 CFR 217.34(a)(1)(ii) (Board); 12 CFR 324.34(a)(1)(ii) (FDIC).

⁴ 12 CFR 3.300(g) (OCC); 12 CFR 217.300(h) (Board); 12 CFR 324.300(g) (FDIC).

⁵ 86 FR 38810 (July 22, 2021) (July 2021 notice).

⁶ 86 FR 24755 (May 10, 2021).

¹ www.ffiec.gov/forms031.htm; www.ffiec.gov/forms041.htm; www.ffiec.gov/forms051.htm.

² 85 FR 4362 (Jan. 24, 2020).

carryforward DTAs in the July 2021 notice.

The agencies are still considering comments received on the Tax NPR. Therefore, the agencies are deferring consideration of any instruction changes related to DTAs to a future Paperwork Reduction Act notice, which will also provide an opportunity for additional comment on the instructions. The agencies did receive two comments on the proposed instruction revisions for DTAs, which will be considered when developing that notice.

III. Timing

As stated in the July 2021 notice, the proposed reporting change for the new item related to SA-CCR would take effect starting with the December 31, 2021, Call Report.

IV. Request for Comment

Public comment is requested on all aspects of this joint notice. Comment is specifically invited on:

(a) Whether the proposed revisions to the collections of information that are the subject of this notice are necessary for the proper performance of the agencies' functions, including whether the information has practical utility;

(b) The accuracy of the agencies' estimates of the burden of the information collections as they are proposed to be revised, including the validity of the methodology and assumptions used;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of information collections on respondents, including through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Comments submitted in response to this joint notice will be shared among the agencies.

Patrick T. Tierney,

Assistant Director, Bank Advisory Office of the Comptroller of the Currency.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

Federal Deposit Insurance Corporation.

Dated at Washington, DC, on October 28, 2021.

James P. Sheesley,

Assistant Executive Secretary.

[FR Doc. 2021-24060 Filed 11-3-21; 8:45 am]

BILLING CODE 4810-33-P; 6210-01-P, 6714-01-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning Form 8928, Return of Certain Excise Taxes of the Internal Revenue Code and information collection requirements related to employer comparable contributions of HSAs and requirement for filing excise tax under section 4980B, 4980D, 4980E & 4980G.

DATES: Written comments should be received on or before January 3, 2022 to be assured of consideration.

ADDRESSES: Direct all written comments to Andres Garcia, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT:

Requests for additional information or copies of this regulation should be directed to Sara Covington, at Internal Revenue Service, Room 6525, 1111 Constitution Avenue NW, Washington, DC 20224, or at (737) 800-6149 or through the internet at Sara.L.Covington@irs.gov.

SUPPLEMENTARY INFORMATION:

Title: Form 8928—Return of Certain Excise Taxes Under Chapter 43 of the Internal Revenue Code & TD 9457—Employer Comparable Contributions to HSAs and requirement of Return for filing excise taxes under sections 4980B, 4980D, 4980E and 4980G.

OMB Number: 1545-2146.

Form Number: 8928.

Regulation Project Number: REG-120476-07 (TD 9457).

Abstract: Form 8928 is used by employers, group health plans HMOs, and third-party administrators to report and pay excise taxes due for failures under sections 4980B, 4980D, 4980E, and 4980G. The information results from the requirement form TD 9457 to file a return for the payment of the excise taxes under sections 4980B, 4980D, 4980E, and 4980G of the code.

Current Actions: There are no changes being made to the form or this existing regulation at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations, not-for-profit organizations, and individuals.

Estimated Number of Respondents: 68.

Estimated Time per Respondent: 23.48 hours.

Estimated Total Annual Burden Hours: 1,597.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: November 1, 2021.

Sara L. Covington,
IRS Tax Analyst.

[FR Doc. 2021-24088 Filed 11-3-21; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0576]

Agency Information Collection Activity: Certification of Affirmation of Enrollment Agreement Correspondence Course**AGENCY:** Veterans Benefits Administration, Department of Veterans Affairs.**ACTION:** Notice.

SUMMARY: The Veterans Benefits Administration (VBA), Department of Veterans Affairs (VBA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed revision of a currently approved collection, and allow 60 days for public comment in response to the notice.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before January 3, 2022.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at www.Regulations.gov or to Nancy J. Kessinger, Veterans Benefits Administration (20M33), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420 or email to nancy.kessinger@va.gov. Please refer to “OMB Control No. 2900–0576” in any correspondence. During the comment period, comments may be viewed online through FDMS.

FOR FURTHER INFORMATION CONTACT: Maribel Aponte, Office of Enterprise and Integration, Data Governance Analytics (008), 1717 H Street NW, Washington, DC 20006, (202) 266–4688 or email maribel.aponte@va.gov. Please refer to “OMB Control No. 2900–0576” in any correspondence.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA’s functions, including whether the information will have practical utility;

(2) the accuracy of VBA’s estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Authority: 38 U.S.C. 3686(b); 38 U.S.C. 3323(a); 10 U.S.C. 16131, and 38 CFR 21.74256(b).

Title: Certification of Affirmation of Enrollment Agreement Correspondence Course.

OMB Control Number: 2900–0576.

Type of Review: Revision of a currently approved collection.

Abstract: VA uses information from the current collection to pay education benefits for correspondence training. This information allows VA to determine if the claimant has been informed of the 5-day reflection period required by law.

Affected Public: Individuals and households.

Estimated Annual Burden: 3 hours.

Estimated Average Burden per Respondent: 3 minutes.

Frequency of Response: Annually.

Estimated Number of Respondents: 69.

By direction of the Secretary.

Maribel Aponte,

VA PRA Clearance Officer, Office of Enterprise and Integration/Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2021–24069 Filed 11–3–21; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS**VA Standards for Quality****AGENCY:** Department of Veterans Affairs.**ACTION:** Solicitation of public comment.

SUMMARY: The Secretary of the Department of Veterans Affairs (VA) is soliciting public comment on VA’s current standards for quality to ensure that they include the most up to date and applicable measures for veterans.

DATES: Comments must be received on or before December 6, 2021.

ADDRESSES: Comments may be submitted through www.regulations.gov. Comments should indicate that they are submitted in response to “VA Standards for Quality.” Comments received will be available at www.regulations.gov for public viewing, inspection or copies.

FOR FURTHER INFORMATION CONTACT: Joseph Francis, VHA Office of Analytics

and Performance Integration (API), 17 API, Veterans Health Administration, Department of Veterans Affairs, 810 Vermont Avenue NW, Room 668, Washington, DC 20420, (202) 461–5517. This is not a toll-free number.

SUPPLEMENTARY INFORMATION: In accordance with section 1703C of 38 U.S.C., as added by section 104 of the VA Maintaining Internal Systems and Strengthening Integrated Outside Networks Act of 2018 or the VA MISSION Act of 2018, VA formally established standards for quality regarding hospital care, medical services, and extended care services furnished by the Department in October 2019 (84 FR 52932). VA’s quality standards were chosen based on a comprehensive assessment of health care industry standards for quality, their relevance to veterans, and the availability of comparative data for community providers. Wide ranging expert guidance and stakeholder input was also sought from veterans, Veteran Service Organizations, federal partners, health care specialty associations and organizations, and the public through focus groups, meetings, and requests for information. The current VA standards for quality and associated measures are publicly available on VA’s Access to Care website (<https://www.accesstocare.va.gov>).

After internal review of VA’s standards for quality in 2021, significant changes were not made to the initial standards established in 2019. The current quality standards address important dimensions of care for veterans and are aligned with industry standards. The addition of new metrics is limited in many cases by the lack of appropriate community comparison data; and this has been compounded in CY 2020 and 2021 by the impact of the COVID–19 pandemic. Notably, the pandemic resulted in gaps in the available healthcare data and temporary suspension of some measures (e.g., COVID–19 Quality Reporting Programs Guidance Memo—Centers for Medicare and Medicaid Services (CMS) (March 27, 2020); <https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf>). This has created a problematic situation where, in some cases, VA’s current quality data results are being compared to pre-COVID periods of community data. VA has an ongoing commitment to evolving the quality standards in accordance with veteran needs and industry advancements. The quality standards will be reviewed internally again in FY 2022 to ensure they are up-

to-date and addressing veteran priorities. As required by 38 U.S.C. 1703C(b)(2), this notice is to solicit and consider public comment on potential changes to VA's current quality standards to ensure that they include the most up-to-date and applicable measures for veterans. VA will use the comments it receives to help update the quality standards. Changes to the standards can be accessed by veterans and the public on VA's Access to Care website (<https://www.accesstocare.va.gov>).

VA's current standards for quality consist of quality domains and quality measures.

- **Quality domains**—broad categories of quality used to describe the desired characteristics of care received by veterans, whether furnished by VA or community-based providers.

- **Quality measures**—an evolving series of numeric indicators that evaluate clinical performance within each of the quality domains.

The standards for quality and included domains are:

- **Timely Care**—provided without inappropriate or harmful delays.
- **Effective Care**—based on scientific knowledge of what is likely to provide benefits to veterans.
- **Safe Care**—avoids harm from care that is intended to help veterans.
- **Veteran-Centered Care**—anticipates and responds to veterans' and their caregivers' preferences and needs and ensures that veterans have input into clinical decisions.

The current quality measures for the quality domains are detailed below along with relevant annotations regarding changes since October 2019:

- **Timely Care**
 - Patient-reported measures on getting timely appointments, care, and information
 - Wait times for outpatient care
- **Effective Care**
 - Risk adjusted mortality rate for heart attack
 - Risk adjusted mortality rate for pneumonia
 - Risk adjusted mortality rate for heart failure
 - Risk adjusted mortality rate for chronic obstructive pulmonary disease
 - Smoking and tobacco use cessation—advising smokers to quit
 - Immunization for influenza
 - Controlling high blood pressure
 - Beta-blocker treatment after a heart attack
 - Comprehensive diabetes care—blood pressure control
 - Comprehensive diabetes care—

Hemoglobin A1c poor control

- Breast cancer screening
- Cervical cancer screening
- Improvement in function (short-stay skilled nursing facility patients)
- Newly received antipsychotic medications (short-stay skilled nursing facility patients)
- **Safe Care**
 - Catheter associated urinary tract infection rate
 - Central line associated bloodstream infection rate
 - Clostridioides difficile infection rate (Note: VA does not currently have patient level comparison data for this measure. VA is undertaking improvements to strengthen the reporting approach going forward as data availability changes.)
 - Death rate among surgical patients with serious treatable complications (Note: Availability of accurate community comparison data has improved since initial publication of this measure in 2019 and related updates will be made to VA's external reporting of this measure.)
 - New or worsened pressure ulcers/pressure injuries (short-stay skilled nursing facility patients)
 - Falls with major injury (long-stay skilled nursing facility patients)
 - Physical restraints (long-stay skilled nursing facility patients)
- **Veteran-Centered Care** (Note: VA now utilizes the measure or composite for these key indicators of patient experience, rather than the star rating, because this allows more precision in comparisons and can better track improvement over time.)
 - Hospital Consumer Assessment of Health Providers and Systems (HCAHPS) overall rating of hospital
 - HCAHPS care transition composite
 - Patient's overall rating of the provider on the Consumer Assessment of Health Providers and Systems (CAHPS) survey
 - Patient's rating of coordination of care on the CAHPS survey

Signing Authority

Denis McDonough, Secretary of Veterans Affairs, approved this document on October 28, 2021, and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs.

Michael P. Shores,

Director, Office of Regulation Policy & Management, Office of General Counsel, Department of Veterans Affairs.

[FR Doc. 2021-24042 Filed 11-3-21; 8:45 am]

BILLING CODE 8320-01-P

DEPARTMENT OF VETERANS AFFAIRS

Notice of Request for Information Regarding Health Care Access Standards

AGENCY: Department of Veterans Affairs.

ACTION: Request for information.

SUMMARY: The Department of Veterans Affairs (VA) is requesting information from the public to inform VA's review of access standards for furnishing hospital care, medical services and extended care services to covered veterans, for purposes of the Veterans Community Care Program (VCCP). Specifically, VA requests information regarding access standards, including but not limited to, information regarding health plans on the use of access standards for the design of health plan provider networks; referrals from network providers to out-of-network providers; the appeals process for exemptions from benefit limits to out-of-network providers; and the measurement of performance against Federal or State regulatory standards. Further, VA is requesting input on Veterans' experience with the access standards established in 2019.

DATES: Comments must be received on or before December 6, 2021.

ADDRESSES: Comments may be submitted through www.regulations.gov. Comments should indicate that they are submitted in response to "Notice of Request for Information Regarding Health Care Access Standards."

FOR FURTHER INFORMATION CONTACT: Natalie Frey, Management Analyst, Office of the Assistant Under Secretary for Health, Office of Community Care, Veterans Health Administration, Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420; 720-429-9171. This is not a toll-free number.

SUPPLEMENTARY INFORMATION: The John S. McCain III, Daniel K. Akaka, and Samuel R. Johnson VA Maintaining Integrated Outside Networks Act of 2018, Public Law 115-182, (VA MISSION Act of 2018) added section 1703B to title 38, United States Code, which required VA to establish access standards for furnishing hospital care, medical services or extended care services to covered Veterans under VCCP. VA established these access standards through rulemaking on June 6, 2019, at 38 CFR 17.4040. Section 1703B(c) specifically requires VA to consult with all pertinent Federal entities, entities in the private sector

and other non-governmental entities in establishing access standards. Section 1703B(e) requires VA, not later than 3 years after the date on which VA establishes access standards, and not less frequently than once every 3 years thereafter, to conduct a review of the established access standards and submit to the appropriate committees of Congress a report on the findings and any modification to the access standards. In reviewing these access standards, VA is choosing to consult with pertinent Federal, private sector and non-governmental entities. VA will use the comments received to help review the access standards established in June 2019. VA will then submit a report (in June 2022), as required by section 1703B(e)(2). Responses to this notice will support industry research and VA's evaluation of access standards.

This notice is a request for information only. Commenters are encouraged to provide complete, but concise responses to the questions outlined below. VA may choose to contact individual commenters, and such communications would serve to further clarify their written comments.

Request for Information: VA requests information that will assist in reviewing the access standards, as required by section 1703B. This includes information regarding access standards, including but not limited to, information with regard to health plans on the use of access standards for the design of health plan provider networks; referrals from network providers to out-of-network providers; the appeals process for exemptions from benefit limits to out-of-network providers; and the measurement of performance against Federal or State regulatory standards.

Regarding health systems, VA requests information from the public including, but not limited to, the existence of standards for appointment wait times; the use of travel distance for establishing service areas; the development or use of guidelines to refer patients to out-of-system providers; the utilization of virtual health services; and the measurement of performance against Federal or State regulatory standards. VA's specific requests for information are as follows:

1. Do health plans use internal access standards for the design of provider networks and the application of in-network/out-of-network benefits that are more stringent than regulatory standards (time or distance of travel, appointment wait times, provider/member ratios)? If so, what are these internal standards? Has the COVID-19 pandemic affected established access standards? How does the health plan measure performance against regulatory and internal access standards? How does the health plan respond to findings when access standards are not being met? Are current regulatory access standards cost-effective while maintaining quality standards? Do health plans have a process to handle routine requests from members or to refer providers for exemptions to benefit limits when members seek out-of-network care or a lower tier provider?

2. Do health plans allow for appeals, by providers or members, to request exemptions from benefit limits related to out-of-network care or care by a lower tier provider? Is external review allowed for such appeals?

3. What are health plan practices regarding internal, regulatory and/or accreditation standards for appointment wait times, including variance by

specialty or type of service? How does the health plan use travel distance or time, and/or provider-to-population ratios, in deciding which geographic areas to consider as primary or secondary service areas? How do health plans use financial modeling/impact to inform established access standards?

4. What virtual health services (*e.g.*, telehealth and telephonic) do health systems provide? Are virtual health services used to ensure compliance with established access standards?

5. Are clinicians within the health system given guidelines or rules on when to refer patients to out-of-system providers? For example, are clinicians encouraged to refer out-of-system if in-system wait times are longer than standard; travel time or distance to an in-system provider is too long; the patient's ability to travel is compromised; or the frequency of treatment makes travel to an in-network provider difficult?

6. What are Veterans' experiences with, and feedback on, the VA access standards established in 2019?

Signing Authority

Denis McDonough, Secretary of Veterans Affairs, approved this document on October 6, 2021, and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs.

Michael P. Shores,

Director, Office of Regulation Policy & Management, Office of General Counsel, Department of Veterans Affairs.

[FR Doc. 2021-24041 Filed 11-3-21; 8:45 am]

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Part II

Department of Energy

10 CFR Part 430

Energy Conservation Program: Test Procedures for Cooking Products;
Proposed Rule

DEPARTMENT OF ENERGY

10 CFR Part 430

[EERE–2021–BT–TP–0023]

RIN 1904–AF18

Energy Conservation Program: Test Procedures for Cooking Products

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Notice of proposed rulemaking (“NOPR”) and announcement of public meeting.

SUMMARY: The U.S. Department of Energy (“DOE”) proposes to establish a test procedure for a category of cooking products, *i.e.*, conventional cooking tops, under a proposed new appendix. The proposed test procedure would adopt the latest version of the relevant industry standard with modifications to adapt the test method to gas cooking tops, offer an optional method for burden reduction, normalize the energy use of each test cycle, include measurement of standby mode and off mode energy use, update certain test conditions, and provide certain clarifying language. This NOPR also proposes to retitle the existing cooking products test procedure for microwave ovens only. DOE is seeking comment from interested parties on the proposal.

DATES: DOE will accept comments, data, and information regarding this proposal no later than January 3, 2022. See section V, “Public Participation,” for details. DOE will hold a webinar on Wednesday, December 15, 2021, from 1:00 p.m. to 5:00 p.m. See section V, “Public Participation,” for webinar registration information, participant instructions, and information about the capabilities available to webinar participants. If no participants register for the webinar, it will be cancelled.

ADDRESSES: Interested persons are encouraged to submit comments using the Federal eRulemaking Portal at www.regulations.gov. Follow the instructions for submitting comments. Alternatively, interested persons may submit comments, identified by docket number EERE–2021–BT–TP–0023, by any of the following methods:

1. *Federal eRulemaking Portal:* www.regulations.gov. Follow the instructions for submitting comments.
2. *Email:* to CookingProducts2021TP0023@ee.doe.gov. Include docket number EERE–2021–BT–TP–0023 in the subject line of the message.

No telefacsimiles (“faxes”) will be accepted. For detailed instructions on

submitting comments and additional information on this process, see section V of this document.

Although DOE has routinely accepted public comment submissions through a variety of mechanisms, including postal mail and hand delivery/courier, the Department has found it necessary to make temporary modifications to the comment submission process in light of the ongoing corona virus 2019 (“COVID–19”) pandemic. DOE is currently suspending receipt of public comments via postal mail and hand delivery/courier. If a commenter finds that this change poses an undue hardship, please contact Appliance Standards Program staff at (202) 586–1445 to discuss the need for alternative arrangements. Once the COVID–19 pandemic health emergency is resolved, DOE anticipates resuming all of its regular options for public comment submission, including postal mail and hand delivery/courier.

Docket: The docket, which includes **Federal Register** notices, public meeting attendee lists and transcripts (if a public meeting is held), comments, and other supporting documents/materials, is available for review at www.regulations.gov. All documents in the docket are listed in the www.regulations.gov index. However, some documents listed in the index, such as those containing information that is exempt from public disclosure, may not be publicly available.

The docket web page can be found at www.regulations.gov/docket/EERE-2021-BT-TP-0023. The docket web page contains instructions on how to access all documents, including public comments, in the docket. See section V for information on how to submit comments through www.regulations.gov.

FOR FURTHER INFORMATION CONTACT:

Dr. Stephanie Johnson, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE–2J, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 287–1943. Email: ApplianceStandardsQuestions@ee.doe.gov.

Celia Sher, U.S. Department of Energy, Office of the General Counsel, GC–33, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 287–6122. Email: Celia.Sher@hq.doe.gov.

For further information on how to submit a comment, review other public comments and the docket, or participate in a public meeting (if one is held), contact the Appliance and Equipment

Standards Program staff at (202) 287–1445 or by email: ApplianceStandardsQuestions@ee.doe.gov.

SUPPLEMENTARY INFORMATION: DOE proposes to maintain previously approved incorporations by reference and incorporate by reference the following industry standard into 10 CFR part 430:

International Electrotechnical Commission (“IEC”) Standard 62301 (“IEC 62301”), “Household electrical appliances—Measurement of standby power” (first edition, June 2005).

International Electrotechnical Commission Standard 62301 (“IEC 62301”), “Household electrical appliances—Measurement of standby power.” (Edition 2.0, 2011–01).

International Electrotechnical Commission Standard 60350–2:2017, (“IEC 60350–2:2017”), “Household electric cooking appliances Part 2: Hobs—Methods for measuring performance.”

Copies of IEC 62301 First Edition, IEC 62301 Second Edition and IEC 60350–2:2017 can be obtained from the International Electrotechnical Commission at 25 W 43rd Street, 4th Floor, New York, NY 10036, or by going to webstore.ansi.org.

See section IV.M of this document for further discussion of these standards.

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I. Authority and Background

Kitchen ranges and ovens are included in the list of “covered

products” for which DOE is authorized to establish and amend energy conservation standards and test procedures. (42 U.S.C. 6292(a)(10)) DOE’s regulations at title 10 of the Code of Federal Regulations (“CFR”) 430.2 include definitions for “cooking products,”¹ which cover cooking appliances that use gas, electricity, or microwave energy as the source of heat; as well as specific categories of cooking products, including conventional cooking tops, conventional ovens, microwave ovens, and other cooking products. DOE’s energy conservation standards and test procedure for cooking products are currently prescribed at 10 CFR 430.32(j) and 10 CFR part 430 subpart B appendix I (“appendix I”). Currently only microwave oven test procedures are specified in appendix I. DOE is proposing to create a new test procedure at 10 CFR part 430 subpart B appendix I1 (“appendix I1”) that would establish a conventional cooking top test procedure. The following sections discuss DOE’s authority to establish a test procedure for conventional cooking tops and relevant background information regarding DOE’s consideration of a test procedure for this product.

A. Authority

The Energy Policy and Conservation Act, as amended (“EPCA”),² authorizes DOE to regulate the energy efficiency of a number of consumer products and certain industrial equipment. (42 U.S.C. 6291–6317) Title III, Part B³ of EPCA established the Energy Conservation Program for Consumer Products Other Than Automobiles, which sets forth a variety of provisions designed to improve energy efficiency. These products include cooking products, and specifically conventional cooking tops, the subject of this document. (42 U.S.C. 6292(a)(10))

The energy conservation program under EPCA consists essentially of four parts: (1) Testing, (2) labeling, (3) Federal energy conservation standards, and (4) certification and enforcement procedures. Relevant provisions of EPCA specifically include definitions

¹ DOE established the regulatory term “cooking products” in lieu of the statutory term “kitchen ranges and ovens” (42 U.S.C. 6292(a)(10)) having determined that the latter is obsolete and does accurately describe the products considered, which include microwave ovens, conventional ranges, cooktops, and ovens. 63 FR 48038, 48052 (Sep. 8, 1998).

² All references to EPCA in this document refer to the statute as amended through the Energy Act of 2020, Public Law 116–260 (Dec. 27, 2020).

³ For editorial reasons, upon codification in the U.S. Code, Part B was redesignated Part A.

(42 U.S.C. 6291), test procedures (42 U.S.C. 6293), labeling provisions (42 U.S.C. 6294), energy conservation standards (42 U.S.C. 6295), and the authority to require information and reports from manufacturers. (42 U.S.C. 6296)

The Federal testing requirements consist of test procedures that manufacturers of covered products must use as the basis for: (1) Certifying to DOE that their products comply with the applicable energy conservation standards adopted pursuant to EPCA (42 U.S.C. 6295(s)), and (2) making representations about the efficiency of those consumer products (42 U.S.C. 6293(c)). Similarly, DOE must use these test procedures to determine whether the products comply with relevant standards promulgated under EPCA. (42 U.S.C. 6295(s))

Federal energy efficiency requirements for covered products established under EPCA generally supersede State laws and regulations concerning energy conservation testing, labeling, and standards. (42 U.S.C. 6297) DOE may, however, grant waivers of Federal preemption for particular State laws or regulations, in accordance with the procedures and other provisions of EPCA. (42 U.S.C. 6297(d))

DOE follows an early assessment review process to conduct a more focused analysis that would allow DOE to determine, based on statutory criteria, whether an amended test procedure is warranted. 10 CFR part 430, subpart C, appendix A section 8(a).

Under 42 U.S.C. 6293, EPCA sets forth the criteria and procedures DOE must follow when prescribing or amending test procedures for covered products. EPCA requires that any test procedures prescribed or amended under this section be reasonably designed to produce test results which measure energy efficiency, energy use or estimated annual operating cost of a covered product during a representative average use cycle or period of use and not be unduly burdensome to conduct. (42 U.S.C. 6293(b)(3))

In addition, EPCA requires that DOE amend its test procedures for all covered products to integrate measures of standby mode and off mode energy consumption. (42 U.S.C. 6295(gg)(2)(A)) Standby mode and off mode energy consumption must be incorporated into the overall energy efficiency, energy consumption, or other energy descriptor for each covered product unless the current test procedures already account for and incorporate standby and off mode energy consumption or such integration is technically infeasible. If an integrated test procedure is

technically infeasible, DOE must prescribe a separate standby mode and off mode energy use test procedure for the covered product, if technically feasible. (42 U.S.C. 6295(gg)(2)(A)(ii)) Any such amendment must consider the most current versions of the International Electrotechnical Commission (“IEC”) Standard 62301⁴ and IEC Standard 62087⁵ as applicable. (42 U.S.C. 6295(gg)(2)(A))

EPCA also requires that, at least once every 7 years, DOE evaluate test procedures for each type of covered product, including cooking products, to determine whether an amended test procedure would more accurately or fully comply with the requirements for the test procedure to not be unduly burdensome to conduct and be reasonably designed to produce test results that reflect energy efficiency, energy use, and estimated operating costs during a representative average use cycle or period of use. (42 U.S.C. 6293(b)(1)(A))

If the Secretary determines, on her own behalf or in response to a petition by any interested person, that a test procedure should be prescribed or amended, the Secretary shall promptly publish in the **Federal Register** a proposed test procedure and afford interested persons an opportunity to present oral and written data, views, and arguments with respect to such procedure. The comment period on a proposed rule to amend a test procedure shall be at least 60 days and may not exceed 270 days. In prescribing or amending a test procedure, the Secretary shall take into account such information as the Secretary determines relevant to such procedure, including technological developments relating to energy use or energy efficiency of the type (or class) of covered products involved. (42 U.S.C. 6293(b)(2)) If DOE determines that test procedure revisions are not appropriate, DOE must publish its determination not to amend the test procedure.

DOE is publishing this NOPR in satisfaction of the statutory authority specified in EPCA. (42 U.S.C. 6293(b)(1)(A)) DOE determined that it was not necessary to do an early assessment request for information prior to initiating this NOPR, as the requirement in 10 CFR part 430, subpart C, appendix A, section 8(a) to do an early assessment applies only when DOE is considering amending a test

procedure, not establishing one. In this NOPR, DOE is proposing to establish a new test procedure for conventional cooking tops. Establishing performance-based test procedures for conventional cooking tops is necessary prior to establishing performance-based energy conservation standards for conventional cooking tops, which DOE is required to evaluate under EPCA. Thus, an early assessment as to whether to move forward with a proposal to establish a test procedure for conventional cooking tops is not necessary. Additionally, in the case of conventional cooking tops, DOE has established a detailed administrative record in previous dockets relating to test procedures for conventional cooking tops, which included expansive product testing, data from that testing, detailed test set up requirements, stakeholder input, and robust public comment. This NOPR builds off of that prior work on developing a test procedure for conventional cooking tops, which also obviates the need for an early assessment for this rulemaking.

B. Background

As stated, DOE’s existing test procedure for cooking products appears at 10 CFR part 430, subpart B, appendix I (“Uniform Test Method for Measuring the Energy Consumption of Cooking Products”). The current Federal test procedure provides for the testing of standby power of microwave ovens, but currently there is not a Federal test procedure applicable to conventional cooking tops.

DOE originally established test procedures for cooking products in a final rule published in the **Federal Register** on May 10, 1978 (“May 1978 Final Rule”). 43 FR 20108, 20120–20128. In the years following, DOE amended the test procedure for conventional cooking tops on several occasions. Those amendments included the adoption of standby and off mode provisions in a final rule published on October 31, 2012 (77 FR 65942, the “October 2012 Final Rule”) that satisfied the EPCA requirement that DOE include measures of standby mode and off mode power in its test procedures for residential products, if technically feasible. (42 U.S.C. 6295(gg)(2)(A))

In a final rule published December 16, 2016 (“December 2016 Final Rule”), DOE amended 10 CFR part 430 to incorporate by reference, for use in the conventional cooking tops test procedure, the relevant sections of Committee for Electrotechnical Standardization (“CENELEC”) Standard 60350–2:2013, “Household electric

appliances—Part 2: Hobs—Method for measuring performance” (“EN 60350–2:2013”), which uses a water-heating test method to measure the energy consumption of electric cooking tops, and extended the water-heating test method specified in EN 60350–2:2013 to gas cooking tops. 81 FR 91418.

On August 18, 2020, DOE published a final rule (“August 2020 Final Rule”) withdrawing the test procedure for conventional cooking tops. 85 FR 50757. DOE initiated the rulemaking for the August 2020 Final Rule in response to a petition for rulemaking submitted by the Association of Home Appliance Manufacturers (“AHAM”) in which AHAM asserted that the then-current test procedure for gas cooking tops was not representative, and, for both gas and electric cooking tops, had such a high level of variation that it did not produce accurate results for certification and enforcement purposes and did not assist consumers in making purchasing decisions based on energy efficiency (“AHAM petition”). 85 FR 50757, 50760; see also 80 FR 17944 (Apr. 25, 2018).

At the time of the AHAM petition, the Federal test procedure for cooking tops measured the integrated annual energy consumption of both gas and electric cooking tops based on EN 60350–2:2013.⁶ See, appendix I of 10 CFR part 430 subpart B edition revised as of January 1, 2020.

DOE withdrew the test procedure for conventional cooking tops based on test data submitted by outside parties. 85 FR 50757, 50760. Although not all of the test results submitted by outside parties were from testing that completely followed the DOE test procedure, these data indicated that the test procedure for conventional cooking tops yielded inconsistent results. *Id.* DOE’s test data for electric cooking tops from testing conducted as a single laboratory showed small variations. Lab-to-lab test results submitted by AHAM showed high levels of variation for gas and electric cooking tops. 85 FR 50757, 50763. DOE determined that the inconsistency in results of such testing showed the results to be unreliable, and at that time DOE determined it unduly burdensome to leave that test procedure in place and require cooking top tests be conducted

⁴ IEC 62301, *Household electrical appliances—Measurement of standby power* (Edition 2.0, 2011–01).

⁵ IEC 62087, *Methods of measurement for the power consumption of audio, video, and related equipment* (Edition 3.0, 2011–04).

⁶ The EN 60350–2:2013 test method was based on the same test methods in the draft version of IEC 60350–2 Second Edition, at the time of publication of the final rule adopting EN 60350–2:2013. Based on the few comments received during the development of the draft, DOE stated in the December 2016 Final Rule that it expected the IEC procedure, once finalized, would retain the same basic test method as contained in EN 60350–2:2013, and incorporated EN 60350–2:2013 by reference in appendix I. 81 FR 91418, 91421 (Dec. 16, 2016).

using that test method without further study to resolve those inconsistencies. 85 FR 50757, 50760.

In January 2020, DOE initiated a round robin test program to further investigate the water-heating approach and the issues raised in the AHAM petition. This testing was on-going as of the August 2020 Final Rule and its results are discussed in section III of this NOPR. Following the August 2020 Final Rule, DOE initiated an additional round robin test program that is on-going at this time.

II. Synopsis of the Notice of Proposed Rulemaking

In this NOPR, DOE proposes to establish a new test procedure at 10 CFR part 430, subpart B, appendix I1, “Uniform Test Method for the Measuring the Energy Consumption of Conventional Cooking Products.” For use in appendix I1, DOE would also amend 10 CFR part 430 to incorporate by reference the current version of the applicable industry standard—IEC 60350–2 (Edition 2.0 2017–08), “Household electric cooking appliances—Part 2: Hobs—Methods for measuring performance” (“IEC 60350–2:2017”). Appendix I1 would:

(1) Reduce the test burden and improve the repeatability and reproducibility of IEC 60350–2:2017 by:

(a) Simplifying the test vessel selection process for electrical cooking tops;

(b) Modifying the room temperature, product temperature, and starting water temperature requirements;

(c) Providing an optional method for determining the initial power setting to be used for measuring energy consumption of cooking tops during the simmering period, based on a draft updated version of IEC 60350–2;

(d) Providing criteria for determination of the simmering setting during energy testing; and

(e) Normalizing the per-cycle energy use to account for the water temperature at the end of the simmering period;

(2) Apply IEC 60350–2:2017 to the measurement of gas cooking tops by including:

(a) Specifications for gas supply instrumentation and test conditions;

(b) Test vessel selection based on nominal heat input rate;

(c) Adjustment methods and specifications for the maximum heat input rate; and

(d) Target power density for the optional potential simmering setting pre-selection test;

(3) Provide additional specifications, including:

(a) Definitions for operating modes, product configurations, test settings, and instrumentation;

(b) Test conditions, including electrical supply characteristics and water load mass tolerance;

(c) Instructions for product installation according to product configuration; and

(d) Instructions for determining power settings for multi-ring cooking zones and cooking zones with infinite power settings and rotating knobs;

(4) Provide means for measuring cooking top annual energy use in standby mode and off mode by:

(a) Applying IEC 62301 (First Edition 2005–06), “Household electrical appliances—Measurement of standby power” (“IEC 62301 First Edition”) and IEC 62301 (Edition 2.0 2011–01), “Household electrical appliances—Measurement of standby power” (“IEC 62301 Second Edition”);

(b) Defining the number of hours spent in combined low-power mode; and

(c) Defining the allocation of combined low-power mode hours to the conventional cooking top component of a combined cooking product; and

(5) Define the integrated annual energy use metric by specifying the representative water load mass and the number of annual cooking top cycles.

DOE is also proposing to add calculations of annual energy consumption and estimated annual operating cost to 10 CFR 430.23(i); and rename the test procedure at 10 CFR part 430, subpart B, appendix I (“appendix I”) to “Uniform Test Method for Measuring the Energy Consumption of Microwave Ovens.” Table II.1 summarizes DOE’s proposed changes for the cooking tops test procedure compared to the current industry test procedure, as well as the reasons for the proposed provisions. DOE’s proposed reorganization of appendix I is summarized in Table II.2.

TABLE II.1—SUMMARY OF CHANGES IN PROPOSED TEST PROCEDURE FOR CONVENTIONAL COOKING PRODUCTS RELATIVE TO THE INDUSTRY TEST PROCEDURE INCORPORATED BY REFERENCE

IEC 60350–2:2017 test procedure	Proposed test procedure	Attribution
Addresses only electric cooking tops	Addresses both electric and gas cooking tops, including new provisions specific to gas test conditions, instrumentation, and test conduct.	Include all covered cooking tops.
Includes an incomplete list of definitions	Includes definitions of operating modes, product configurations, power settings, and specialty cooking zone.	Improve readability of test procedure.
Installation instructions specify only that the cooking product is to be installed in accordance with manufacturer instructions.	Provides additional detail for the installation instructions, by product configuration, as well as definitions of those configurations.	Improve readability of test procedure.
Does not include provisions for measuring standby mode and off mode energy.	Incorporates provisions of IEC 62301 to measure standby mode and off mode power and calculate annual combined low-power mode energy.	EPCA requirement.
Specifies a room and product temperature of 23 ± 2 °C	Specifies a room and product temperature of 25 ± 5 °C. Specifies that the temperature must be stable, defines stable temperature, and specifies how to measure the product temperature.	Decrease test burden.
Specifies a starting water temperature of 15 ± 0.5 °C	Specifies a starting water temperature of 25 ± 0.5 °C ...	Decrease test burden.
Specifies complex requirements for determining test vessel sizes for cooking tops with 4 or more cooking zones, requiring that the set of vessels comprise at least 3 of 4 defined cookware size categories.	Requires the use of the cookware that is closest in size to the heating element diameter, without consideration of cookware size categories.	Improve readability of test procedure and decrease test burden.
Does not include a tolerance on the mass of the water load.	Specifies a 0.5g tolerance on the mass of the water load.	Improve repeatability and reproducibility.
Requires the measurement of all power settings spanning the lowest available through the identified Energy Test Cycle setting.	Offers the option of a “potential simmering setting pre-selection” test to reduce number of test cycles needed to identify the Energy Test Cycle. Further offers the option of starting testing at a known potential simmering setting.	Decrease test burden.

TABLE II.1—SUMMARY OF CHANGES IN PROPOSED TEST PROCEDURE FOR CONVENTIONAL COOKING PRODUCTS RELATIVE TO THE INDUSTRY TEST PROCEDURE INCORPORATED BY REFERENCE—Continued

IEC 60350–2:2017 test procedure	Proposed test procedure	Attribution
The measured energy consumption of the simmering period is not normalized to account for a final water temperature above the nominal 90 °C.	The energy consumption of the simmering period is normalized to represent a final water temperature of exactly 90 °C.	Improve representativeness of test results.
Uses a 1000g water load to normalize energy consumption.	Uses a 2853g water load to normalize energy consumption.	Improve representativeness of test results.
Does not calculate annual energy use	Calculates annual energy use based on 418 cooking cycles per year and 31 minutes per cycle.	Provide a representative measure of annual energy consumption

TABLE II.2—SUMMARY OF CHANGES IN PROPOSED TEST PROCEDURE FOR MICROWAVE OVENS RELATIVE TO CURRENT TEST PROCEDURE

Current DOE test procedure	Proposed test procedure	Attribution
Appendix I title covers all cooking products, but includes test procedures only for microwave ovens.	Appendix I title refers only to microwave ovens	Improve readability of test procedure.

DOE has tentatively determined that the proposed test procedure described in section III of this NOPR would, if made final, produce measurements of energy use that are representative of an average use cycle and not be unduly burdensome to conduct. Discussion of DOE's proposed actions are addressed in detail in section III of this NOPR. Additionally, DOE provides initial estimates of the cost of testing for industry in section III.L of this document. DOE notes that there are currently no performance-based energy conservation standards prescribed for conventional cooking tops. Manufacturers would not be required to conduct the proposed test procedure, if made final, until such time as compliance is required with any future applicable standards that are established, unless manufacturers voluntarily choose to make representations as to the energy use or energy efficiency of a conventional cooking top.

III. Discussion

In this NOPR, DOE is proposing to establish a new test procedure for conventional cooking tops in a proposed new appendix I1. The proposed test procedure is based primarily on an industry standard for measuring the energy consumption of electric cooking tops, IEC 60350–2:2017, with certain adjustments and clarifications as discussed in the following sections of this document. Whereas IEC 60350–2:2017 applies only to electric cooking tops, the proposed methodology is extended to gas cooking tops by means of additional instrumentation and test setup provisions to allow for testing of this heating technology.

DOE is also proposing to rename existing appendix I to “Uniform Test Method for Measuring the Energy Consumption of Microwave Ovens” to clarify that it applies only to microwave ovens.

A. Scope of Applicability

This rulemaking applies to conventional cooking tops, a category of cooking products which are household cooking appliances consisting of a horizontal surface containing one or more surface units that utilize a gas flame, electric resistance heating, or electric inductive heating. 10 CFR 430.2. A conventional cooking top includes any conventional cooking top component of a combined cooking product. 10 CFR 430.2.

As discussed in section I.A of this document, DOE has the authority to establish and amend test procedures for covered products. EPCA identifies kitchen ranges and ovens as a covered product. (42 U.S.C. 6292(a)(10)) In a final rule published on September 8, 1998 (63 FR 48038), DOE amended its regulations in certain places to substitute the term “kitchen ranges and ovens” with “cooking products.” DOE regulations currently define “cooking products” as consumer products that are used as the major household cooking appliances. Cooking products are designed to cook or heat different types of food by one or more of the following sources of heat: Gas, electricity, or microwave energy. Each product may consist of a horizontal cooking top containing one or more surface units and/or one or more heating compartments. 10 CFR 430.2.

Certain residential household cooking appliances combine a conventional cooking product component with other

appliance functionality, which may or may not perform a cooking-related function. Examples of such “combined cooking products” include a conventional range, which combines a conventional cooking top and one or more conventional ovens; a microwave/conventional cooking top, which combines a microwave oven and a conventional cooking top; a microwave/conventional oven, which combines a microwave oven and a conventional range, which combines a microwave oven and a conventional oven in separate compartments and a conventional cooking top. Because combined cooking products may consist of multiple classes of cooking products, any established energy conservation standard applies to each individual component of the combined cooking product. As determined in the December 2016 Final Rule, DOE proposes in this NOPR that the cooking top test procedures would apply to the individual conventional cooking top portion of a combined cooking product. See 81 FR 91418, 91423.

As discussed in the December 2016 Final Rule, DOE observed that for combined cooking products, the annual combined low-power mode energy consumption can only be measured for the combined cooking product and not the individual components. 81 FR 91418, 91423 (Dec. 16, 2016). As discussed in section III.H.3 of this document, DOE is proposing similar methods to those adopted in the December 2016 Final Rule to calculate the integrated annual energy consumption of the conventional cooking top component separately by allocating a portion of the combined low-power mode energy consumption

measured for the combined cooking product to the conventional cooking top component using the estimated annual cooking hours for the given components comprising the combined cooking product.

B. Incorporation by Reference of IEC 60350–2:2017 for Measuring Energy Consumption

1. Water-Heating Test Methodology

As discussed previously, DOE is proposing to create a new appendix I1 that would generally adopt the test procedure in IEC 60350–2:2017, which is an industry test procedure that measures the energy consumption of a cooking top using a water-heating method. In the IEC 60350–2:2017 test method, each heating element is tested individually by heating a specified water load in a standardized test vessel at the maximum power setting until the temperature of the water, including any overshoot after reducing the input power, reaches 90 °C (*i.e.*, the “heat-up period”).⁷ At that time, the power is reduced to a lower setting so that the water temperature remains as close to 90 °C as possible, without dropping below that temperature threshold, for a

20-minute period (*i.e.*, the “simmering period”). Energy consumption is measured over the entire duration of the initial heat-up period and 20-minute simmering period, which together comprise the Energy Test Cycle for that heating element. The energy consumption for each heating element is normalized by the weight of the tested water load and averaged among all tested heating elements to obtain an average energy consumption value for the cooking top, as discussed in section III.H.1 of this NOPR.

Both DOE’s proposed new appendix I1 and IEC 60350–2:2017 on which it is based are similar to the approach used in the earlier DOE test procedure as established in the December 2016 Final Rule, which incorporated certain provisions from EN 60350–2:2013. A more detailed comparison of IEC 60350–2:2017 and EN 60350–2:2013 is provided in section III.B.2 of this NOPR.

As discussed in the NOPR preceding the December 2016 Final Rule, published on June 10, 2015 (“June 2015 NOPR”), manufacturers that produce and sell products in Europe supported the use of a water-heating test method and harmonization with IEC Standard 60350–2⁸ for measuring the energy

consumption of electric cooking tops. 80 FR 33030, 33039–33040. Efficiency advocates also supported a water-heating test method to produce a measure of cooking efficiency for conventional cooking tops. *Id.*

In January 2020, DOE commenced an initial round robin test program to further investigate the suitability of the water-heating approach in the then-current version of appendix I and to evaluate issues raised in the AHAM petition. Ten cooking top units were tested according to the then-current version of appendix I at three third-party certified laboratories⁹ as well as one non-certified laboratory¹⁰ to investigate the repeatability and reproducibility of the test procedure. Each laboratory conducted three tests of each unit¹¹ to measure the annual energy consumption (excluding combined low-power mode energy), yielding a coefficient of variation (“COV”) that can be used to assess the repeatability of results. The averages between the laboratories were also compared to determine a COV of reproducibility. The results of this initial round robin testing are shown in Table III.1 and Table III.2.

TABLE III.1—SUMMARY OF INITIAL ROUND ROBIN TESTING: AVERAGE ANNUAL ENERGY USE

Unit No.	Type	Average annual energy use				
		Certified laboratory A	Certified laboratory B	Certified laboratory C ¹²	Laboratory D	Overall average
1	Electric-Coil	108.3 kWh	107.4 kWh	n/a	101.9 kWh	105.9 kWh
2	Electric-Smooth (Radiant)	102.0 kWh	105.9 kWh	n/a	101.6 kWh** ..	103.2 kWh
3	Electric-Smooth (Radiant)	106.9 kWh	107.7 kWh	105.9 kWh* ..	102.9 kWh** ..	105.8 kWh
4	Electric-Smooth (Induction)	98.1 kWh	98.6 kWh	101.6 kWh** ..	101.0 kWh	99.8 kWh
5	Electric-Smooth (Induction)	97.7 kWh	98.3 kWh	99.8 kWh* ..	101.8 kWh** ..	98.4 kWh
6	Gas	565 kBtu	648 kBtu	629 kBtu** ..	n/a	614 kBtu
7	Gas	724 kBtu	899 kBtu	789 kBtu	n/a	804 kBtu
8	Gas	841 kBtu	913 kBtu	n/a	n/a	877 kBtu
9	Gas	866 kBtu	937 kBtu	950 kBtu	n/a	918 kBtu
10	Gas	869 kBtu	948 kBtu	997 kBtu	n/a	938 kBtu

* Only one valid test cycle, see footnote 11.

** Only two valid test cycles, see footnote 11.

“n/a” represents units that were not tested at the laboratory in question.

⁷ See discussion of the turndown temperature in sections III.B.2.a and III.E.5 of this NOPR.

⁸ At the time of the June 2015 NOPR, the second edition of the IEC Standard 60350–2 was still in draft form. The second edition published in August 2017.

⁹ Three of the ten cooking tops were tested at two of the three third-party certified laboratories,

whereas the remaining seven were tested at all three third-party certified laboratories.

¹⁰ Only the five electric cooking tops were tested at the non-certified laboratory.

¹¹ After reviewing data from Laboratory C and Laboratory D, DOE has determined that not all tests were conducted according to the now-withdrawn Appendix I test procedure. These tests were

removed from consideration, leaving some elements with only one or two valid tests, instead of three. In these cases, Annual Energy Use values were calculated using only the valid tests on each element. Annual Energy Use values that are based on fewer than three valid tests are marked with an asterisk in Table III.1.

TABLE III.2—SUMMARY OF INITIAL ROUND ROBIN TESTING: COEFFICIENTS OF VARIATION ASSESSING REPEATABILITY AND REPRODUCIBILITY

Unit No.	Type	Repeatability COV				Reproducibility COV among certified laboratories (%)	Reproducibility COV among all laboratories (%)
		Certified lab A (%)	Certified lab B (%)	Certified lab C (%)	Lab D		
1	Electric-Coil	0.7	0.7	n/a	0.4	0.4	2.7
2	Electric-Smooth (Radiant) ..	0.4	1.5	n/a	** 0.3	1.9	1.9
3	Electric-Smooth (Radiant) ..	1.0	0.4	*	** 0.1	0.7	1.7
4	Electric-Smooth (Induction)	0.3	0.2	** 1.4	0.5	1.6	1.5
5	Electric-Smooth (Induction)	0.6	1.2	*	** 0.9	0.9	1.6
6	Gas	2.1	0.6	** 1.1	n/a	5.8	
7	Gas	1.3	3.7	1.6	n/a	8.9	
8	Gas	0.3	0.7	n/a	n/a	4.1	
9	Gas	1.1	1.4	2.3	n/a	4.0	
10	Gas	1.3	2.4	0.7	n/a	5.6	

* Only one valid test cycle, see footnote 11.

** Only two valid test cycles, see footnote 11.

“n/a” represents units that were not tested at the laboratory in question.

These initial round robin test results showed repeatability and reproducibility COVs under 2 percent for electric cooking tops tested at the certified laboratories. A COV of 2 percent has previously been considered by some stakeholders to be an acceptable threshold for repeatability and reproducibility. (AHAM, EERE–2018–BT–TP–0004, No. 25 at p. 4)¹³ As discussed, the test method employed (*i.e.*, the then-current DOE test procedure) relied generally on the methodology in EN 60350–2:2013. DOE also observed that, when extended to gas cooking tops, this test methodology provided results with repeatability COVs for gas cooking tops of 0.3–3.7 percent, and with reproducibility COVs ranging from 4.0 to 8.9 percent.

The results of the initial round robin test program were not available for consideration at the time of the August 2020 Final Rule. Since the August 2020 Final Rule, DOE has initiated further testing. In particular, DOE initiated a second round robin in May 2021 in response to changes to electric cooking

tops on the market and to evaluate variability in testing gas cooking tops.

In response to AHAM’s petition, Whirlpool submitted comments regarding the frequency of heating element cycling, stating that the introduction of a “coil surface unit cooking oil ignition test” to the 16th edition of the Underwriters Laboratory (“UL”) standard 858, “Household Electric Ranges Standard for Safety” (“UL 858”) resulted in manufacturers making design changes to electric-coil cooking tops that increased cycling frequency over shorter durations in order to maintain a constant temperature. (Whirlpool, EERE–2018–BT–TP–0004, No. 20 at pp. 2–3)

The 16th edition of UL 858 published on November 7, 2014. On June 18, 2015, UL issued a revision to UL 858 that added a new performance requirement for electric-coil cooking tops intended to address unattended cooking, the “Abnormal Operation—Coil Surface Unit Cooking Oil Ignition Test.” This revision had an effective date of April 4, 2019. Because the electric-coil cooking top in DOE’s initial round robin testing was purchased prior to that effective date, DOE could not be certain whether that test unit contained design features that would meet the performance specifications in the updated UL 858. To address the lack of test data on electric-coil cooking tops that comply with the UL 858 safety standard, DOE included one electric-coil cooking top meeting the revised UL 858 safety standard in its second round robin, which is being conducted according to the test procedure proposed in this NOPR.

To address the reproducibility concerns with the prior gas cooking top test results, DOE is also testing four gas

cooking tops, according to the test procedure proposed in this NOPR. As discussed in the following sections, several of the test procedure provisions proposed in this NOPR are intended to specifically reduce the testing variability for gas cooking tops. The second round robin test program is ongoing at this time. Once complete, the results will be made available for comment and summarized for inclusion in the docket for this rulemaking.

DOE proposes to use a water-heating method, based primarily on IEC 60350–2:2017, to measure cooking top energy consumption, but with modifications to extend the test methodology to gas cooking tops and to reduce the variability of test results, as discussed in sections III.C through III.E of this NOPR.

2. IEC 60350–2:2017

After the publication of the December 2016 Final Rule, IEC issued the 2017 version of IEC 60350–2. This updated edition included informative methodology for significantly reducing testing burden during the determination of the simmering setting. This updated version retains substantively the same provisions for the water-heating methodology evaluated in the first round robin testing and provides the basis for the test procedure being evaluated in the second round robin testing, with certain modifications. DOE proposes in this NOPR to incorporate certain provisions of IEC 60350–2:2017 for measuring the energy consumption of cooking tops. DOE further proposes certain modifications and clarifications to the referenced sections of IEC 60350–2:2017. The relevant provisions of IEC 60350–2:2017 and the proposed modifications to the industry standard are discussed in the following sections.

¹² The gas data at Laboratory C was measured using a volumetric gas meter that must be read manually at the start and end of the test instead of recording measurements continuously during the test. In instances in which the start and end of the simmer period were not identified during the test conduct, two manually-recorded gas volume measurements at and near the end of the test were recorded and used later to interpolate the gas volume used during the Energy Test Cycle.

¹³ The parenthetical reference provides a reference for information located in the docket of DOE’s rulemaking regarding test procedures for conventional cooking tops. The references are arranged as follows: (commenter name, comment docket ID number, page of that document). (Docket No. EERE–2018–BT–TP–0004, which is maintained at www.regulations.gov/docket/EERE-2018-BT-TP-0004).

a. Temperature Averaging

In the December 2016 Final Rule, DOE discussed that the water temperature may occasionally oscillate slightly above and below 90 °C due to minor fluctuations (*i.e.*, “noise”) in the temperature measurement. 81 FR 91418, 91430. These temperature oscillations may cause difficulty in determining when the 20-minute simmering period starts after the water temperature first reaches 90 °C. EN 60350–2:2013 did not contain provisions that addressed issues of temperature oscillations. In contrast, IEC 60350–2:2017 introduces the use of “smoothened” temperature measurements to minimize the effect of minor temperature oscillations in determining the water temperature. The smoothened water temperature is calculated as a 40-second moving-average over the period 20 seconds before to 20 seconds after each instantaneous temperature measurement.

DOE has evaluated the impact of implementing “smoothened” water temperature averaging on two aspects of the test procedure: (1) Validating that the water temperature at which the power setting is reduced during the energy test (*i.e.*, the “turndown temperature”) was within a certain defined tolerance; and (2) the determination of the start of the 20-minute simmering period.

Regarding validation of the turndown temperature, Section 7.5.2.1 of IEC 60350–2:2017 provides a methodology for conducting a preliminary test to determine the water temperature at which the power setting will be reduced to the “simmering setting” during the subsequent energy test (*i.e.*, the “target”

turndown temperature). Section 7.5.3 of IEC 60350–2:2017 specifies that while conducting the energy test, the water temperature when the power setting is reduced (*i.e.*, the “measured” turndown temperature) must be recorded. Section 7.5.4.1 of IEC 60350–2:2017 provides a methodology for validating that the measured turndown temperature was within a tolerance of +1 °C/–0.5 °C of the target turndown temperature. Section 7.5.4.1 requires that this validation be performed based on the smoothened water temperature (as described previously) rather than using the instantaneous measured water temperature.

DOE testing suggests that using the smoothened water temperature measurement, rather than the instantaneous water temperature measurement, to validate that the measured turndown temperature was within the specified tolerance of the target turndown temperature could introduce unnecessary test burden by invalidating test cycles that otherwise would have been valid if the instantaneous water temperature measurement had been used instead (as was previously required by EN 60350–2:2013). The potential for this to occur is highest for cooking top types that have particularly fast water temperature response times to changes in input power; *e.g.*, electric-smooth radiant and induction types. On such products, the rate at which the water temperature rises begins to quickly drop (*i.e.*, the temperature rise “flattens” out) within a few seconds after the power setting is turned down to the simmering setting. Because the smoothened water temperature calculation incorporates 20

seconds of forward-looking data into the average during which time the temperature curve is flattening out, the smoothened turndown temperature can be a few degrees lower than the instantaneous turndown temperature. This can result in a measured turndown temperature that is within the allowable tolerance of the target turndown temperature based on the instantaneous water temperature, but below the allowable tolerance when determined based on the smoothened average method (and thus invalid). On such products, using the instantaneous water temperature, rather than the smoothened water temperature, would provide a more accurate and representative validation that the measured turndown temperature was within the specified tolerance of the target turndown temperature.

To illustrate this, DOE conducted an analysis to evaluate the use of the smoothened water temperature to validate whether the measured turndown temperature was within the allowable tolerance of the target turndown temperature for test cycles that were deemed valid using the instantaneous water temperature. DOE used water temperature data from tests conducted according to the now-withdrawn DOE test procedure for cooking tops that was smoothened post-test for the purpose of this analysis. Table III.3 presents a summary of the percentage of test cycles previously validated with the instantaneous water temperature measurements that did not remain within the specified tolerance when evaluated based on the smoothened water temperature.

TABLE III.3—PERCENTAGE OF TEST CYCLES DEEMED VALID USING INSTANTANEOUS WATER TEMPERATURE THAT WOULD BE DEEMED INVALID USING SMOOTHENED WATER TEMPERATURE

Unit #	Type	Number of test cycles evaluated	Percent of invalid test cycles based on smoothened temperature (%)
1	Electric-Coil	48	0
2	Electric-Smooth (Radiant)	48	13
3	Electric-Smooth (Radiant)	60	5
4	Electric-Smooth (Induction)	48	52
5	Electric-Smooth (Induction)	48	27
6	Gas	48	0
7	Gas	48	0
8	Gas	45	0
9	Gas	48	0
10	Gas	48	1

As indicated in Table III.3, all four electric-smooth cooking tops exhibited test cycles for which the measured

turndown temperature was within the allowable tolerance of the target turndown temperature based on the

instantaneous water temperature, but below the allowable tolerance (and thus invalid) when determined based on the

smoothened water temperature. DOE has tentatively determined that the requirement in IEC 60350–2:2017 to use the smoothened water temperature measurement, rather than the instantaneous water temperature measurement, to validate that the measured turndown temperature was within the specified tolerance of the target turndown temperature may be unduly burdensome, particularly for electric-smooth radiant and induction cooking tops. Therefore, proposed new appendix I1 specifies that the instantaneous water temperature measurement (rather than the smoothened water temperature measurement) be used to validate that the measured turndown temperature was within $+1\text{ }^{\circ}\text{C}/-0.5\text{ }^{\circ}\text{C}$ of the target turndown temperature.

DOE requests comment on its proposal to require that the instantaneous, rather than the smoothened, water temperature at which the power setting is reduced during the energy test be within $+1\text{ }^{\circ}\text{C}/-0.5\text{ }^{\circ}\text{C}$ of the target turndown temperature.

Regarding the determination of the start of the 20-minute simmering period, DOE analyzed approaches for determining the start of the simmering period that account for water temperature fluctuations. Section 7.5.3 of IEC 60350–2:2017 specifies that the start of the 20-minute simmering period is when the water temperature first meets or exceeds $90\text{ }^{\circ}\text{C}$. The 2016 version of appendix I¹⁴ allowed for a brief “grace period” after the water temperature initially reached $90\text{ }^{\circ}\text{C}$, during which temperature fluctuations below $90\text{ }^{\circ}\text{C}$ for up to 20 seconds were permitted without changing the determination of whether the power setting under test met the requirements for a simmering setting (namely, maintaining the water temperature above $90\text{ }^{\circ}\text{C}$ for 20 minutes). For this NOPR analysis, DOE analyzed test data from the initial January 2020 round robin test program and observed that none of the test cycles that had required such a “grace period” when evaluating the start of the simmering period using the instantaneous water temperature needed such an allowance when using the smoothened water temperature approach described in Section 7.5.4.1 of IEC 60350–2:2017; that is, for those test cycles, the smoothened water temperature did not drop below $90\text{ }^{\circ}\text{C}$ after the initial time it reached that temperature. Therefore, DOE is

proposing in proposed new appendix I1 to determine the start of the simmering period as defined in Sections 7.5.3 and 7.5.4.1 of IEC 60350–2:2017, using the smoothened water temperature and without further qualification (*i.e.*, not including any “grace period”). DOE tentatively concludes that a grace period is unnecessary when relying on smoothened water temperature and such a provision could cause confusion regarding the start time of the 20-minute simmering period, which in turn could reduce repeatability and reproducibility of the test procedure.

DOE requests comment on its proposal to include the requirement to evaluate the start of the simmering period as the time that the 40-second “smoothened” average water temperature first meets or exceeds $90\text{ }^{\circ}\text{C}$.

To add further clarity, DOE is proposing to add a definition of “smoothened water temperature” to section 1 of proposed new appendix I1, which would specify that the averaged values be rounded to the nearest $0.1\text{ }^{\circ}\text{C}$, in accordance with the resolution requirements of IEC 60350–2:2017. DOE is proposing to define smoothened water temperature as “the 40-second moving-average temperature as calculated in Section 7.5.4.1 of IEC 60350–2:2017, rounded to the nearest $0.1\text{ degree Celsius}$.”

DOE requests comment on its proposed definition of smoothened water temperature as well as its proposal to require the smoothened water temperature be rounded to the nearest $0.1\text{ }^{\circ}\text{C}$.

Water Hardness

Section 7.1.Z6.1 of EN 60350–2:2013 and Section 7.6 of IEC 60350–2:2017 specify that the test water shall be potable, while Section 7.5.1 of IEC 60350–2:2017 further states that distilled water may be used to avoid lime sediment. Based on DOE’s January 2020 round robin test results that showed high reproducibility among three certified test laboratories with different water supplies that were not subject to specific tolerances on water hardness (see Table III.2), DOE does not expect the use of distilled water to significantly affect the energy use of the cooking top in comparison to test results that would be obtained using water with a hardness within potable limits.¹⁵ DOE

has also tentatively determined that a reduction in lime sediment could extend the lifetime of the test vessels. Therefore, DOE proposes to allow the use of distilled water in proposed new appendix I1.

DOE requests comment on its proposal to allow the use of distilled water for testing in the proposed new appendix I1.

Cooking Top Preparation

Section 7.1.Z6.1 of EN 60350–2:2013 specifies that before the energy consumption measurement is conducted, the cooking top shall be operated for at least 10 minutes to ensure that residual water in the components is vaporized. (Residual water may accumulate in the components during the manufacturing process, shipping, or storage of a unit.) In the past, DOE received questions from test laboratories on how frequently this cooking top pre-test preparation should be conducted. Section 7.5.1 of IEC 60350–2:2017 includes a similar requirement and clarifies that this vaporization process need only be run once per tested unit. As DOE would expect that conducting the vaporization process once would be sufficient to eliminate residual water, DOE is proposing that the vaporization process need only be run once per tested unit by adopting the provision in IEC 60350–2:2017 in proposed new appendix I1.

DOE requests comment on its proposal to include the cooking top preparation requirements for water vaporization from IEC 60350–2:2017 in its proposed new appendix I1.

C. Modifications to IEC 60350–2:2017 Methodology To Reduce Testing Burden

1. Test Vessel Selection for Electric Cooking Tops

Section 5.6.1 of IEC 60350–2:2017 specifies a set of standardized cylindrical test vessels and respective lids of varying diameters, measured in millimeters (“mm”) that must be used for conducting the cooking top energy consumption tests. Table 3 in Section 5.6.1.5 of IEC 60350–2:2017 defines four “standardized cookware categories¹⁶”

(such as taste, odor, or color) in drinking water. These secondary standards specify a maximum limit of 500 milligrams/liter of total dissolved solids. The table of secondary standards is available at: www.epa.gov/sdwa/secondary-drinking-water-standards-guidance-nuisance-chemicals#table.

¹⁶ The four categories are defined as A, B, C, and D. The vessel diameters associated with each category are as follows: Category A: 120 mm and 150 mm; Category B: 180 mm; Category C: 210 mm and 240 mm; and Category D: 270 mm, 300 mm, and 330 mm.

¹⁴ The term “the 2016 version of appendix I” refers to the version of appendix I as finalized in the December 2016 Final Rule.

¹⁵ While the United States does not regulate the water hardness of drinking water, the U.S. Environmental Protection Agency (“EPA”) has established non-mandatory Secondary Drinking Water Standards that provide limits on contaminants that may cause cosmetic effects (such as skin or tooth discoloration) or aesthetic effects

that are used to group test vessels by diameter range.

Sections 6.3 and 7.3 of IEC 60350–2:2017 specify a procedure to select the set of test vessels necessary to conduct testing for an electric cooking top. The process requires determining the number of cooking zones based on the number of controls that can be operated independently at the same time. For cooking tops without limitative markings, Annex A of IEC 60350–2:2017 defines the set of test vessels to be used for testing all of the cooking zones on the cooking top, based on the number of cooking zones.

For electric cooking tops with limitative markings (the most common), an initial test vessel selection is made based on matching the outermost diameter of the markings to the outer diameter of a corresponding test vessel, using Table 3 in Section 5.6.1.5 of IEC 60350–2:2017. IEC 60350–2:2017 specifies in Table 4 of Section 7.3 that for electric cooking tops with four or more controls, the set of test vessels used to test the cooking top must comprise at least three of the standardized cookware categories. If the initially selected test vessel set does not meet this criterion, a substitution must be made using the next best-fitting test vessel from one of the other standardized cookware categories. If a selected test vessel size is out of the range of the sizes allowed by the user manual, the closest compatible diameter is to be used.

DOE has tentatively determined through a market survey of electric cooking tops that the typical difference in diameter between the initial test vessel selection and the substituted test vessel is less than 30 mm, suggesting that the energy consumption using the substituted test vessel compared to using the test vessel whose diameter is closest to the heating element diameter will not substantially differ, and that any corresponding difference in measured energy consumption for the entire cooking top will be even more minimal. DOE has also observed through testing conducted in support of the December 2016 Final Rule that the complex test vessel selection process has, in some cases, resulted in electric cooking tops being tested with the wrong set of test vessels.

To reduce the burden of implementing the complex test vessel selection procedure and to thereby improve test procedure reproducibility, DOE is proposing to require much simpler test vessel selection criteria for proposed new appendix I1. Specifically, DOE proposes that for electric cooking tops with limitative markings, each

cooking zone would be tested with the test vessel that most closely matches the outer diameter of the marking, from among the test vessels defined in Table 3 in Section 5.6.1.5 of IEC 60350–2:2017. Table A.1 in Annex A of IEC 60350–2:2017 would be used to determine the set of test vessels required for electric cooking tops without limitative markings, for which such matching of test vessel diameter to limitative marking diameter is not possible. To ensure that these approaches are properly implemented, DOE is additionally proposing to explicitly exclude the provisions from Section 7.3 of IEC 60350–2:2017 in proposed new appendix I1. DOE is further proposing that if a selected test vessel cannot be centered on the cooking zone due to interference with a structural component of the cooking top (for example, a raised outer border), the test vessel with the largest diameter that can be centered on the cooking zone be used instead. This process of vessel selection would reflect expected consumer practice of matching cookware to the size of a heating element (*i.e.*, cookware is placed on the burner that is the closest in size to the cookware).

DOE requests comment on its proposal to exclude the provisions from Section 7.3 of IEC 60350–2:2017 and instead require that each cooking zone be tested with the test vessel that most closely matches the outer diameter of the marking for electric cooking tops with limitative markings; and that Table A.1 of Annex A of IEC 60350–2:2017 be used to define the test vessels for electric cooking tops without limitative markings. DOE also requests comment on its proposal to substitute the largest test vessel that can be centered on the cooking zone in the case where a structural component of the cooking top interferes with the test vessel.

2. Temperature Specifications

a. Room Temperature

Section 5.1 of IEC 60350–2:2017 specifies an ambient room temperature of 23 ± 2 °C for the tests conducted under proposed new appendix I1. From discussions with cooking top manufacturers as part of a task force that AHAM assembled to update its cooking product test procedures,¹⁷ DOE is aware that conducting energy testing on cooking tops in the same conditioned

space that safety testing is conducted could significantly reduce testing burden. Section 40 of UL 858, a relevant safety standard for cooking tops, requires a room temperature of 25 ± 5 °C for certain safety testing that manufacturers are likely conducting.

The IEC ambient room temperature specifications (23 ± 2 °C) are within the range allowed by UL 858 (25 ± 5 °C). Based on its understanding of the primary heat transfer mechanisms to the water load (*i.e.*, by conduction to the test vessel for electric-coil and electric-smooth cooking tops other than induction type; by joule heating in the test vessel itself by induced eddy currents for electric-smooth induction cooking tops; and by convective heat transfer from the flames and conduction from the grates for gas cooking tops), DOE does not expect that the slightly different nominal value and larger tolerance on the ambient room temperature (corresponding to the range allowed by UL 858) would significantly impact the measured cooking top energy consumption. In consideration of this relatively minimal impact on testing results and the potential for significant reduction in test burden on manufacturers, DOE has tentatively determined that expanding the ambient temperature tolerance to match that used for safety testing (*i.e.*, 25 ± 5 °C) would be warranted and would not impact repeatability or reproducibility of the test procedure. To address concerns raised by manufacturers in the AHAM task force that test laboratories could consistently test at the extremes of the temperature tolerances, DOE is proposing to specify that the target ambient room temperature is the nominal midpoint of the temperature range. Therefore, DOE is proposing in proposed new appendix I1 to specify an ambient room temperature of 25 ± 5 °C, with a target temperature of 25 °C.

DOE requests comment on its proposal to specify an ambient room temperature of 25 ± 5 °C.

Product Temperature

Section 5.5 of IEC 60350–2:2017 specifies that the product shall be at the laboratory's ambient temperature at the beginning of each test, and that forced cooling may be used to assist in reducing the temperature from a prior test. This provision ensures a repeatable starting temperature of the cooking top prior to testing. A cooking top that is warmer or colder than the ambient temperature would consume a different amount of energy during testing. Section 5.5 of IEC 60350–2:2017 does not specify how to measure the temperature of the product prior to each test.

¹⁷ The AHAM cooking product task force includes AHAM member manufacturers, a representative of the Appliance Standard Awareness Project, and DOE members and contractors. The task force's first meeting was in January 2021. The task force has been developing test procedures for electric and gas cooking tops.

DOE is proposing to require that the product temperature must be stable, which DOE is proposing to define as “a temperature that does not vary by more than 1 °C over a 5-minute period.” DOE is also proposing to specify that forced cooling must not be used during the period of time used to assess temperature stability.

DOE is further proposing to specify where to measure the temperature of the product. Prior to any active mode testing, the product temperature would be measured at the center of the cooking zone under test. Prior to the standby mode and off mode power test, the product temperature would be measured as the average of the temperature measured at the center of each cooking zone.

DOE requests comments on its proposal to require that the product temperature be stable, its proposed definition of a stable temperature, and its proposed methods for measuring the product temperature for active mode testing as well as standby mode and off mode power testing.

Initial Water Temperature

Section 7.5.1 of IEC 60350–2:2017 specifies an initial water temperature of 15 ± 0.5 °C, and that the test vessel should not be stored in a refrigerator to avoid the rims getting “too cold.” As part of conversations within the AHAM

task force in which DOE has participated, manufacturers have expressed concerns regarding the test burden of maintaining a supply of water for test loads that is colder than the ambient temperature, especially when the test vessels cannot be placed in a refrigerator prior to testing.

As discussed, DOE is proposing to specify an ambient room temperature of 25 ± 5 °C. DOE expects that using an initial nominal temperature of 25 °C, rather than the currently specified 15 °C, would not impact the repeatability and reproducibility of the test procedure. Furthermore, DOE expects that an initial nominal temperature of 25 °C may more accurately represent an average temperature of food or water loads with which consumers would fill their cookware prior to the start of a cooking cycle. DOE surmises that consumers would be expected to fill cookware not only with refrigerated foods or water from the cold water supply (*i.e.*, food and water loads at 15 °C or lower), but also with water from the hot water supply and food items at room temperature (*i.e.*, food and water loads at 25 °C or higher).

DOE tentatively determines, however, that it is critical to maintain the tolerance of ± 0.5 °C on the initial water temperature as specified by IEC 60350–2:2017 so that the energy consumption

during the initial heat-up phase to 90 °C is repeatable and reproducible. DOE has tentatively determined that it is not feasible to normalize the measured energy consumption to reflect different starting water temperatures due to the non-linearity of the water temperature curve during the initial portion of the test. As shown in Figure III.1, the rate of temperature rise of the water during the initial minutes of the test is significantly lower than during the remainder of the heat-up phase because in the initial minutes of the test, the cooking top itself and the test vessel are both heating up, such that a substantive portion of the input power is not transferred directly to the water load. The specific shape of the non-linear water temperature rise during this initial portion of the test is highly dependent on multiple factors, including heating technology, thermal mass of the cooking top, and, for gas cooking tops, the design of the burner system. DOE does not have sufficient data at this time to determine whether a single methodology for normalizing the energy use could be developed to accommodate the wide variety of cooktop heating technologies and designs. For these reasons, DOE proposes to maintain a tolerance of ± 0.5 °C on the initial water temperature as specified by IEC 60350–2:2017.

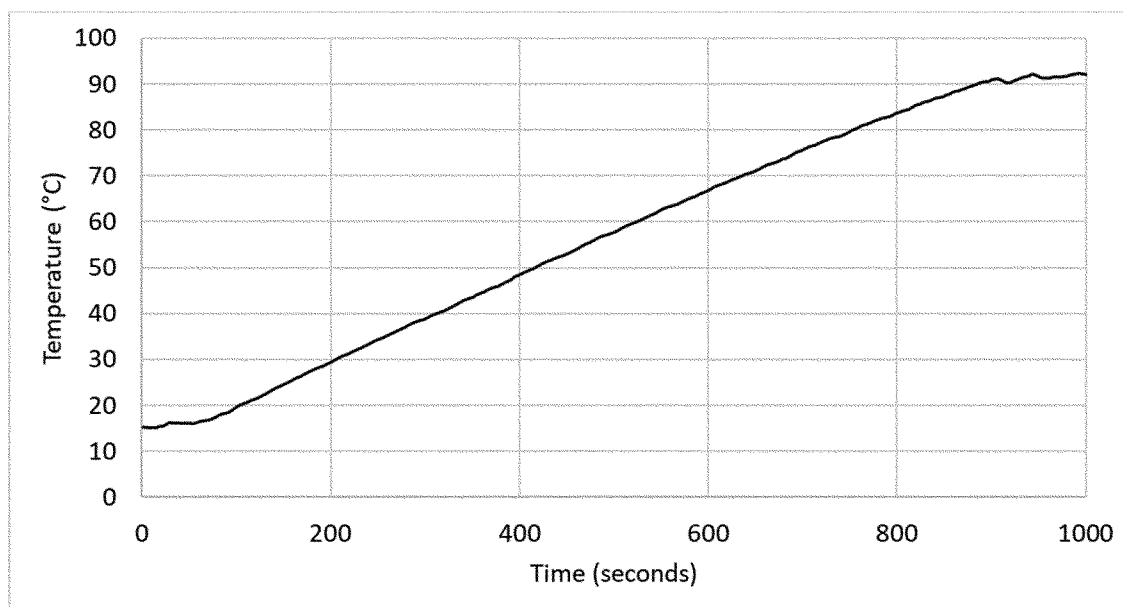


Figure III.1 Example Water Temperature During the Heat-up Period (Unit 7, Laboratory A)

In summary, DOE is proposing to specify in proposed new appendix I1

that the water must have an initial temperature of 25 ± 0.5 °C.

DOE requests comment on its proposal to specify an initial water temperature of 25 ± 0.5 °C.

3. Optional Potential Simmering Setting Pre-Selection Test

As discussed, DOE is proposing to adopt the water-heating methodology in IEC 60350–2:2017, which consists of measuring energy consumption during an initial heat-up period and a subsequent 20-minute simmering period, which together comprise the Energy Test Cycle. Conducting the IEC 60350–2:2017 test method requires the determination of the simmering setting by means of repeated test cycles, each with a successively higher input power setting after turndown, starting with the lowest input setting. This methodology can require a laboratory to conduct numerous test cycles before identifying the one in which the simmering period criteria are met.

In March of 2021, IEC released to its associated committee members a Final Draft International Standard (“IEC 60350–2:FDIS”) amendment to IEC 60350–2:2017, which was approved by the members in April 2021. Although an amended version of the IEC test method has not yet published, DOE is proposing to include several of the relevant changes into proposed new appendix I1. If IEC were to publish the amended version of the standard that includes these amendments prior to the publication of any final rule, DOE would consider incorporating by reference the updated version of the IEC test method instead of including each of these specific provisions in proposed new appendix I1.

Annex H of IEC 60350–2:FDIS provides an informative test method for determining the potential simmering setting (*i.e.*, the first setting used to conduct a simmering test in order to determine the simmering setting). Annex H states that, for electric cooking tops, empirical test data show that the power density of the minimum-above-threshold power setting (*i.e.*, simmering setting) is close to 0.8 watts per square centimeter (“W/cm²”).¹⁸ The method in Annex H provides a means to determine which power setting is closest to the target power density, and thus to more easily identify the first power setting that may be used for determining which power setting will be used for the Energy Test Cycle.

In response to manufacturer concerns regarding the test burden of IEC 60350–2:2017, DOE is proposing to include the procedure from Annex H of IEC 60350–2:FDIS in its proposed new appendix I1. In DOE’s testing experience, using this “pre-selection test” can significantly

reduce the test burden associated with determining the simmering setting to be used for the Energy Test Cycle.

Although this would represent an additional procedure, performing the potential simmering setting pre-selection test can reduce the number of tests cycles necessary to determine the Energy Test Cycle from as many as 12 to as few as two; thus, the net overall testing time for a cooking top may be substantially shorter.¹⁹

Consistent with Annex H of IEC 60350–2:FDIS, DOE is proposing that during the potential simmering setting pre-selection test, the power density measurement be repeated for each successively higher power setting until the measured power density exceeds the specified threshold power density. Of the last two power settings tested (*i.e.*, the last one that results in a power density below the threshold and the first one that results in a power density above the threshold), the potential simmering setting would be the power setting that produces a power density closest to the threshold value. The closest power density may be higher or lower than the applicable threshold value.

DOE is further proposing to make the potential simmering setting pre-selection test optional. If the tester has prior knowledge of the unit’s operation and has previously determined through a different method which power setting is the potential simmering setting, DOE proposes that the tester may use that setting as the initial power setting for the test cycles. Irrespective of the method used for determining the potential simmering setting, a valid test shall confirm whether the power setting under test meets the requirements of an Energy Test Cycle (see section III.C.4 of this NOPR). If a tester decides to use a different method to select the potential simmering setting, and chooses an incorrect power setting, the tester may then be required to conduct additional simmering tests until finding the power setting that meets the requirements of an Energy Test Cycle.

DOE requests comment on its proposal to include the potential simmering setting pre-selection test specified in Annex H of IEC 60350–2:FDIS as an optional test in proposed new appendix I1. DOE also requests comment on its proposal to allow that if the tester has prior knowledge of the

unit’s operation and has previously determined through a different method which power setting is the potential simmering setting, the tester may use that setting as the initial power setting for the test cycles.

4. Determination of the Simmering Setting

IEC 60350–2:FDIS adds a clause to Section 7.5.4.1 of IEC 60350–2:2017 stating that if the smoothened water temperature is measured to be below 90 °C during the simmering period, the energy consumption measurement shall be repeated with an increased power setting. The new clause also adds that if the smoothened water temperature is measured to be above 91 °C during the simmering period, the test cycle is repeated using next lower power setting and checked in order to guarantee that the lowest possible power setting that remains above 90 °C is identified for the Energy Test Cycle. DOE infers from this new clause that if the smoothened water temperature does not drop below 90 °C or rise above 91 °C during the simmering period, no additional testing is needed. This new clause provides clarity as to what setting is “as close to 90 °C as possible,” as required in Section 7.5.2.2 of IEC 60350–2:2017, and therefore improves the reproducibility of the simmering setting determination.

DOE is proposing to define the “maximum-below-threshold power setting” as “the power setting on a conventional cooking top that is the highest power setting that results in smoothened water temperature data that does not meet the evaluation criteria specified in Section 7.5.4.1 of IEC 60350–2:2017,” and to define the “minimum-above-threshold power setting” as “the power setting on a conventional cooking top that is the lowest power setting that results in smoothened water temperature data that meet the evaluation criteria specified in Section 7.5.4.1 of IEC 60350–2:2017. This power setting is also referred to as the simmering setting.”

DOE is proposing to include a flow chart in proposed new Appendix I1 that would require that any valid²⁰ simmering test conducted according to Section 7.5.2 of IEC 60350–2:2017 to be evaluated as follows:

(1) If the smoothened temperature does not exceed 91 °C or drop below 90 °C at any time in the 20-minute period

¹⁸ The power density is defined as the average wattage of the power setting divided by the area of the cookware bottom.

¹⁹ The potential simmering setting pre-selection tests takes 10 minutes per power setting tested (with no cool-down required between each test), whereas testing each setting as described in IEC 60350–2:2017 takes approximately 1 hour per power setting tested (including cool-down time between each test).

²⁰ DOE proposes to define a valid simmering test as one where the test conditions in section 2 of Appendix I1 are met and the measured water temperature at the time the power setting is reduced, Tc, must be within –0.5 °C and +1 °C of the target turndown temperature.

following t90, the power setting under test is considered to be the simmering setting, and no further evaluation or testing is required. The test is considered the Energy Test Cycle.²¹

(2) If the smoothed temperature exceeds 91 °C and does not drop below 90 °C at any time in the 20-minute period following t90, the power setting under test is considered to be above the threshold power setting. The simmering test is repeated using the next lower power setting, after allowing the product temperature to return to ambient conditions, until two consecutive power settings have been determined to be above the threshold power setting and below the threshold power setting, respectively. These power settings are considered to be the minimum-above-threshold power setting and the maximum-below-threshold power setting, respectively. The energy consumption representative of an Energy Test Cycle is calculated based on an interpolation of the energy use of both of these cycles, as discussed in section III.C.5 of this NOPR.

(3) If the smoothed temperature drops below 90 °C at any time in the 20-minute period following t90, the power setting under test is considered to be below the threshold power setting. The simmering test is repeated using the next higher power setting, after allowing the product temperature to return to ambient conditions, until two consecutive power settings have been determined to be above the threshold power setting and below the threshold power setting, respectively. These power settings are considered to be the minimum-above-threshold power setting and the maximum-below-threshold power setting, respectively. The energy consumption representative of an Energy Test Cycle is calculated based on an interpolation of the energy use of both of these cycles, as discussed in section III.C.5 of this NOPR.

DOE requests comment on its proposed definitions of the minimum-above-threshold power setting and the maximum-below-threshold power setting, and on its proposed methodology for determining the simmering setting.

5. Normalizing Per-Cycle Energy Use for the Final Water Temperature

As discussed, the test conduct can conclude with either a single Energy Test Cycle wherein the smoothed water temperature during the simmering period remains between 90 °C and 91

°C, or with a pair of cycles designated as the minimum-above-threshold cycle (wherein the smoothed water temperature during the simmering period remains above 90 °C, and for a portion of the time exceeds 91 °C) and the maximum-below-threshold cycle (wherein the smoothed water temperature during the simmering period does not remain above 90 °C). In IEC 60350-2:2017, energy use is calculated based on the minimum-above-threshold cycle, regardless of whether the smoothed water temperature exceeds 91 °C during the simmering period.

In conversations as part of the AHAM task force in which DOE has participated, some manufacturers have expressed concerns that a test cycle with a water temperature at the end of the simmering period that is above 91 °C may not be comparable to a test cycle with a water temperature at the end of the simmering period that is closer to 90 °C, particularly because there is no limit on how far above 91 °C the final water temperature may be (so long as the setting is the minimum-above-threshold cycle). This concern is particularly relevant to cooking tops with a small number of discrete power settings that result in relatively large differences in simmering temperature between each setting. In addition, repeatably identifying the minimum-above-threshold cycle is particularly challenging for cooking tops with continuous (*i.e.*, infinite) power settings.²²

In order to reduce test burden on cooking tops with infinite power settings, and to provide comparable energy use for all cooking tops including those with discrete power settings, DOE is proposing to normalize the energy use of the minimum-above-threshold cycle to represent an Energy Test Cycle with a final water temperature of exactly 90 °C, using an interpolation of the energy use of the maximum-below-threshold cycle and the respective final smoothed water temperatures. DOE is proposing to not perform this normalization on test cycles where the smoothed water temperature during the simmering period does not exceed 91 °C, because IEC 60350-2:2017 does not require the next lowest power setting to be tested under these circumstances, and DOE has tentatively determined the extra test burden would not be warranted by the resulting small adjustment to the energy use.

DOE is further proposing that if the minimum-above-threshold power setting is the lowest available power setting on the heating element under test, or if the smoothed water temperature during the maximum-below-threshold power setting does not meet or exceed 90 °C during a 20-minute period following the time the power setting is reduced, a normalization calculation would not be possible. Under these circumstances, DOE proposes that the minimum-above-threshold power setting test is the Energy Test Cycle.

DOE is considering whether the smoothed final water temperature is the most appropriate measurement to perform this normalization and may consider using a different metric as the basis for normalization, such as the average temperature of the water during the 20-minute simmering period or the maximum smoothed water temperature during the 20-minute simmering period. DOE may also consider other methods of normalizing the energy use of a heating element to provide comparable energy use for all cooking tops including those with discrete power settings.

DOE requests comment on its proposal to normalize the energy use of the tested cycle if the smoothed water temperature exceeds 91 °C during the simmering period, to represent an Energy Test Cycle with a final water of 90 °C. DOE specifically requests comment on its proposal to use the smoothed final water temperature to perform this normalization and on whether a different normalization method would be more appropriate. DOE also requests comment on its proposal to not require the normalization when the smoothed water temperature remains between 90 °C and 91 °C during the simmering period, when the minimum-above-threshold power setting is the lowest available power setting on the heating element under test, or when the smoothed water temperature during the maximum-below-threshold power setting does not meet or exceed 90 °C during a 20-minute period following the time the power setting is reduced.

D. Extension of Methodology to Gas Cooking Tops

The IEC 60350-2:2017 test method is designed for testing the energy consumption of electric cooking tops. DOE extended this methodology to gas cooking tops in the December 2016 Final Rule, based on the incorporation of test provisions in the European Standard EN 30-2-1:1998, "Domestic cooking appliances burning gas—Part 2—

²¹ t90 is the start of the simmering period and is defined as the time at which the smoothed water temperature first meets or exceeds 90 °C.

²² See section III.E.3 of this NOPR for further discussion of the proposed methodology for cooking tops with infinite power settings.

1: Rational use of energy—General” (“EN 30–2–1”). After further consideration for this NOPR, similar to the prior DOE test procedure for gas cooking tops, DOE is proposing to include certain specifications for testing gas cooking tops based on EN 30–2–1, but with additional provisions to clarify testing requirements and improve the reproducibility of test results for gas cooking tops. Round robin testing of gas cooking tops, as presented in section III.B.1 of this NOPR and additional analysis described in the following sections suggest that a test procedure based on IEC 60350–2:2017 and EN 30–2–1, with modification as proposed in this NOPR, would provide test results with acceptable repeatability and reproducibility for gas cooking tops.

1. Gas Test Conditions

DOE is proposing that the supply pressure immediately ahead of all controls of the gas cooking top under test must be between 7 and 10 inches of water column for testing with natural gas, and between 11 and 13 inches of water column for testing with propane. DOE is further proposing to specify that the higher heating value of natural gas be approximately 1,025 British thermal units (“Btu”) per standard cubic foot, and that the higher heating value of propane be approximately 2,500 Btu per standard cubic foot. These values are consistent with industry standards, and other DOE test procedure for gas-fired appliances.

DOE is also proposing to define a standard cubic foot of gas as “the quantity of gas that occupies 1 cubic foot when saturated with water vapor at a temperature of 60 °F and a pressure of 14.73 pounds per square inch (101.6 kPa).” Standard cubic feet are used to measure the energy use of a gas appliance in a repeatable manner despite potential variation in the gas line conditions.

DOE requests comment on its proposed test conditions for gas cooking tops, and its proposed definition of a standard cubic foot of gas.

2. Gas Supply Instrumentation

DOE is proposing to specify in proposed new appendix I1 a gas meter for testing gas cooking tops using the same specifications as in the 2016 version of appendix I, which read as follows: The gas meter used for measuring gas consumption must have

a resolution of 0.01 cubic foot or less and a maximum error no greater than 1 percent of the measured value for any demand greater than 2.2 cubic feet per hour.

DOE is proposing to include in section 4.1.1.2.1 of proposed new appendix I1 the formula for the correction factor to standard temperature and pressure conditions, rather than reference the U.S. Bureau of Standards Circular C417, 1938, as was done in the 2016 version of appendix I. By providing this explicit formula, DOE expects to reduce the potential for confusion or miscalculations.

In order to measure the gas temperature and line pressure required for the calculation of the correction factor to standard temperature and pressure conditions, DOE is proposing to specify the instrumentation for measuring the gas temperature and line pressure. DOE is proposing to require that the instrument for measuring the gas line temperature must have a maximum error no greater than ± 2 °F over the operating range and that the instrument for measuring the gas line pressure must have a maximum error no greater than 0.1 inches of water column. These requirements are consistent with the gas temperature and line pressure requirements from the test procedures at 10 CFR part 430, subpart B, appendices N and E, for furnaces and for water heaters, respectively.

DOE is proposing to require the use of a standard continuous flow calorimeter to measure the higher heating value of the gas, with an operating range of 750 to 3,500 Btu per cubic foot, a maximum error no greater than 0.2 percent of the actual heating value of the gas used in the test, an indicator readout maximum error no greater than 0.5 percent of the measured value within the operating range and a resolution of 0.2 percent of the full-scale reading of the indicator instrument. These requirements are consistent with the calorimeter requirements from the test procedure at 10 CFR part 430, subpart B, appendix D2, for gas clothes dryers.

The 2016 version of appendix I required that the heating value be measured with an unspecified instrument with a maximum error of 0.5 percent of the measured value and a resolution of 0.2 percent of the full scale reading. The heating value would then be corrected to standard temperature and pressure. 81 FR 91418, 91440. DOE

is proposing the same error and resolution requirements for the instrumentation, but is proposing a different approach for determining the heating value because, after discussions with test laboratories and manufacturers, applying the gas correction factor to the heating value does not reflect common practice in the industry. Instead, DOE is proposing to calculate gas energy use as the product of the measured gas volume consumed (in cubic feet), a correction factor converting measured cubic feet of gas to standard cubic feet of gas, and the heating value of the gas (in Btu per standard cubic foot) in proposed new appendix I1. DOE is proposing to further specify that the heating value would be the higher heating value on a dry-basis of gas. It is DOE’s understanding that this is the typical heating value used by the industry and third-party test laboratories.

DOE requests comment on its proposed instrumentation specifications for gas cooking tops, and any cost burden for manufacturers who may not already have the required instrumentation.

3. Test Vessel Selection for Gas Cooking Tops

In proposing to apply the test method in IEC 60350–2:2017 to gas cooking tops, DOE must define test vessels that are appropriate for each type of burner. The test vessels specified in Section 5.6.1 of IEC 60350–2:2017 are constructed from a 1-mm thick stainless steel sidewall welded to a 5-mm thick circular stainless steel base, with additional heat-resistant sealant applied.

The EN 30–2–1 test method, which is designed for use in gas cooking tops, specifies test vessels that differ in dimensions, material, and construction from those in IEC 60350–2:2017. Further, Table 1 of EN 30–2–1 defines the test vessel selection based on the nominal heat input rate (specified in kilowatts (“kW”) of each burner under test, as shown in Table III.4). These test vessels are fabricated from a single piece of aluminum, with a wall thickness between 1.5 and 1.8 mm. Because they are not made of a ferromagnetic material (such as stainless steel), the EN 30–2–1 test vessels could not be used for electric-smooth induction cooking tops.

TABLE III.4—TEST VESSEL SELECTION FOR GAS COOKING TOPS IN EN 30–2–1

Nominal heat input range (kW)	Test vessel diameter (mm)	Notes
between 1.16 and 1.64 inclusive	220	Adjust the heat input rate of the burner to 2.36 kW $\pm$ 2%. Adjust the heat input rate of the burner to 4.2 kW $\pm$ 2%.
between 1.65 and 1.98 inclusive	* 240	
between 1.99 and 2.36 inclusive	* 260	
between 2.37 and 4.2 inclusive	* 260	
greater than 4.2	* 300	

* If the indicated diameter is greater than the maximum diameter given in the instructions, conduct the test using the next lower diameter and adjust the heat input rate to the highest heat input of the allowable range for that test vessel size, $\pm$ 2%.

To use a consistent set of test vessels for all types of gas and electric cooking tops, DOE is proposing in proposed new appendix I1 to specify the IEC 60350–2:2017 test vessel to be used for each gas burner,²³ based on heat input rate ranges equivalent to those in Table 1 of EN 30–2–1, although expressed in Btu per hour (“Btu/h”). The test vessel diameters in EN 30–2–1 do not exactly match those of the test vessels in IEC

60350–2:2017, but DOE selected the closest match possible, as shown in Table III.5. DOE also proposes to adjust the lower limit of one of the burner heat input rate ranges corresponding to the EN 260 mm test vessel (1.99–2.36 kW, equivalent to 6,800–8,050 Btu/h) and allocate some of its range to the IEC 240 mm test vessel to provide more evenly balanced ranges and avoid a significant mismatch between the heat input rate

and test vessel sizes at the lower end of the heat input range. DOE is not proposing to include the notes included in EN 30–2–1, which require burners with nominal heat input rates greater than 8,050 Btu/h to be tested at heat input rates lower than their maximum rated value, which DOE preliminarily determines would not be representative of consumer use of such burners.

TABLE III.5—TEST VESSEL SELECTION FOR GAS COOKING TOPS IN PROPOSED NEW APPENDIX I1

Nominal gas burner input rate (btu/h)		EN 30–2–1 Test vessel diameter (mm)	IEC 60350– 2:2017 Test vessel diameter (mm)	Water load mass (g)
Minimum (>)	Maximum ($\leq$)			
.....	5,600	220	210	2,050
5,600	8,050	240 and 260	240	2,700
8,050	14,300	260	270	3,420
14,300		300	300	4,240

Similar to electric cooking tops, DOE is also proposing in proposed new appendix I1 that if a selected test vessel cannot be centered on the cooking zone due to interference with a structural component of the cooking top, the test vessel with the largest diameter that can be centered on the cooking zone be used.

DOE requests comment on its proposal to require the use of IEC test vessels for gas cooking tops and on its proposed method for selecting the test vessel size to use based on the gas burner’s heat input rate.

4. Burner Heat Input Rate Adjustment

DOE recognizes that the 2016 version of appendix I did not include a tolerance on the regulator outlet pressure or specifications for the nominal heat input rate for burners on gas cooking tops. From review of the test results from its initial round robin testing, DOE has tentatively concluded

that the lack of such provisions was likely a significant contributor to the greater reproducibility COV values observed for gas cooking tops in relation to those for electric cooking tops. To improve test procedure reproducibility, DOE is proposing in this NOPR to incorporate gas supply pressure and regulator outlet pressure requirements into proposed new appendix I1, as described further in the following discussion.

Other industry procedures for gas cooking tops include specifications for the heat input rate. For example, EN 30–2–1 specifies that prior to testing, each burner is adjusted to within 2 percent of its nominal heat input rate. Section 5.3.5 of the American National Standards Institute (“ANSI”) Standard Z21.1–2016, “Household cooking gas appliances” (“ANSI Z21.1”) requires that individual burners be adjusted to their Btu rating at normal inlet test pressure, and that when measured after

5 minutes of operation, the measured heat input rate must be within $\pm$ 5 percent of the nameplate value.

Based on review of the maximum heat input rates and correlation with the resulting temperature rise in the water loads and energy use measured during the initial heat-up period, DOE has initially determined that the energy use measured using proposed new appendix I1 varies with the nominal heat input rate supplied to each burner on the cooking top. To achieve repeatable and reproducible results, the heat input rate must be specified within appropriate tolerances. To determine the appropriate tolerances, DOE analyzed 37 Energy Test Cycles conducted at multiple heat input rates on nine burners, from three different gas cooking tops.²⁴ For each burner, the measured energy use over each Energy Test Cycle, divided by the grams of water in the test load, referred to as the normalized per-burner energy use, was calculated in Btu

²³ As described previously, IEC 60350–2:2017 specifies test vessels in the following diameters: 120 mm, 150 mm, 180 mm, 210 mm, 240 mm, 270 mm, 300 mm, and 330 mm.

²⁴ DOE analyzed three burners with nameplate heat input rates of 18,000 Btu/h, three burners with nameplate heat input rates of 15,000 Btu/h, and three burners with nameplate heat input rates close

to 5,000 Btu/h. Each burner was tested at four different set points, and one burner was tested at a fifth set point.

per gram ("Btu/g"). A linear curve fit was applied to the set of normalized per-burner energy use data versus measured heat input rate for each burner, and DOE calculated the value of the normalized per-burner energy use on the curve corresponding to the burner's nominal (*i.e.*, nameplate) heat input rate. For each of the nine burners, DOE then plotted the percent change in normalized per-burner energy use from the calculated value as a function of the percent change in the measured heat input rate from the nominal heat input rate, and again applied a linear curve fit

to each data set. These graphs are shown in the Annex to this NOPR, which is available in the docket for this rulemaking.²⁵ Table III.4 presents the slopes of these nine curves, and based on these slopes, DOE calculated the percentage variation in normalized per-burner energy use for a ± 2 percent variation (the EN 30-2-1 specification) and a ± 5 percent variation (the ANSI Z21.1 specification) in heat input rate from nominal. Because each burner exhibits a different relationship between heat input rate and normalized per-burner energy use, identifying a single

correction factor across all gas cooking tops may not be possible, further justifying the need to establish tolerances around the heat input rate. Among the burners in its test sample, DOE's analysis shows that a ± 5 -percent tolerance on the heat input rate of a burner resulted in a variation in per-burner energy use of as much as ± 4.9 percent, whereas a ± 2 -percent tolerance on the heat input rate limited the variation in per-burner energy use in its test sample to ± 2.0 percent.

TABLE III.6—GAS COOKING TOP INPUT RATE VARIATION INVESTIGATION

Unit No.	Burner location	Nameplate heat input rate (Btu/h)	Slope of best-fit line	Calculated variation in energy based on a $\pm 2\%$ variation in heat input rate (%)	Calculated variation in energy based on a $\pm 5\%$ variation in heat input rate (%)
12	FL	18,000	-0.67	± 1.3	± 3.4
13	FL	18,000	0.81	± 1.6	± 4.1
14	C	18,000	0.98	± 2.0	± 4.9
12	BL	15,000	0.51	± 1.0	± 2.5
13	BL	15,000	0.04	± 0.1	± 0.2
15	FR	15,000	0.63	± 1.3	± 3.2
12	BR	5,000	0.56	± 1.1	± 2.8
14	BR	5,500	0.06	± 0.1	± 0.3
15	BL	5,000	-0.24	± 0.5	± 1.2

Based on these results, DOE has tentatively determined that specifying a tolerance of ± 5 percent from the nominal heat input rate may not produce repeatable and reproducible test results. Therefore, DOE is proposing to specify in proposed new appendix I1 that the measured heat input rate be within 2 percent of the nominal heat input rate as specified by the manufacturer.

DOE is proposing that the heat input rate be measured and adjusted for each burner of the cooking top before conducting testing on that burner. The measurement would be taken at the maximum heat input rate, with the properly sized test vessel and water load centered above the burner to be measured. If the measured average heat input rate of the burner is within 2 percent of the nominal heat input rate of the burner as specified by the manufacturer, no adjustment of the heat input rate would be made for any testing of that burner.

DOE is proposing that if the measured average heat input rate of the burner is not within 2 percent of the nominal heat input rate of the burner as specified by the manufacturer, the average heat input rate would be adjusted. For gas cooking

tops with an adjustable internal pressure regulator, the pressure regulator would be adjusted such that the average heat input rate of the burner under test is within 2 percent of the nominal heat input rate of the burner as specified by the manufacturer. For gas cooking tops with a non-adjustable internal pressure regulator or without an internal pressure regulator, the regulator would be removed or blocked in the open position, and the gas pressure ahead of all controls would be maintained at the nominal manifold pressure specified by the manufacturer. These proposed instructions are in accordance with provisions for burner adjustment in Section 5.3.3 of ANSI Z21.1. The gas supply pressure would then be adjusted such that the average heat input rate of the burner under test is within 2 percent of the nominal heat input rate of the burner as specified by the manufacturer. In either case, the burner would be adjusted such that the air flow is sufficient to prevent a yellow flame or flame with yellow tips. Once the heat input rate has been set for a burner, it would not be adjusted during testing of that burner.

DOE requests comment on its proposal for adjusting the burner heat

input rate to the nominal heat input rate as specified by the manufacturer, and to include a 2-percent tolerance on the heat input rate of each burner on a gas cooking top.

5. Target Power Density for Optional Potential Simmering Setting Pre-Selection Test

As discussed in section III.C.3 of this NOPR, Annex H of IEC 60350-2:FDIS provides a target power density for the potential simmering setting pre-selection test for electric cooking tops. In this NOPR, DOE is proposing to specify a separate target power density specific to gas cooking tops, which would be measured in Btu per hour divided by the area of the cookware bottom in square centimeters ("Btu/h-cm²"). To evaluate possible values for this target power density, DOE investigated test data from five gas cooking tops at Laboratory A, as shown in Table III.7, to develop a proposed target power density.

Among the five cooking tops, 22 individual burners were tested three times each, and four individual burners were tested two times each, for a total of 66 test cycles at the minimum-above-threshold power setting (Energy Test

²⁵ The docket web page can be found at www.regulations.gov/docket/EERE-2021-BT-TP-0023.

Cycles) and 66 test cycles at the maximum-below-threshold power setting. In reviewing the estimated corresponding power densities of both sets of energy test cycles, including the individual values and ranges of values for all burners, DOE preliminarily estimates that a target power density of 4.0 Btu/h-cm² would be appropriate.

That is, in the majority of cases, the target power density falls between the power densities at the minimum-above-threshold power setting and maximum-below-threshold power setting. In such cases, the optional potential simmering setting pre-selection test would result in no more than two test cycles being conducted to obtain the Energy Test

Cycle. DOE could consider specifying a different target power density for the potential simmering setting pre-selection test if additional data were to suggest that a different value would be more representative than the proposed value of 4.0 Btu/h-cm².

TABLE III.7—ESTIMATED POWER DENSITY FROM GAS COOKING TOP TESTS

Unit No.	Burner position	Power density of input setting used for the energy test (Btu/h-cm ²)			Power density of input setting below the energy test (Btu/h-cm ²)		
		Test 1	Test 2	Test 3	Test 1	Test 2	Test 3
6	FL	4.3	3.8	5.5	3.2	2.8	3.5
	BL	4.4	4.2	4.4	3.8	2.7	3.2
	BR	6.2	3.9	5.1	3.7	3.0	3.6
	FR	4.5	4.6	4.7	2.7	3.0	3.6
7	FL	6.0	6.4	6.1	4.3	4.5	4.3
	BL	6.2	6.1	6.2	3.1	3.8	4.1
	BR	6.5	6.3	6.0	4.3	5.6	5.9
	FR	6.7	5.8	7.0	4.3	4.3	4.3
8	FL	6.5	6.1	6.3	4.0	4.0	3.9
	BL	6.3	7.1	5.7	4.2	4.0	4.1
	BR	5.4	5.4	5.8	3.2	3.2	3.2
	FR	8.4	7.4	9.2	5.1	4.2	4.1
9	FL	9.3	5.5	5.1	4.9	3.6	3.8
	BL	4.8	6.1	6.3	3.8	3.6	3.6
	BR	7.0	7.7	7.6	3.4	4.1	4.3
	FR	6.4	7.1	7.1	3.7	3.9	4.1
10	FL	5.9	5.9	5.8	2.9	3.0	3.0
	BL	11.6	10.8	11.2	4.7	4.5	4.4
	BC	5.3	4.9	5.4	2.9	2.9	2.9
	FC	7.1	5.8	7.2	4.0	3.8	3.6
	FR	10.7	10.8	5.3	3.9	4.6	2.6
	BR	7.3	7.1	6.1	3.0	2.9	3.0
Range		3.8–11.6			2.6–5.9		

DOE requests comment on its proposed target power density for gas cooking tops of 4.0 Btu/h-cm².

6. Product Temperature Measurement for Gas Cooking Tops

As discussed in section III.C.2.b of this NOPR, DOE is proposing to specify in proposed new appendix I1 that the temperature of the product must be measured at the center of the cooking zone under test prior to any active mode testing. DOE is proposing to specify that this requirement would also apply to gas burner adjustments. DOE is further proposing that for a conventional gas cooking top, the product temperature would be measured inside the burner body of the cooking zone under test, after temporarily removing the burner cap. Prior to the standby mode and off mode power test, the product temperature would be measured as the average of the temperature measured at the center of each cooking zone.

DOE requests comment on its proposal to require the product temperature of a gas cooking top be

measured inside the burner body of the cooking zone under test, after temporarily removing the burner cap.

E. Definitions and Clarifications

As part of this NOPR, DOE is proposing to add certain definitions and clarifications to proposed new appendix I1 in addition to those already described.

1. Operating Modes

To clarify provisions relating to the various operating modes, DOE is proposing to add definitions of “active mode,” “off mode,” “standby mode,” “inactive mode,” and “combined low-power mode” to proposed new appendix I1. These definitions are identical to those that had been established in the 2016 version of appendix I.

DOE is proposing to define active mode as “a mode in which the product is connected to a mains power source, has been activated, and is performing the main function of producing heat by

means of a gas flame, electric resistance heating, or electric inductive heating.”

DOE is proposing to define off mode as “any mode in which a product is connected to a mains power source and is not providing any active mode or standby function, and where the mode may persist for an indefinite time. An indicator that only shows the user that the product is in the off position is included within the classification of an off mode.”

DOE is proposing to define standby mode as “any mode in which a product is connected to a mains power source and offers one or more of the following user-oriented or protective functions which may persist for an indefinite time:

- (1) Facilitation of the activation of other modes (including activation or deactivation of active mode) by remote switch (including remote control), internal sensor, or timer;
- (2) Provision of continuous functions, including information or status displays (including clocks) or sensor-based functions. A timer is a continuous clock

function (which may or may not be associated with a display) that allows for regularly scheduled tasks and that operates on a continuous basis.”

DOE is proposing to define inactive mode as “a standby mode that facilitates the activation of active mode by remote switch (including remote control), internal sensor, or timer, or that provides continuous status display.”

DOE is proposing to define combined low-power mode as “the aggregate of available modes other than active mode, but including the delay start mode portion of active mode.”

DOE requests comment on its proposed definitions of “active mode,” “off mode,” “standby mode,” “inactive mode,” and “combined low-power mode.”

2. Product Configuration and Installation Requirements

For additional clarity, DOE is proposing to add definitions of “combined cooking product,” “freestanding,” “built-in,” and “drop-in” to proposed new appendix I1 that were included in the 2016 version of appendix I, and installation instructions for each of these configurations.

DOE is proposing to define combined cooking product as “a household cooking appliance that combines a cooking product with other appliance functionality, which may or may not include another cooking product. Combined cooking products include the following products: Conventional range, microwave/conventional cooking top, microwave/conventional oven, and microwave/conventional range.”

DOE is proposing that a conventional cooking top or combined cooking product be installed in accordance with the manufacturer’s instructions. If the manufacturer’s instructions specify that the product may be used in multiple installation conditions, the product would be installed according to the built-in configuration. DOE is proposing to require complete assembly of the product with all handles, knobs, guards, and similar components mounted in place; and that any electric resistance heaters, gas burners, and baffles be positioned in accordance with the manufacturer’s instructions. DOE is proposing that if the product can communicate through a network (*e.g.*, Bluetooth® or internet connection), the network function be disabled, if it is possible to disable it by means provided in the manufacturer’s user manual, for the duration of testing. If the network function cannot be disabled, or if means for disabling the function are not provided in the manufacturer’s user manual, the product would be tested in

the factory default setting or in the as-shipped condition. These proposals are consistent with comparable provisions in the supplemental NOPR that DOE published for its microwave oven test procedure on August 3, 2021 (86 FR 41759).

DOE is proposing to define freestanding as applying when “the product is supported by the floor and is not specified in the manufacturer’s instructions as able to be installed such that it is enclosed by surrounding cabinetry, walls, or other similar structures.” DOE is proposing that a freestanding combined cooking product be installed with the back directly against, or as near as possible to, a vertical wall which extends at least 1 foot above the product and 1 foot beyond both sides of the product, and with no side walls.

DOE is proposing to define built-in as applying when “the product is enclosed in surrounding cabinetry, walls, or other similar structures on at least three sides, and can be supported by surrounding cabinetry or the floor.” DOE is proposing to define drop-in as applying when “the product is supported by horizontal surface cabinetry.” DOE is proposing that a drop-in or built-in combined cooking product be installed in a test enclosure in accordance with manufacturer’s instructions.

DOE is proposing that a conventional cooking top be installed with the back directly against, or as near as possible to, a vertical wall which extends at least 1 foot above the product and 1 foot beyond both sides of the product.

DOE requests comment on its proposed definitions of product configurations and installation requirements.

3. Power Settings

DOE is proposing to clarify power setting selection by adding definitions of “power setting,” “infinite power settings,” “multi-ring cooking zone,” and “maximum power setting” in proposed new appendix I1, and by specifying which power settings are considered for each type of cooking zone.

DOE proposes to define power setting as “a setting on a cooking zone control that offers a gas flame, electric resistance heating, or electric inductive heating.”

DOE proposes to define infinite power settings as “a cooking zone control without discrete power settings, allowing for selection of any power setting below the maximum power setting.”

DOE proposes to define a multi-ring cooking zone as “a cooking zone on a

conventional cooking top with multiple concentric sizes of electric resistance heating elements or gas burner rings.”

DOE proposes to define maximum power setting as “the maximum possible power setting if only one cookware item is used on the cooking zone or cooking area of a conventional cooking top, including any optional power boosting features. For conventional electric cooking tops with multi-ring cooking zones or cooking areas, the maximum power setting is the maximum power corresponding to the concentric heating element with the largest diameter, which may correspond to a power setting which may include one or more of the smaller concentric heating elements. For conventional gas cooking tops with multi-ring cooking zones, the maximum power is the maximum heat input rate when the maximum number of rings of the cooking zone are ignited.” This definition is based on the definition of “maximum power” in Section 3.14 of IEC 60350–2:2017 which includes a note specifying that boost function should be considered in determining the maximum power setting.

DOE is also proposing to clarify in proposed new appendix I1 which power settings would be considered in the search for the simmering setting, based on its testing experience. On a multi-ring cooking zone on a conventional gas cooking top, all power settings would be considered, whether they ignite all rings of orifices or not. On a multi-ring cooking zone on a conventional electric cooking top, only power settings corresponding to the concentric heating element with the largest diameter would be considered, which may correspond to operation with one or more of the smaller concentric heating elements energized.

On a cooking zone with infinite power settings where the available range of rotation from maximum to minimum is more than 150 rotational degrees, power settings that are spaced by 10 rotational degrees would be evaluated. On a cooking zone with infinite power settings where the available range of rotation from maximum to minimum is less than or equal to 150 rotational degrees, power settings that are spaced by 5 rotational degrees would be evaluated. Based on its round robin testing and its own testing experience, DOE has tentatively determined that 5 or 10 rotational degrees, as appropriate, would provide sufficient granularity in determining the simmering setting. Given DOE’s proposal, outlined in section III.C.5 of this NOPR, to normalize the energy use of the Energy Test Cycle to a value representative of

an energy test with a final water temperature of 90 °C, DOE has tentatively determined that testing more settings would be unduly burdensome.

DOE requests comment on its proposed definitions of “power setting,” “infinite power settings,” “multi-ring cooking zone,” and “maximum power setting.” DOE also requests comments on its proposal for the subset of power settings on each type of cooking zone that are considered as part of the identification of the simmering setting.

For cooking tops with rotating knobs for selecting the power setting, DOE is aware that the knob may yield different input power results for the same setting depending on the direction in which the knob is turned to reach that setting, due to hysteresis caused by potential backlash in the knob or valve. To avoid hysteresis and ensure consistent input power results for the same knob setting, DOE is proposing that the selection knob be turned in the direction from higher power to lower power to select the potential simmering setting for the test, and that if the appropriate setting is passed, the test must be repeated after allowing the product to return to ambient conditions. DOE has tentatively determined that this proposal would help obtain consistent input power for a given power setting, particularly on gas cooking tops, and thus improve repeatability and reproducibility of the test procedure.

DOE requests comment on its proposal that for cooking tops with rotating knobs for selecting the power setting, the selection knob always be turned in the direction from higher power to lower power to select the potential simmering setting for an energy test.

4. Specialty Cooking Zone

DOE is proposing to include a definition of a “specialty cooking zone,” including the clarification that such a cooking zone would not be tested under proposed new appendix I1. DOE is proposing to define a specialty cooking zone as “any cooking zone that is designed for use only with non-circular cookware, such as bridge zones, warming plates, grills, and griddles.

Specialty cooking zones are not tested under this appendix.”

DOE requests comments on its proposed definition of specialty cooking zone.

5. Target Turndown Temperature

DOE is proposing to include in the proposed new appendix I1 the formula for calculating the target turndown temperature after conducting the overshoot test,²⁶ because DOE testing experience has shown that referencing the definition of this value in IEC 60350–2:2017 (rather than providing the definition within the DOE test procedure) can lead to inadvertent errors in performing the calculation. The target turndown temperature is calculated as 93 °C minus the difference between the maximum measured temperature during the overshoot test, T_{max} , and the 20-second average temperature at the time the power is turned off during the overshoot test, T_{70} . Two common mistakes in calculating the target turndown temperature include using the target value of 70 °C rather than the measured T_{70} in the formula, and failing to round the target turndown temperature to the nearest degree Celsius. By including the formula for the target turndown temperature in the proposed new appendix I1, DOE aims to reduce the incidence of such errors.

DOE requests comments on its proposal to include the formula for the target turndown temperature in the proposed new appendix I1.

F. Test Conditions and Instrumentation

DOE is proposing to incorporate the test conditions and instrumentation requirements of IEC 60350–2:2017 into the proposed new appendix I1 with the following additions.

²⁶ The overshoot test is a test conducted before any simmering tests are initiated. The appropriate test vessel and water load are placed on the heating element or burner, which is turned to the maximum power setting. The power or heat input is shut off when the water temperature reaches 70 °C. The maximum water temperature reached after the power/heat input is shut off is used to calculate the nominal turndown temperature.

1. Electrical Supply

Section 5.2 of IEC 60350–2:2017 specifies that the electrical supply is required to be at “the rated voltage with a relative tolerance of $\pm 1\%$ ” and “the rated frequency $\pm 1\%$.” IEC 60350–2:2017 further specifies that the supply voltage and frequency shall be the nominal voltage and frequency of the country in which the appliance is intended to be used. DOE proposes to specify in the proposed new appendix I1 that the electrical supply for active mode testing be maintained at either 240 volts ± 1 percent or 120 volts ± 1 percent, according to the manufacturer’s instructions, and at 60 Hz ± 1 percent, except for products which do not allow for a mains electrical supply.

DOE requests comment on its proposed electrical supply requirements for active mode testing.

2. Water Load Mass Tolerance

DOE is proposing to specify a tolerance on the water load mass in the proposed new appendix I1. Neither the 2016 version of appendix I nor IEC 60350–2:2017 includes a tolerance on the water load mass. DOE is proposing to specify a tolerance of ± 0.5 grams for each water load mass, to improve the repeatability, and reproducibility of the test procedure.

DOE requests comment on the proposed tolerance of ± 0.5 grams for each water load mass.

3. Test Vessel Flatness

In its petition, AHAM raised concerns about the impact of pan warpage on the repeatability and reproducibility of the test procedure. 83 FR 17944, 17958. For this NOPR, DOE investigated the issue of potential pan warpage over repeated test cycles. DOE conducted repeated testing trials on electric cooking tops, and measured each test vessels’ flatness after every five tests. Figure III.2 shows the measured change in flatness (in mm) from the initial reading for the four test vessel sizes that were most frequently used during this testing.

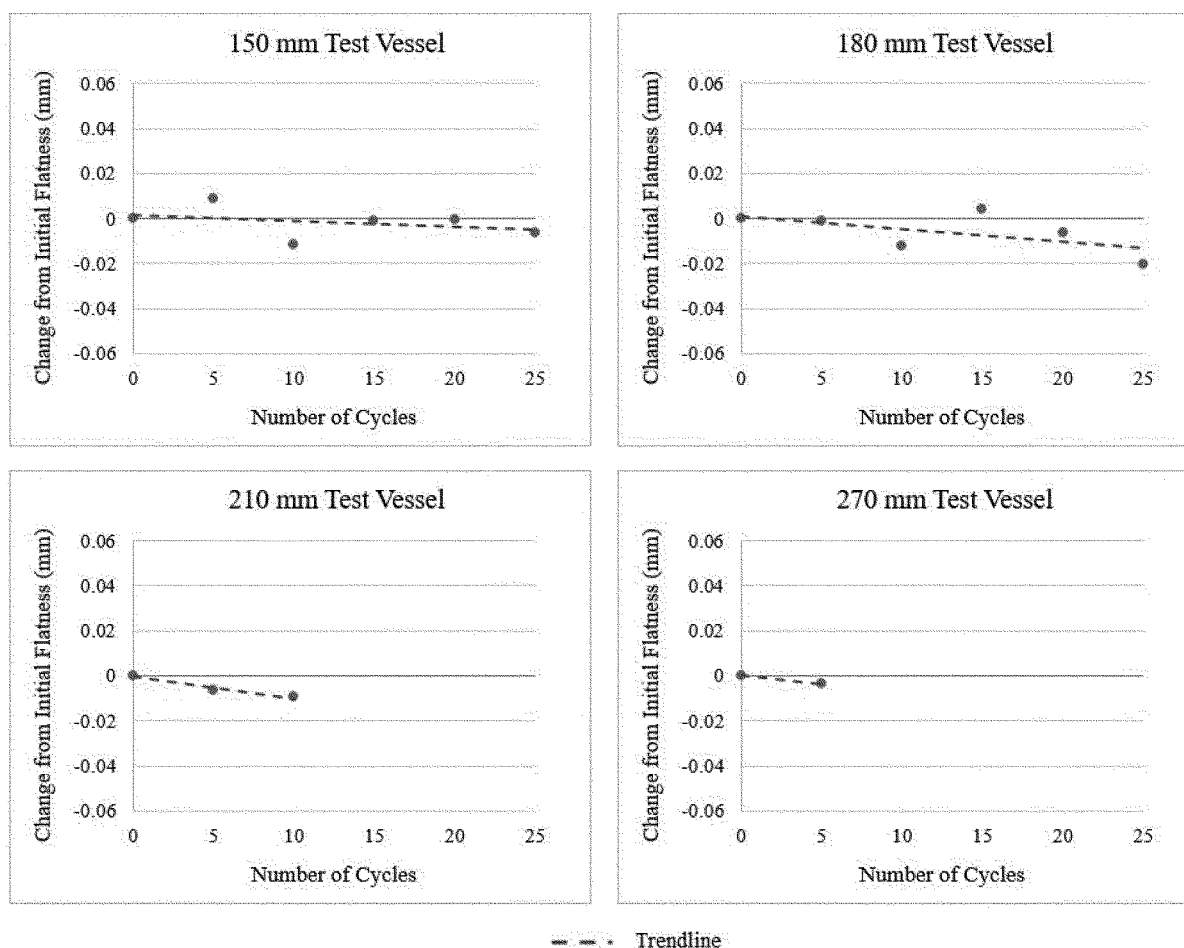


Figure III.2 Measurement of Test Vessel Flatness over Time

Figure III.2 shows there is some variation in the flatness measurement over time for each test vessel, but there is no consistent or substantive trend. Therefore, DOE has tentatively determined that pan warpage is not an issue for the test procedure.

DOE requests comment on its proposed determination that pan warpage does not affect repeatability and reproducibility of the test procedure.

G. Standby Mode and Off Mode Energy Consumption

1. Incorporation by Reference of IEC 62301

EPCA requires DOE to include the standby mode and off mode energy consumption in any energy consumption metric, if technically feasible. In the October 2012 Final Rule, DOE incorporated IEC Standard 62301 Edition 2.0, 2011–01, “Household electrical appliances—Measurement of standby power” (“IEC 62301 Second Edition”) for measuring the power in standby mode and off mode of conventional cooking products,

including the provisions for the room ambient air temperature from Section 4, Paragraph 4.2 of IEC 62301 Second Edition, electrical supply voltage from Section 4, Paragraph 4.3.2 of IEC 62301 Second Edition, watt-meter from Section 4, Paragraph 4.4 of IEC 62301 Second Edition, portions of the installation and set-up from Section 5, Paragraph 5.2 of IEC 62301 Second Edition, and stabilization requirements from Section 5, Paragraph 5.1, Note 1 of IEC 62301 Second Edition. 77 FR 65942, 65948. DOE also specified that the measurement of standby mode and off mode power be made according to Section 5, Paragraph 5.3.2 of IEC 62301 Second Edition, except for conventional cooking products in which power varies as a function of the clock time displayed in standby mode (see section III.G.2 of this NOPR). This procedure is used by microwave ovens in the current version of appendix I. DOE is proposing to include the same procedure in the proposed new appendix I1 for conventional cooking tops.

DOE requests comment on its proposal to incorporate IEC 62301

Second Edition to provide the method for measuring standby mode and off mode power, except for conventional cooking products in which power varies as a function of the clock time displayed in standby mode.

2. Standby Power Measurement for Cooking Tops With Varying Power as a Function of Clock Time

In the October 2012 Final Rule, DOE determined that the measurement of standby mode and off mode power according to Section 5, Paragraph 5.3.2 of IEC 62301 Second Edition for conventional cooking products in which power varies as a function of the clock time displayed in standby mode would cause manufacturers to incur significant burden that would not be warranted by any potential improved accuracy of the test measurement. 77 FR 65942, 65948. Therefore, DOE implemented the following language in the 2012 version of appendix I: For units in which power varies as a function of displayed time in standby mode, clock time would be set to 3:23 at the end of the stabilization period specified in Section 5, Paragraph

5.3 of IEC Standard 62301 (First Edition, June 2005), “Household electrical appliances—Measurement of standby power” (“IEC 62301 First Edition”), and the average power approach described in Section 5, Paragraph 5.3.2(a) of IEC 62301 First Edition would be used, but with a single test period of 10 minutes +0/–2 sec after an additional stabilization period until the clock time reached 3:33. *Id.*

DOE subsequently implemented the same language for microwave ovens in appendix I as part of a final rule published on January 18, 2013. 78 FR 4015, 4020.

In this NOPR, DOE is proposing to incorporate in the proposed new appendix I1 the use of IEC 62301 First Edition for measuring the standby power of cooking tops in which the power consumption of the display varies as a function of the time displayed. DOE is also proposing to update the wording from the 2016 version of appendix I to provide additional direction regarding the two stabilization periods in response to a test laboratory’s feedback. The updated language would read, “For units in which power varies as a function of displayed time in standby mode, set the clock time to 3:23 at the end of an initial stabilization period, as specified in Section 5, Paragraph 5.3 of IEC 62301 First Edition. After an additional 10 minute stabilization period, measure the power use for a single test period of 10 minutes +0/–2 seconds that starts when the clock time first reads 3:33. Use the average power approach described in Section 5, Paragraph 5.3.2(a) of IEC 62301 First Edition.”

DOE requests comment on its proposal to incorporate IEC 62301 First Edition for measuring standby mode and off mode power for conventional cooking tops in which power varies as a function of the clock time displayed in standby mode.

H. Metrics

1. Annual Active Mode Energy Consumption

DOE is proposing to calculate cooking top annual active mode energy consumption as the average normalized per-cycle energy use across all tested cooking zones multiplied by the number of annual cycles. The per-cycle energy use would be normalized in two ways: First, by interpolating to represent a final water temperature of 90 °C, as described in section III.C.5 of this NOPR, and second, by scaling according to the ratio of a representative water load mass to the water mass used in the test.

To determine the representative water load mass for both electric and gas cooking tops, DOE reviewed the surface unit diameters and input rates for cooking tops (including those incorporated into combined cooking products) available on the market at the time of a supplemental NOPR that DOE published prior to the December 2016 Final Rule. 81 FR 57374, 57387 (Aug. 22, 2016). Using the methodology in IEC 60350–2 for selecting test vessel diameters and their corresponding water load masses, DOE determined that the market-weighted average water load mass for both electric and gas cooking top models available on the U.S. market was 2,853 g, and used that value in the December 2016 Final Rule. 81 FR 91418, 91437.

DOE is proposing to use the same representative water load mass for per-cycle energy use normalization of 2,853 g in the proposed new appendix I1.

DOE requests comment on its proposal to use a representative water load mass of 2,853 g in the proposed new appendix I1.

In the December 2016 Final Rule, DOE used data from the 2009 Residential Energy Consumption Survey (“RECS”) and a review of field energy consumption survey data of residential cooking from 2009 and 2010 to estimate 207.5 cycles per year for electric cooking tops and 214.5 cycles per year for gas cooking tops. 81 FR 91418, 91438. For this NOPR, DOE analyzed data available from more recent sources to determine an updated value of annual cooking top cycles.

DOE analyzed the 5,686 household responses from the 2015 RECS to estimate the number of annual cooking top cycles by installation configuration. The 2015 RECS asked respondents, geographically distributed in the United States, to provide the number of uses per week of their standalone cooking top and the cooking top portion of a combined cooking product (which included a cooking top with a conventional oven.) From these weekly frequency-of-use data, DOE calculated weighted-average annual cooking top cycles of 418. This value represents an average of both gas and electric cooking tops, as well as an average of both standalone cooking tops, and of the cooking top component of a combined cooking product. DOE has tentatively determined that a single value for both gas and electric cooking tops is most representative of consumer usage, as DOE is not aware of any reason for consumers of products with different energy sources to use their cooking products differently.

DOE reviewed data provided by AHAM through its task force, which summarized the cooking patterns of 3,508 consumers with connected cooking products, based on information collected via their network functions. Although specific geographical locations were not identified, AHAM indicated the sample of consumers represented a distribution of connected cooking product owners across the United States. This AHAM data set showed an average annual number of cooking top cycles of 365.

DOE also analyzed field-metered data from Pecan Street Inc.’s sample of 246 volunteer homes across four states (California, Texas, New York, and Colorado),²⁷ obtained over a varying number of years per household between 2012 and 2021, which showed a median of 437 annual cooking top cycles.

DOE is proposing to use the 2015 RECS value of 418 cycles per year for calculating annual active mode energy use. This value corresponds to the median of the three considered values and is based on the largest sample size and broadest distribution by geography and household characteristics.

DOE requests comment on its proposal to use a value of 418 annual cooking top cycles per year.

2. Combined Low-Power Mode Hours

The number of cooking top annual combined low-power mode hours is calculated as the number of hours in a year, 8,760, minus the number of annual active mode hours for the cooking top, which is typically equal to the number of annual cycles multiplied by cycle time. Additional calculations, as discussed below, are necessary for the cooking top component of a combined cooking product.

In a NOPR preceding the October 2012 Final Rule, DOE investigated the hours and energy consumption associated with each possible operating mode for conventional cooking tops, including inactive, Sabbath, off, and active modes. 75 FR 75290, 75310 (Dec. 2, 2010). “Sabbath mode” is defined as a mode in which the automatic shutoff is overridden to allow for warming of pre-cooked foods during such periods as the Jewish Sabbath. In its analysis leading up to the October 2012 Final Rule, DOE assigned the hours for which the cooking product is in Sabbath mode as active mode hours, because the energy use of those hours is similar to the energy use of the active mode. 75 FR 75290, 75311. DOE estimated each

²⁷ Information about Pecan Street Inc.’s data set is available at www.pecanstreet.org/dataport/about/.

household's oven spends an equivalent of 8.6 hours in Sabbath mode, based on the number of annual work-free hours and the percentage of U.S. households that observe kosher practices. *Id.* In that rule, DOE scaled the 8.6 hours according to the number of annual cooking cycles, the number of cooking products per household, and an assumption that a cooking top would only be used on the Sabbath a quarter of the time. *Id.*

In 2010, DOE estimated that the total number of cooking top cycles per year was 211 (see section III.H.1 of this NOPR), the average cycle time was 1 hour, and cooking tops spent 2.1 annual hours in Sabbath mode. *Id.* Therefore, in the October 2012 Final Rule, DOE specified that the number of annual active-mode hours was 213.2 and the number of annual combined low-power mode hours was 8,546.9. 77 FR 65942, 65994.

In the December 2016 Final Rule, DOE observed that for combined cooking products, the annual combined low-power mode energy consumption could be measured only for the combined cooking product and not the individual components. 81 FR 91418, 91423. DOE calculated the annual combined low-power mode of the conventional cooking top component of a combined cooking product separately by allocating a portion of the combined low-power mode energy consumption measured for the combined cooking product to the conventional cooking top component using the estimated annual cooking hours for the given components comprising the combined cooking product.

DOE is proposing for this NOPR to update the estimate of the annual combined low-power mode hours for standalone cooking tops and for the cooking top component of combined cooking products, using more recent estimates for the number of annual cooking top cycles and the representative cycle time. As discussed in section III.H.1 of this NOPR, DOE is proposing to use a value of 418 annual cooking top cycles for all cooking tops.

For representative average cooking top cycle time, DOE reviewed data provided by AHAM, which summarized the cooking patterns of 3,508 consumers with connected cooking products, based on information collected via their network functions. Although specific geographical locations were not identified, AHAM indicated the sample of consumers represented a distribution of connected cooking product owners across the United States. This AHAM data set showed an average cooking top cycle time of 18 minutes. DOE is concerned, however, that the usage patterns of consumers with connected cooking products, which are relatively higher-cost premium products, may not be representative of the usage patterns for all U.S. consumers.

DOE also analyzed the field-metered data from Pecan Street Inc.'s sample of 246 volunteer homes,²⁸ which showed a median cycle time of 31 minutes. The distribution of usage patterns among these homes may be representative of consumer habits in the United States as a whole because the metering was not limited to premium products which tend to be purchased by higher-income households.

DOE is proposing to calculate the number of cooking top annual active mode hours per installation configuration by multiplying the annual cycles estimated from the 2015 RECS by the 31-minute median cycle time, and then adding the appropriate number of Sabbath mode hours.²⁹ Using additional values, including the number of cooking tops per household, which was determined to be 1.02 using the 2015 RECS; the annual number of conventional oven cycles conducted per year on combined cooking products, which was determined to be 145 using the 2015 RECS; the number of microwave oven cycles per year, which was determined to be 627 using the 2015 RECS; the average cycle time for a conventional oven, which was assumed to be 1 hour; and the average cycle time for a microwave oven, which was assumed to be 6 minutes, the number of annual active mode hours for the overall cooking product could be estimated. By subtracting the resulting annual active mode hours from 8,760 annual hours, DOE proposes to estimate the annual combined low-power mode hours for the overall product by installation configuration. Finally, the percentages of combined lower-power mode hours assigned to the cooking top component were calculated by determining the proportion of overall active mode hours that are associated with the cooking top component of the combined cooking product. The results for DOE's proposed combined low-power mode usage factors and resulting cooking top annual combined low-power mode hours are shown in Table III.8.

TABLE III.8—COMBINED LOW-POWER MODE USAGE FACTORS

Product type	Overall product		Cooking top	
	Active mode hours per year	Combined low-power mode hours per year	Percentage of overall combined low-power mode hours allocated to the cooking top	Combined low-power mode hours per year
Standalone cooking top	216	8,544	100	8,544
Conventional range (cooking top + conventional oven)	368	8,392	60	5,004
Cooking top + microwave oven	279	8,481	77	6,560
Cooking top + conventional oven + microwave oven	431	8,329	51	4,228

DOE requests comment on its proposed usage factors and annual hours for cooking top combined low-

power mode, as well as on any of the underlying assumptions.

3. Annual Combined Low-Power Mode Energy

DOE is proposing that the annual energy in combined low-power mode

²⁸ Information about Pecan Street Inc.'s data set is available at www.pecanstreet.org/dataport/about/.

²⁹ Given the value of 1.02 cooking tops per household determined using 2015 RECS, and using

the same 25-percent assumption of the percent of time a cooking top is left on during the Sabbath (as opposed to a conventional oven), DOE assumed 2.2 hours per year in Sabbath mode for standalone cooking tops and for combined cooking products

comprised of a microwave oven and a cooking top; and 8.8 hours per year in Sabbath mode for combined cooking products that include a conventional oven.

for a cooking top be calculated as the power consumption of the overall cooking product in standby and/or off mode (see sections III.G.1 and III.G.2 of this NOPR) multiplied by the number of annual combined low-power mode

hours for the cooking top or cooking top component of a combined cooking product (see section III.H.2 of this NOPR). DOE is proposing, as it has done in the test procedures for other appliances which can have either an

inactive (standby) mode, an off mode, or both, that the total number of cooking top annual combined low-power mode hours be allocated to each of inactive mode or off mode as illustrated in Table III.9.

TABLE III.9—ALLOCATION OF COOKING TOP COMBINED LOW-POWER MODE HOURS

Types of low-power mode(s) available	Allocation to inactive mode	Allocation to off mode
Both inactive and off mode	0.5	0.5
Inactive mode only	1	0
Off mode only	0	1

DOE requests comment on its proposed allocation of combined low-power mode hours.

4. Integrated Annual Energy Consumption

DOE is proposing to define the integrated annual energy consumption ("IAEC") for each tested cooking top. For electric cooking tops, IAEC is defined in kilowatt-hours ("kWh") per year and is equal to the sum of the annual active mode energy and the annual combined low-power mode energy. For gas cooking tops, IAEC is defined in kilo-British thermal units ("kBtu") per year and is equal to the sum of the annual active mode gas energy consumption, the annual active mode electric energy consumption (converted into kBtu per year), and the annual combined low-power mode energy (converted into kBtu per year).

5. Annual Energy Consumption and Annual Cost

Section 430.23(i) of title 10 of the CFR lists the test procedures for the measurement of energy consumption of cooking products. As there are no current test procedures for conventional cooking tops, 10 CFR 430.23(i) currently contains provisions only for microwave ovens.

DOE is proposing to renumber the existing microwave oven paragraph as 10 CFR 430.23(i)(1) and to add new paragraphs (i)(2) through (i)(6) containing provisions for measuring the electrical energy consumption, gas energy consumption, and annual cost of conventional cooking tops.

New paragraph (i)(2) would provide the means of calculating the integrated annual energy consumption for either a conventional electric cooking top or a conventional gas cooking top, including any conventional cooking top component of a combined cooking product. The result would be rounded to the nearest 1 kWh per year for electric

cooking tops, and to the nearest 1 kBtu per year for gas cooking tops.

New paragraph (i)(3) would provide the means of calculating the total annual gas energy consumption of a conventional gas cooking top, including any conventional cooking top component of a combined cooking product. The result would be rounded to the nearest 1 kBtu per year.

New paragraph (4) would provide the means of calculating the total annual electrical energy consumption for either a conventional electric cooking top or a conventional gas cooking top, including any conventional cooking top component of a combined cooking product. The result would be rounded to the nearest 1 kWh per year. The total annual electrical energy consumption of a conventional electric cooking top would equal the integrated annual energy consumption of the conventional electric cooking top, as determined in paragraph (i)(2).

New paragraph (i)(5) would provide the means of calculating the estimated annual operating cost corresponding to the energy consumption of a conventional cooking top, including any conventional cooking top component of a combined cooking product. The result would be rounded to the nearest dollar per year.

New paragraph (i)(6) would allow the definition of other useful measures of energy consumption for conventional cooking tops that the Secretary determines are likely to assist consumers in making purchasing decisions and that are derived from the application of appendix I1.

DOE requests comment on its proposed provisions for measuring annual energy consumption and estimated annual cost.

I. Alternate Proposals

DOE is aware of alternate approaches to the proposed cooking top test procedure that are currently being considered by stakeholders, such as

those described in the subsections that follow. While in most cases DOE does not have data by which to evaluate such alternate approaches, DOE would consider the alternates discussed if sufficient data were available to evaluate whether such test procedures are reasonably designed to produce test results which measure energy use of conventional cooking tops during a representative average use cycle or period of use and are not be unduly burdensome to conduct. (See 42 U.S.C. 6293(b)(3))

1. Separate Boiling and Simmering Tests

DOE is aware that some manufacturers have indicated a preference for a test procedure that does not include a simmering portion. A test procedure that omits simmering would only capture the energy use associated with boiling and therefore would not be representative of an average energy use cycle, which DOE asserts would include a simmering period. Therefore, DOE has tentatively determined that a cooking top test procedure that does not include both a heat-up period and a simmering period would not produce test results that measure energy efficiency, energy use or estimated annual operating cost of a covered product during a representative average use cycle or period of use, as required by EPCA. (42 U.S.C. 6293(b)(3))

However, DOE could consider separating the heat-up and the simmering portions of the test into two shorter test runs, which could each be subject to fewer failure conditions. For instance, DOE could consider a heat-up test that is similar to the overshoot test in IEC 60350-2:2017, but for which the power is turned off at 90 °C instead of 70 °C. If DOE were to consider this approach, the temperature overshoot by the water after the power is turned off could be used to normalize the energy used per degree of water heated. The test procedure could then require a separate test to measure the simmering

energy of a cooking top, for example by starting with already-simmering water at 90 °C and maintaining it at that temperature.

This approach could potentially reduce burden by reducing the overall time required to test each power setting.

DOE requests data on the test burden, repeatability, reproducibility, and representativeness of a test procedure that would separate the boiling and simmering tests.

2. Replacing the Simmering Test With a Simmering Usage Factor

Another approach could be to simplify the test procedure such that it requires only a single test per cooking zone. This test could entail a simple heat-up test at the maximum power setting until the water temperature reaches a threshold temperature, such as 90 °C or the target turndown temperature. A simmering usage factor could then be applied to the measured energy use in order to scale the energy

of the heat-up only test to a value that is representative of typical consumer usage including a simmering phase.

An initial analysis of DOE test data suggests that for electric cooking tops, the simmering energy may be a consistent fraction of the heat-up energy for each heating technology type. However, for gas cooking tops, the potential simmering usage factor is more variable by individual cooking top and cooking zone. DOE test data for Laboratory A is presented in Table III.10.

TABLE III.10—SIMMERING ENERGY AS A FRACTION OF HEAT-UP ENERGY

Unit No.	Type	Potential simmering usage factor (average of 3 replications)						Average by cooking top	Average by technology
	Cooking zone No.:	1	2	3	4	5	6		
1	Electric-Coil	1.34	1.39	1.36	1.42			1.38	1.38
2	Electric-Smooth (Radiant)	1.34	1.36	1.32	1.38			1.35	1.35
3	Electric-Smooth (Radiant)	1.34	1.34	1.36	1.34	1.37		1.35	
4	Electric-Smooth (Induction)	1.47	1.45	1.41	1.38			1.43	1.41
5	Electric-Smooth (Induction)	1.40	1.38	1.42	1.38			1.40	
6	Gas	1.41	1.39	1.45	1.38			1.41	1.38
7	Gas	1.27	1.34	1.36	1.27			1.31	
10	Gas	1.33	1.63	1.29	1.37	1.50	1.38	1.41	

If DOE were to adopt a test procedure that uses a simmering usage factor, the usage factor would need to be based on test data and would need to be representative of a tested simmering period on multiple types of products. DOE has tentatively determined, based on the available data, that no such single simmering usage factor by heating technology can be defined, and is not proposing to pursue this approach at this time.

DOE requests data on the representativeness of a simmering usage factor across technology types.

3. Changing the Setting Used To Calculate Simmering Energy

IEC 60350–2:2017 defines the simmering setting according to the temperature characteristics of the water load at that power setting. As an alternative, DOE could consider defining the simmering setting according to the power supplied at each power setting. For instance, DOE could define the simmering setting as the lowest power setting that is at or above 25 percent of maximum power (or maximum heat input rate for gas cooking tops). This alternative approach could result in only a single simmering test being required.

To the extent that consumers choose a simmering power setting based on knob position (or setting number) rather than by directly or indirectly monitoring the temperature variation of the food or water in the cookware, this potential alternative could yield more

representative results than the current proposal. DOE previously established a power-level-based test procedure as part of the October 2012 Final Rule. 77 FR 65942.

DOE requests data on the representativeness of a simmering setting based on a percentage of the maximum power setting.

4. Industry Test Procedures

DOE is aware that AHAM is developing test procedures for electric and gas cooking tops as part of its task force efforts. Although AHAM's test procedures have not been finalized at the time of publication of this NOPR, DOE understands the provisions in the draft test procedures as of September 1, 2021 to be substantially the same as those proposed in this NOPR. If AHAM were to finalize its test procedures ahead of the publication of any DOE test procedure final rule for conventional cooking tops, DOE could consider incorporating the AHAM procedure by reference, instead of using the language proposed in this NOPR, if the provisions are substantively the same as those proposed in this NOPR. If the finalized AHAM procedure were to contain significant differences from the procedures proposed in this NOPR, DOE would publish a supplemental proposal before proceeding to a final rule.

J. Representations

1. Sampling Plan

DOE is proposing to maintain the sampling plan requirements for cooking products in 10 CFR 429.23(a), which specify that for each basic model of cooking products a sample of sufficient size shall be randomly selected and tested to ensure that any represented value for which consumers would favor lower values shall be greater than or equal to the higher of the mean of the sample or the upper 97.5 percent confidence limit of the true mean divided by 1.05.

DOE seeks comment on the proposed method for establishing a sampling plan.

2. Convertible Cooking Appliances

DOE defines a convertible cooking appliance as any kitchen range and oven which is a household cooking appliance designed by the manufacturer to be changed in service from use with natural gas to use with LP-gas, and *vice versa*, by incorporating in the appliance convertible orifices for the main gas burners and a convertible gas pressure regulator. 10 CFR 430.2.

In the May 1978 Final Rule, DOE established a requirement for two estimated annual operating costs for convertible cooking appliances: An estimated annual operating cost reflecting testing with natural gas and a cost reflecting testing with propane. 43 FR 20108, 20110. DOE allowed manufacturers to use the amount of

energy consumed during the test with natural gas to determine the estimated annual operating cost of the appliance reflecting testing with propane. DOE provided this allowance based on test data that showed that conventional cooking products tested with propane yielded slightly higher efficiencies than the same products tested with natural gas. *Id.*

In the version of 10 CFR 430.23 finalized in the December 2016 Final Rule, convertible cooking tops were required to be tested using both natural gas and propane, although the version of appendix I finalized in that same rule listed the test gas as natural gas or propane. 81 FR 91418, 91488. DOE does not require testing both natural gas and propane for any other convertible appliances.

In this NOPR, DOE is proposing to specify that all gas cooking tops shall be tested using the default test gas (*i.e.*, the appropriate test gas given the as-shipped configuration of the cooking top) and is proposing to not require any convertible cooking top to be tested using both natural gas and propane.

DOE requests comment on its proposal to test all gas cooking tops using the default test gas, as defined by the as-shipped configuration of the unit.

Therefore, DOE is further proposing to delete the definition of convertible cooking appliance in 10 CFR 430.2, since such distinction would no longer be needed and may cause confusion.

DOE requests comment on its proposal to delete the definition of convertible cooking appliance from 10 CFR 430.2.

K. Reporting

DOE is not proposing to require reporting of cooking top energy use

until such time as compliance is required with a performance-based energy conservation standard, should such a standard be established. DOE is proposing to add an introductory note to proposed new appendix I1 to that effect.

L. Test Procedure Costs

In this NOPR, DOE proposes to establish a new test procedure for conventional cooking tops in a new appendix I1. The test procedure proposed in this NOPR would adopt the latest version of the relevant industry standard with modifications to adapt the test method to gas cooking tops (including specifying gas supply tolerances), offer an optional method for burden reduction, normalize the energy use of each test cycle, include measurement of standby mode and off mode energy use, update certain test conditions, and provide certain clarifying language. If manufacturers voluntarily chose to make representations regarding the energy efficiency of conventional cooking tops, manufacturers would be required to test according to the DOE test procedure, if finalized.

DOE has initially determined that this proposal, if finalized, would result in added costs to conventional cooking top manufacturers, if manufacturers choose to make efficiency representations for the conventional cooking tops that they manufacture. Additionally, manufacturers would incur testing costs if DOE were to establish a performance-based energy conservation standard for conventional cooking tops.

To determine this potential cost to manufacturers, DOE first attempted to estimate the number of models that could be covered under these proposed

test procedures. DOE used data from DOE's publicly available Compliance Certification Database ("CCD"),³⁰ California Energy Commission's ("CEC's") Modernized Appliance Efficiency Database ("MAEDBS"),³¹ Natural Resources Canada's publicly searchable database,³² AHAM's member directory,³³ and individual catalog data from identified conventional cooking top manufacturers to estimate both the number of conventional cooking top manufacturers and the number of models potentially covered by the proposed test procedure. Based on DOE's analysis, DOE identified approximately 45 manufacturers selling an estimated 1,606 unique basic models of conventional cooking tops covered by this proposed test procedure.

Based on an initial market assessment, DOE conservatively estimated that the largest seven manufacturers account for at least 75 percent of the conventional cooking tops sold in the United States. DOE assumed that these largest seven companies would test all their conventional cooking top models covered by this proposed test procedure at their in-house test facility (representing 1,205 basic models), while the remaining 25 percent would be tested at a third-party testing facility (representing 401 basic models). DOE assumed that the per-unit test costs differ between conducting testing at in-house test facilities versus testing at third-party test facilities. Table III.11 lists the estimated in-house and third-party test costs potentially incurred by manufacturers.

TABLE III.11—ESTIMATED NUMBER OF CONVENTIONAL COOKING TOP MODELS TESTED AND ASSOCIATED ONE-TIME PER-UNIT TEST COST

Type of test facility	Per-unit test cost	Number of models tested	Units tested per model	Total one-time testing cost
In-House Testing Facility	\$729	1,205	2	\$1,756,890
Third-Party Testing Facility	3,000	401	2	2,406,000
Total				4,162,890

³⁰ DOE currently requires manufacturers to certify that all conventional cooking product models using gas are not equipped with a standing pilot light. See www.regulations.doe.gov/certification-data. Last accessed on May 24, 2021.

³¹ cacertappliances.energy.ca.gov/Pages/Search/AdvancedSearch.aspx. Last accessed on May 24, 2021.

³² oe.nrcan.gc.ca/pml-lmp/index.cfm?action=app.welcome-bienvenue. Last accessed on May 24, 2021.

³³ www.aham.org/AHAM/AuxCurrentMembers. Last accessed on May 24, 2021.

To estimate in-house testing cost, DOE estimated based on its testing experience that testing a single conventional cooking top unit to the proposed test procedure requires approximately 17.5 hours of a technician's time. Based on data from the Bureau of Labor Statistics' ("BLS's") Occupational Employment and Wage Statistics, the mean hourly wage for mechanical engineering technologists and technicians is \$29.27.³⁴ Additionally, DOE used data from BLS's Employer Costs for Employee Compensation to estimate the percent that wages comprise the total compensation for an employee. DOE estimates that wages make up 70.3 percent of the total compensation for private industry employees.³⁵ Therefore, DOE estimated that the total hourly compensation (including all fringe benefits) of a technician performing the testing is \$41.64.³⁶ Using these labor rates and time estimates, DOE estimates that it would cost conventional cooking top manufacturers approximately \$729 to conduct a single test on a conventional cooking top unit, if this test was conducted at an in-house test facility.

To estimate third-party laboratory costs, DOE received quotes from test laboratories on the price of conducting a similar conventional cooking top test procedure. DOE then averaged these prices to arrive at an estimate of what the manufacturers would have to spend to test their product using a third-party test laboratory. Using these quotes, DOE estimates that it would cost conventional cooking top manufacturers approximately \$3,000 to conduct a single test on a conventional cooking top unit, if this test was conducted at a third-party laboratory test facility. Using this assumption, DOE estimates that it would cost conventional cooking top manufacturers approximately \$1,458 per basic model, if tested at an in-house test facility and approximately \$6,000 per basic model, if tested at a third-party laboratory test facility.

Based on these estimates, DOE estimated that conventional cooking top

manufacturers would incur approximately \$4.2 million³⁷ to initially test all conventional cooking top basic models that are currently on the market according to the test procedure proposed in this NOPR.

DOE requests comment on any aspect of the estimated initial testing costs associated with DOE's proposed test procedures.

DOE also estimated that conventional cooking top manufacturers would need to purchase test vessels in accordance with the test procedures proposed in this NOPR. DOE estimated that, on average, the largest seven manufacturers would purchase approximately 20 sets of test vessels each; while 19 manufacturers would purchase approximately two sets of testing vessels each; and the remaining 19 manufacturers would not purchase any testing vessels, as all the models manufactured by these manufacturers would be tested at a third-party testing facility. Based on these assumptions, DOE estimated that the entire conventional cooking top industry would purchase approximately 178 sets of test vessels to be able to conduct this proposed test procedure, if finalized.³⁸ DOE estimated that each set of test vessels would cost approximately \$6,000. Therefore, DOE estimated that all conventional cooking top manufacturers would incur approximately \$1.1 million to purchase the equipment necessary to conduct the test procedure proposed in this NOPR.³⁹

In addition to these one-time testing costs to initially test all covered conventional cooking top basic models and the testing equipment needed to conduct the proposed test procedure, DOE assumed smaller annual recurring testing costs as conventional cooking top models are either newly introduced into the market or existing models are remodeled. DOE estimated that conventional cooking tops are redesigned approximately once every 3 years on average. Using this redesign cycle time-frame and the test costs and model count estimates previously stated, DOE estimated that conventional cooking top manufacturers would incur approximately \$1.4 million every year to test these newly introduced or remodeled conventional cooking top models.⁴⁰

DOE requests comment on any aspect of the estimated recurring testing costs associated with conventional cooking tops.

M. Compliance Date

EPCA prescribes that, if DOE establishes a new test procedure, all representations of energy efficiency and energy use, including those made on marketing materials and product labels, must be made in accordance with that new test procedure, beginning 180 days after publication of such a test procedure final rule in the **Federal Register**. (42 U.S.C. 6293(c)(2))

If DOE were to publish a new test procedure for conventional cooking tops, EPCA provides an allowance for individual manufacturers to petition DOE for an extension of the 180-day period if the manufacturer may experience undue hardship in meeting the deadline. (42 U.S.C. 6293(c)(3)) To receive such an extension, petitions must be filed with DOE no later than 60 days before the end of the 180-day period and must detail how the manufacturer will experience undue hardship. (*Id.*)

As previously stated, currently no performance-based energy conservation standards are prescribed for conventional cooking tops. Were DOE to finalize the test procedure as proposed, manufacturers would not be required to test according to the DOE test procedure unless manufacturers voluntarily choose to make representations as to the energy efficiency or energy use of a conventional cooking top. Were DOE to establish energy conservation standards for conventional cooking tops, manufacturers would be required to test according to the finalized test procedure at such time as compliance would be required with the established standards.

IV. Procedural Issues and Regulatory Review

A. Review Under Executive Order 12866

The Office of Management and Budget ("OMB") has determined that this test procedure rulemaking does not constitute "significant regulatory actions" under section 3(f) of Executive Order ("E.O.") 12866, Regulatory Planning and Review, 58 FR 51735 (Oct. 4, 1993). Accordingly, this action was not subject to review under the Executive order by the Office of Information and Regulatory Affairs ("OIRA") in OMB.

facility and approximately 134 unique basic models would be tested at a third-party test facility each year. These estimates add up to approximately one-third of the total estimated number of unique basic models currently on the market.

³⁴ DOE used the mean hourly wage of the "17–3027 Mechanical Engineering Technologists and Technicians" from the most recent BLS Occupational Employment and Wage Statistics (May 2020) to estimate the hourly wage rate of a technician assumed to perform this testing. See www.bls.gov/oes/current/oes173027.htm. Last accessed on May 26, 2021.

³⁵ DOE used the December 2020 "Employer Costs for Employee Compensation" to estimate that for "Private Industry Workers," "Wages and Salaries" are 70.3 percent of the total employee compensation. See www.bls.gov/news.release/archives/ecec_03182021.pdf. Last accessed on May 26, 2021.

³⁶ \$29.27 + 0.703 = \$41.64.

³⁷ In-House: $\$1,458 \times 1,205 = \$1,756,890$. Third-Party: $\$6,000 \times 401 = \$2,406,000$. Total: $\$1,756,890 + \$2,406,000 = \$4,162,890$ (rounded to \$4.2 million).

³⁸ $(7 \times 20) + (19 \times 2) = 178$.

³⁹ $\$6,000 \times 178 = \$1,068,000$ (rounded to \$1.1 million).

⁴⁰ DOE estimated that approximately 401 unique basic models would be tested at an in-house test

B. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires preparation of an initial regulatory flexibility analysis (“IRFA”) for any rule that by law must be proposed for public comment, unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. As required by Executive Order 13272, “Proper Consideration of Small Entities in Agency Rulemaking,” 67 FR 53461 (August 16, 2002), DOE published procedures and policies on February 19, 2003, to ensure that the potential impacts of its rules on small entities are properly considered during the DOE rulemaking process. 68 FR 7990. DOE has made its procedures and policies available on the Office of the General Counsel’s website: <https://energy.gov/gc/office-general-counsel>.

1. Description of Reasons Why Action Is Being Considered

DOE is proposing to establish test procedures for conventional cooking tops. Establishing test procedures for conventional cooking tops assists DOE in fulfilling its statutory deadline for amending energy conservation standards for cooking products that achieve the maximum improvement in energy efficiency that is technologically feasible and economically justified. (42 U.S.C. 6295(o)(2)(A)) Additionally, establishing test procedures for conventional cooking tops, allows manufacturers to produce measurements of energy use that are representative of an average use cycle and uniform for all manufacturers.

2. Objectives of, and Legal Basis for, Rule

DOE has undertaken this rulemaking pursuant to 42 U.S.C. 6292(a)(10), which authorizes DOE to regulate the energy efficiency of a number of consumer products and certain industrial equipment, including the cooking products that are the subject of this rulemaking.

3. Description and Estimated Number of Small Entities Regulated

For manufacturers of conventional cooking tops, the Small Business Administration (“SBA”) has set a size threshold, which defines those entities classified as “small businesses” for the purposes of the statute. DOE used the SBA’s small business size standards to determine whether any small entities would be subject to the requirements of the rule. (See 13 CFR part 121.) The size standards are listed by North American Industry Classification System (“NAICS”) code and industry description and are available at www.sba.gov/document/support—table-size-standards. Manufacturing conventional cooking tops is classified under NAICS 335220, “major household appliance manufacturing.” The SBA sets a threshold of 1,500 employees or fewer for an entity to be considered as a small business for this category.

DOE reviewed the test procedures proposed in this NOPR under the provisions of the Regulatory Flexibility Act and the procedures and policies published on February 19, 2003. DOE used publicly available information to identify potential small businesses that manufacture conventional cooking tops. DOE used data from DOE’s publicly available CCD,⁴¹ CEC’s MAEDBS,⁴² Natural Resources Canada’s publicly searchable database,⁴³ AHAM’s member directory,⁴⁴ and manufacturers identified in previous DOE rulemakings to identify all potential manufacturers of conventional cooking tops sold in the United States. Once DOE created a list of potential manufacturers, DOE used market research tools (*e.g.*, D&B Hoover) to determine whether they met the SBA’s definition of a small entity, based on the total number of employees for each company.

Based DOE’s analysis, DOE identified 45 companies potentially selling conventional cooking tops covered by this proposed test procedure in the United States. DOE screened out companies that do not offer products impacted by this proposed rulemaking, do not meet the definition of a “small business,” or are foreign-owned and operated. Of these 45 conventional cooking top manufacturers, DOE identified up to 13 small businesses.

4. Description and Estimate of Compliance Requirements Including Differences in Cost, if Any, for Different Groups of Small Entities

As previously stated, DOE identified 13 small businesses potentially selling conventional cooking tops in the United States. Based on a review of publicly available model databases and individual company product catalogues, DOE estimated the number of conventional cooking tops covered by this test procedure proposal for each small business. DOE estimated the number of conventional cooking top models covered by this test procedure proposal for each small business ranges from four unique basic covered models to 93 unique basic covered models, depending on the specific small business. DOE conservatively estimated that all small businesses would have all their conventional cooking top models tested at a third-party testing facility.⁴⁵ As discussed in section III.L of this document, DOE estimated it would cost conventional cooking top manufacturers approximately \$6,000 per unique basic model to be tested at a third-party test facility. Therefore, DOE estimated that a small business could incur anywhere from \$24,000 to \$558,000 if all their conventional cooking top models covered by this test procedure proposal were tested at a third-party test facility.⁴⁶ These costs represent the minimum and maximum one-time cost that a small business would incur to initially test all unique basic covered models.

Additionally, DOE used D&B Hoover to estimate the annual revenue for each potential small business. DOE used these annual revenue estimates in addition to the number of conventional cooking top models covered by this test procedure proposal to estimate the potential impact of initially testing all unique basic covered models on small businesses. These costs represent the initial one-time cost to test all unique basic covered models. DOE grouped these small businesses together based on the estimated annual revenue. Table IV.1 displays the one-time testing burden on potential small businesses.

⁴¹ DOE currently requires manufacturers to certify that all conventional cooking product models using gas are not equipped with a standing pilot light. See www.regulations.doe.gov/certification-data. Last accessed on May 24, 2021.

⁴² cacertappliances.energy.ca.gov/Pages/Search/AdvancedSearch.aspx. Last accessed on May 24, 2021.

⁴³ oe.nrcan.gc.ca/pml-lmp/index.cfm?action=app.welcome-bienvenue. Last accessed on May 24, 2021.

⁴⁴ www.aham.org/AHAM/AuxCurrentMembers. Last accessed on May 24, 2021.

⁴⁵ DOE estimated a higher per-model testing cost when the test was conducted at a third-party testing

facility versus if the test was conducted at an in-house testing facility.

⁴⁶ 4 models × \$6,000 = \$24,000. 93 models × \$6,000 = \$558,000.

TABLE IV.1—ESTIMATED ONE-TIME TESTING BURDEN ON SMALL BUSINESSES, BY ANNUAL REVENUE

Firm size (by annual revenue)	Number of small businesses	Average annual revenue	Average number of models	Average one-time testing cost	Testing cost as a percent of annual revenue
<\$2,000,000	3	\$1,196,667	5.7	\$34,200	2.9
\$2 million –	4	8,825,000	58.5	351,000	4.0
\$15 million	4	25,250,000	54.0	324,000	1.3
\$15 million –					
>\$50 million	2	158,000,000	10.5	63,000	0.0

In section III.L of this document, DOE estimated that conventional cooking top manufacturers that conducted testing at in-house testing facilities would be required to purchase test vessels in accordance with the test procedures proposed in this NOPR. DOE assumed that all small businesses would conduct testing at a third-party test facility. Therefore, DOE did not estimate small

businesses would incur any costs to purchase test vessels.

In addition to these one-time testing costs to initially test all covered conventional cooking top basic models, DOE assumed smaller annual recurring testing costs as conventional cooking top models are either newly introduced into the market or existing models are remodeled. DOE estimated that

conventional cooking tops are redesigned approximately once every 3 years on average. Using this redesign cycle time-frame and the annual revenue estimates previously described, DOE estimated the potential impact of the annual recurring testing costs on small businesses. Table IV.2 displays the annual testing burden on potential small businesses.

TABLE IV.2—ESTIMATED ANNUAL TESTING BURDEN ON SMALL BUSINESSES, BY ANNUAL REVENUE

Firm size (by annual revenue)	Number of small businesses	Average annual revenue	Average number of models introduced annually	Average annual testing cost	Testing cost as a percent of annual revenue
<\$2,000,000	3	\$1,196,667	1.9	\$11,400	1.0
\$2 million –	4	8,825,000	19.5	117,000	1.3
\$15 million	4	25,250,000	18.0	108,000	0.4
\$15 million –					
>\$50 million	2	158,000,000	3.5	21,000	0.0

5. Duplication, Overlap, and Conflict with Other Rules and Regulations

DOE is not aware of any rules or regulations that duplicate, overlap, or conflict with the rule being considered today.

6. Significant Alternatives to the Rule

The discussion in the previous section analyzes impacts on small businesses that would result from DOE's proposed test procedure, if finalized. In reviewing alternatives to the proposed test procedure, DOE examined not establishing a performance-based test procedure for conventional cooking tops or establishing prescriptive-based test procedures for conventional cooking tops. While not establishing performance-based test procedures or establishing prescriptive-based test procedures for conventional cooking tops would reduce the burden on small businesses, DOE must use test procedures to determine whether the products comply with relevant standards promulgated under EPCA. (42 U.S.C. 6295(s)) Since establishing

performance-based test procedures for conventional cooking tops is necessary prior to establishing performance-based energy conservation standards for conventional cooking tops, and DOE is required under EPCA to evaluate energy conservation standards for conventional cooking products, including cooking tops, DOE tentatively concludes that establishing performance-based test procedures, as proposed in this NOPR, supports DOE's authority to achieve the maximum improvement in energy efficiency that is technologically feasible and economically justified. (42 U.S.C. 6295(o)(2)(A))

DOE notes there currently are no energy conservation standards prescribed for conventional cooking tops. Therefore, manufacturers would not be required to conduct the proposed test procedure, if made final, until such time as compliance is required with energy conservation standards, should DOE establish such standards, unless manufacturers voluntarily chose to make representations as to the energy use or energy efficiency of a conventional cooking top.

Additional compliance flexibilities may be available through other means. EPCA provides that a manufacturer whose annual gross revenue from all of its operations does not exceed \$8 million may apply for an exemption from all or part of an energy conservation standard for a period not longer than 24 months after the effective date of a final rule establishing the standard. (42 U.S.C. 6295(t)) Additionally, manufacturers subject to DOE's energy efficiency standards may apply to DOE's Office of Hearings and Appeals for exception relief under certain circumstances. Manufacturers should refer to 10 CFR part 430, subpart E, and 10 CFR part 1003 for additional details.

C. Review Under the Paperwork Reduction Act of 1995

Manufacturers of covered products must certify to DOE that their products comply with any applicable energy conservation standards. To certify compliance, manufacturers must first obtain test data for their products according to the DOE test procedures,

including any amendments adopted for those test procedures. DOE has established regulations for the certification and recordkeeping requirements for all covered consumer products and commercial equipment. (See generally 10 CFR part 429.) The collection-of-information requirement for the certification and recordkeeping is subject to review and approval by OMB under the Paperwork Reduction Act ("PRA"). This requirement has been approved by OMB under OMB control number 1910-1400. Public reporting burden for the certification is estimated to average 35 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

There is currently no performance-based energy conservation standard for conventional cooking tops. As such, if finalized, the test procedure as proposed would not establish a reporting requirement.

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB Control Number.

D. Review Under the National Environmental Policy Act of 1969

In this proposed rule, DOE proposes test procedure amendments that it expects will be used to develop and implement future energy conservation standards for conventional cooking tops. DOE has determined that this rule falls into a class of actions that are categorically excluded from review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) and DOE's implementing regulations at 10 CFR part 1021. Specifically, DOE has determined that adopting test procedures for measuring energy efficiency of consumer products and industrial equipment is consistent with activities identified in 10 CFR part 1021, Appendix A to Subpart D, A5 and A6. Accordingly, neither an environmental assessment nor an environmental impact statement is required.

E. Review Under Executive Order 13132

Executive Order 13132, "Federalism," 64 FR 43255 (Aug. 4, 1999) imposes certain requirements on agencies formulating and implementing policies or regulations that preempt State law or that have federalism implications. The Executive order requires agencies to

examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and to carefully assess the necessity for such actions. The Executive order also requires agencies to have an accountable process to ensure meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications. On March 14, 2000, DOE published a statement of policy describing the intergovernmental consultation process it will follow in the development of such regulations. 65 FR 13735. DOE has examined this proposed rule and has determined that it would 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. EPCA governs and prescribes Federal preemption of State regulations as to energy conservation for the products that are the subject of this proposed rule. States can petition DOE for exemption from such preemption to the extent, and based on criteria, set forth in EPCA. (42 U.S.C. 6297(d)) No further action is required by Executive Order 13132.

F. Review Under Executive Order 12988

Regarding the review of existing regulations and the promulgation of new regulations, section 3(a) of Executive Order 12988, "Civil Justice Reform," 61 FR 4729 (Feb. 7, 1996), imposes on Federal agencies the general duty to adhere to the following requirements: (1) Eliminate drafting errors and ambiguity, (2) write regulations to minimize litigation, (3) provide a clear legal standard for affected conduct rather than a general standard, and (4) promote simplification and burden reduction. Section 3(b) of Executive Order 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation (1) clearly specifies the preemptive effect, if any, (2) clearly specifies any effect on existing Federal law or regulation, (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction, (4) specifies the retroactive effect, if any, (5) adequately defines key terms, and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires executive agencies to review regulations in light of applicable standards in sections 3(a) and 3(b) to determine whether they are met or it is unreasonable to meet one or more of

them. DOE has completed the required review and determined that, to the extent permitted by law, the proposed rule meets the relevant standards of Executive Order 12988.

G. Review Under the Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 ("UMRA") requires each Federal agency to assess the effects of Federal regulatory actions on State, local, and Tribal governments and the private sector. Public Law 104-4, sec. 201 (codified at 2 U.S.C. 1531). For a proposed regulatory action likely to result in a rule that may cause the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector of \$100 million or more in any one year (adjusted annually for inflation), section 202 of UMRA requires a Federal agency to publish a written statement that estimates the resulting costs, benefits, and other effects on the national economy. (2 U.S.C. 1532(a), (b)). The UMRA also requires a Federal agency to develop an effective process to permit timely input by elected officers of State, local, and Tribal governments on a proposed "significant intergovernmental mandate," and requires an agency plan for giving notice and opportunity for timely input to potentially affected small governments before establishing any requirements that might significantly or uniquely affect small governments. On March 18, 1997, DOE published a statement of policy on its process for intergovernmental consultation under UMRA. 62 FR 12820; also available at www.energy.gov/gc/office-general-counsel. DOE examined this proposed rule according to UMRA and its statement of policy and determined that the rule contains neither an intergovernmental mandate, nor a mandate that may result in the expenditure of \$100 million or more in any year, so these requirements do not apply.

H. Review Under the Treasury and General Government Appropriations Act, 1999

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Pub. L. 105-277) requires Federal agencies to issue a Family Policymaking Assessment for any rule that may affect family well-being. This proposed rule would not have any impact on the autonomy or integrity of the family as an institution. Accordingly, DOE has concluded that it is not necessary to prepare a Family Policymaking Assessment.

I. Review Under Executive Order 12630

DOE has determined, under Executive Order 12630, “Governmental Actions and Interference with Constitutionally Protected Property Rights” 53 FR 8859 (March 18, 1988), that this proposed regulation would not result in any takings that might require compensation under the Fifth Amendment to the U.S. Constitution.

J. Review Under Treasury and General Government Appropriations Act, 2001

Section 515 of the Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516 *note*) provides for agencies to review most disseminations of information to the public under guidelines established by each agency pursuant to general guidelines issued by OMB. OMB’s guidelines were published at 67 FR 8452 (Feb. 22, 2002), and DOE’s guidelines were published at 67 FR 62446 (Oct. 7, 2002). Pursuant to OMB Memorandum M–19–15, Improving Implementation of the Information Quality Act (April 24, 2019), DOE published updated guidelines which are available at www.energy.gov/sites/prod/files/2019/12/f70/DOE%20Final%20Updated%20IQA%20Guidelines%20Dec%202019.pdf. DOE has reviewed this proposed rule under the OMB and DOE guidelines and has concluded that it is consistent with applicable policies in those guidelines.

K. Review Under Executive Order 13211

Executive Order 13211, “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use,” 66 FR 28355 (May 22, 2001), requires Federal agencies to prepare and submit to OMB, a Statement of Energy Effects for any proposed significant energy action. A “significant energy action” is defined as any action by an agency that promulgated or is expected to lead to promulgation of a final rule, and that (1) is a significant regulatory action under Executive Order 12866, or any successor order; and (2) is likely to have a significant adverse effect on the supply, distribution, or use of energy; or (3) is designated by the Administrator of OIRA as a significant energy action. For any proposed significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution, or use should the proposal be implemented, and of reasonable alternatives to the action and their expected benefits on energy supply, distribution, and use.

The proposed regulatory action to establish a test procedure for measuring

the energy use of conventional cooking tops is not a significant regulatory action under Executive Order 12866.

Moreover, it would not have a significant adverse effect on the supply, distribution, or use of energy, nor has it been designated as a significant energy action by the Administrator of OIRA. Therefore, it is not a significant energy action, and, accordingly, DOE has not prepared a Statement of Energy Effects.

L. Review Under Section 32 of the Federal Energy Administration Act of 1974

Under section 301 of the Department of Energy Organization Act (Pub. L. 95–91; 42 U.S.C. 7101), DOE must comply with section 32 of the Federal Energy Administration Act of 1974, as amended by the Federal Energy Administration Authorization Act of 1977. (15 U.S.C. 788; “FEAA”) Section 32 essentially provides in relevant part that, where a proposed rule authorizes or requires use of commercial standards, the notice of proposed rulemaking must inform the public of the use and background of such standards. In addition, section 32(c) requires DOE to consult with the Attorney General and the Chairman of the Federal Trade Commission (“FTC”) concerning the impact of the commercial or industry standards on competition.

The proposed test procedure for conventional cooking tops would incorporate testing methods contained in certain sections of the following commercial standards: IEC 60350–2:2017, IEC 62301 First Edition, and IEC 62301 Second Edition. DOE has evaluated these standards and is unable to conclude whether it fully complies with the requirements of section 32(b) of the FEAA (*i.e.*, whether it was developed in a manner that fully provides for public participation, comment, and review.) DOE will consult with both the Attorney General and the Chairman of the FTC concerning the impact of these test procedures on competition, prior to prescribing a final rule.

M. Description of Materials Incorporated by Reference

In this NOPR, DOE proposes to incorporate by reference sections of the test standard published by IEC, titled “Household electric cooking appliances Part 2: Hobs—Methods for measuring performance,” IEC 60350–2:2017. IEC 60350–2:2017 is an industry-accepted test procedure that measures conventional electric cooking top energy use, using a water heating approach. The test procedure proposed in this NOPR references various sections of IEC

60350–2:2017 that address test setup, instrumentation, test conduct, and calculations.

In this NOPR, DOE proposes to incorporate by reference sections of the test standard published by IEC, titled “Household electrical appliances—Measurement of standby power,” IEC 62301, both the First Edition from June 2005 and the Second Edition from January 2011. IEC 62301 is an industry-accepted test procedure that measures standby power in household appliances. The test procedure proposed in this NOPR references various sections of IEC 62301 that address test setup, instrumentation, and test conduct.

IEC 60350–2:2017, and both editions of IEC 62301 are readily available from the American National Standards Institute, 25 W 43rd Street, 4th Floor, New York, NY 10036, (212) 642–4900, or by going to webstore.ansi.org.

V. Public Participation*A. Participation in the Webinar*

The time and date of the webinar are listed in the **DATES** section at the beginning of this document. If no participants register for the webinar, it will be cancelled. Webinar registration information, participant instructions, and information about the capabilities available to webinar participants will be published on DOE’s website: www.regulations.gov/docket/EERE-2021-BT-TP-0023. Participants are responsible for ensuring their systems are compatible with the webinar software.

B. Submission of Comments

DOE will accept comments, data, and information regarding this proposed rule no later than the date provided in the **DATES** section at the beginning of this proposed rule.⁴⁷ Interested parties

⁴⁷ DOE has historically provided a 75-day comment period for test procedure NOPRs pursuant to the North American Free Trade Agreement, U.S.-Canada-Mexico (“NAFTA”), Dec. 17, 1992, 32 I.L.M. 289 (1993); the North American Free Trade Agreement Implementation Act, Public Law 103–182, 107 Stat. 2057 (1993) (codified as amended at 10 U.S.C.A. 2576) (1993) (“NAFTA Implementation Act”); and Executive Order 12889, “Implementation of the North American Free Trade Agreement,” 58 FR 69681 (Dec. 30, 1993). However, on July 1, 2020, the Agreement between the United States of America, the United Mexican States, and the United Canadian States (“USMCA”), Nov. 30, 2018, 134 Stat. 11 (*i.e.*, the successor to NAFTA), went into effect, and Congress’s action in replacing NAFTA through the USMCA Implementation Act, 19 U.S.C. 4501 *et seq.* (2020), implies the repeal of E.O. 12889 and its 75-day comment period requirement for technical regulations. Thus, the controlling laws are EPCA and the USMCA Implementation Act. Consistent with EPCA’s public comment period requirements for consumer products, the USMCA only requires a minimum comment period of 60

may submit comments using any of the methods described in the **ADDRESSES** section at the beginning of this document.

Submitting comments via www.regulations.gov. The www.regulations.gov web page will require you to provide your name and contact information. Your contact information will be viewable to DOE Building Technologies staff only. Your contact information will not be publicly viewable except for your first and last names, organization name (if any), and submitter representative name (if any). If your comment is not processed properly because of technical difficulties, DOE will use this information to contact you. If DOE cannot read your comment due to technical difficulties and cannot contact you for clarification, DOE may not be able to consider your comment.

However, your contact information will be publicly viewable if you include it in the comment or in any documents attached to your comment. Any information that you do not want to be publicly viewable should not be included in your comment, nor in any document attached to your comment. Persons viewing comments will see only first and last names, organization names, correspondence containing comments, and any documents submitted with the comments.

Do not submit to www.regulations.gov information for which disclosure is restricted by statute, such as trade secrets and commercial or financial information (hereinafter referred to as Confidential Business Information (“CBI”). Comments submitted through www.regulations.gov cannot be claimed as CBI. Comments received through the website will waive any CBI claims for the information submitted. For information on submitting CBI, see the Confidential Business Information section.

DOE processes submissions made through www.regulations.gov before posting. Normally, comments will be posted within a few days of being submitted. However, if large volumes of comments are being processed simultaneously, your comment may not be viewable for up to several weeks. Please keep the comment tracking number that www.regulations.gov provides after you have successfully uploaded your comment.

Submitting comments via email. Comments and documents submitted via email also will be posted to www.regulations.gov. If you do not want

your personal contact information to be publicly viewable, do not include it in your comment or any accompanying documents. Instead, provide your contact information on a cover letter. Include your first and last names, email address, telephone number, and optional mailing address. The cover letter will not be publicly viewable as long as it does not include any comments.

Include contact information each time you submit comments, data, documents, and other information to DOE. No faxes will be accepted.

Comments, data, and other information submitted to DOE electronically should be provided in PDF (preferred), Microsoft Word or Excel, WordPerfect, or text (ASCII) file format. Provide documents that are not secured, written in English and free of any defects or viruses. Documents should not contain special characters or any form of encryption and, if possible, they should carry the electronic signature of the author.

Campaign form letters. Please submit campaign form letters by the originating organization in batches of between 50 to 500 form letters per PDF or as one form letter with a list of supporters' names compiled into one or more PDFs. This reduces comment processing and posting time.

Confidential Business Information. Pursuant to 10 CFR 1004.11, any person submitting information that he or she believes to be confidential and exempt by law from public disclosure should submit via email two well-marked copies: One copy of the document marked confidential including all the information believed to be confidential, and one copy of the document marked non-confidential with the information believed to be confidential deleted. DOE will make its own determination about the confidential status of the information and treat it according to its determination.

It is DOE's policy that all comments may be included in the public docket, without change and as received, including any personal information provided in the comments (except information deemed to be exempt from public disclosure).

C. Issues on Which DOE Seeks Comment

Although DOE welcomes comments on any aspect of this proposal, DOE is particularly interested in receiving comments and views of interested parties concerning the following issues:

(1) DOE requests comment on its proposal to require that the instantaneous, rather than the smoothed, water temperature at which

the power setting is reduced during the energy test be within +1 °C/–0.5 °C of the target shutdown temperature.

(2) DOE requests comment on its proposal to include the requirement to evaluate the start of the simmering period as the time that the 40-second “smoothed” average water temperature first meets or exceeds 90 °C.

(3) DOE requests comment on its proposed definition of smoothed water temperature as well as its proposal to require the smoothed water temperature be rounded to the nearest 0.1 °C.

(4) DOE requests comment on its proposal to allow the use of distilled water for testing in the proposed new appendix I1.

(5) DOE requests comment on its proposal to include the cooking top preparation requirements for water vaporization from IEC 60350–2:2017 in its proposed new appendix I1.

(6) DOE requests comment on its proposal to exclude the provisions from Section 7.3 of IEC 60350–2:2017 and instead require that each cooking zone be tested with the test vessel that most closely matches the outer diameter of the marking for electric cooking tops with limitative markings; and that Table A.1 of Annex A of IEC 60350–2:2017 be used to define the test vessels for electric cooking tops without limitative markings. DOE also requests comment on its proposal to substitute the largest test vessel that can be centered on the cooking zone in the case where a structural component of the cooking top interferes with the test vessel.

(7) DOE requests comment on its proposal to specify an ambient room temperature of 25 ±5 °C.

(8) DOE requests comments on its proposal to require that the product temperature be stable, its proposed definition of a stable temperature, and its proposed methods for measuring the product temperature for active mode testing as well as standby mode and off mode power testing.

(9) DOE requests comment on its proposal to specify an initial water temperature of 25 ±0.5 °C.

(10) DOE requests comment on its proposal to include the potential simmering setting pre-selection test specified in Annex H of IEC 60350–2:FDIS as an optional test in proposed new appendix I1. DOE also requests comment on its proposal to allow that if the tester has prior knowledge of the unit's operation and has previously determined through a different method which power setting is the potential simmering setting, the tester may use that setting as the initial power setting for the test cycles.

(11) DOE requests comment on its proposed definitions of the minimum-above-threshold power setting and the maximum-below-threshold power setting, and on its proposed methodology for determining the simmering setting.

(12) DOE requests comment on its proposal to normalize the energy use of the tested cycle if the smoothed water temperature exceeds 91 °C during the simmering period, to represent an Energy Test Cycle with a final water of 90 °C. DOE specifically requests comment on its proposal to use the smoothed final water temperature to perform this normalization and on whether a

different normalization method would be more appropriate. DOE also requests comment on its proposal to not require the normalization when the smoothened water temperature remains between 90 °C and 91 °C during the simmering period, when the minimum-above-threshold power setting is the lowest available power setting on the heating element under test, or when the smoothened water temperature during the maximum-below-threshold power setting does not meet or exceed 90 °C during a 20-minute period following the time the power setting is reduced.

(13) DOE requests comment on its proposed test conditions for gas cooking tops, and its proposed definition of a standard cubic foot of gas.

(14) DOE requests comment on its proposed instrumentation specifications for gas cooking tops, and any cost burden for manufacturers who may not already have the required instrumentation.

(15) DOE requests comment on its proposal to require the use of IEC test vessels for gas cooking tops and on its proposed method for selecting the test vessel size to use based on the gas burner's heat input rate.

(16) DOE requests comment on its proposal for adjusting the burner heat input rate to the nominal heat input rate as specified by the manufacturer, and to include a 2-percent tolerance on the heat input rate of each burner on a gas cooking top.

(17) DOE requests comment on its proposed target power density for gas cooking tops of 4.0 Btu/h-cm².

(18) DOE requests comment on its proposal to require the product temperature of a gas cooking top be measured inside the burner body of the cooking zone under test, after temporarily removing the burner cap.

(19) DOE requests comment on its proposed definitions of "active mode," "off mode," "standby mode," "inactive mode," and "combined low-power mode."

(20) DOE requests comment on its proposed definitions of product configurations and installation requirements.

(21) DOE requests comment on its proposed definitions of "power setting," "infinite power settings," "multi-ring cooking zone," and "maximum power setting." DOE also requests comments on its proposal for the subset of power settings on each type of cooking zone that are considered as part of the identification of the simmering setting.

(22) DOE requests comment on its proposal that for cooking tops with rotating knobs for selecting the power setting, the selection knob always be turned in the direction from higher power to lower power to select the potential simmering setting for an energy test.

(23) DOE requests comments on its proposed definition of specialty cooking zone.

(24) DOE requests comments on its proposal to include the formula for the target turndown temperature in the proposed new appendix I1.

(25) DOE requests comment on its proposed electrical supply requirements for active mode testing.

(26) DOE requests comment on the proposed tolerance of ± 0.5 grams for each water load mass.

(27) DOE requests comment on its proposed determination that pan warpage does not affect repeatability and reproducibility of the test procedure.

(28) DOE requests comment on its proposal to incorporate IEC 62301 Second Edition to provide the method for measuring standby mode and off mode power, except for conventional cooking products in which power varies as a function of the clock time displayed in standby mode.

(29) DOE requests comment on its proposal to incorporate IEC 62301 First Edition for measuring standby mode and off mode power for conventional cooking tops in which power varies as a function of the clock time displayed in standby mode.

(30) DOE requests comment on its proposal to use a representative water load mass of 2,853 g in the proposed new appendix I1.

(31) DOE requests comment on its proposal to use a value of 418 annual cooking top cycles per year.

(32) DOE requests comment on its proposed usage factors and annual hours for cooking top combined low-power mode, as well as on any of the underlying assumptions.

(33) DOE requests comment on its proposed allocation of combined low-power mode hours.

(34) DOE requests comment on its proposed provisions for measuring annual energy consumption and estimated annual cost.

(35) DOE requests data on the test burden, repeatability, reproducibility, and representativeness of a test procedure that would separate the boiling and simmering tests.

(36) DOE requests data on the representativeness of a simmering usage factor across technology types.

(37) DOE requests data on the representativeness of a simmering setting based on a percentage of the maximum power setting.

(38) DOE seeks comment on the proposed method for establishing a sampling plan.

(39) DOE requests comment on its proposal to test all gas cooking tops using the default test gas, as defined by the as-shipped configuration of the unit.

(40) DOE requests comment on its proposal to delete the definition of convertible cooking appliance from 10 CFR 430.2.

(41) DOE requests comment on any aspect of the estimated initial testing costs associated with DOE's proposed test procedures.

(42) DOE requests comment on any aspect of the estimated recurring testing costs associated with conventional cooking tops.

VI. Approval of the Office of the Secretary

The Secretary of Energy has approved publication of this proposed rule.

List of Subjects in 10 CFR Part 430

Administrative practice and procedure, Confidential business

information, Energy conservation, Household appliances, Imports, Incorporation by reference, Intergovernmental relations, Small businesses.

Signing Authority

This document of the Department of Energy was signed on October 21, 2021, by Kelly Speakes-Backman, Principal Deputy Assistant Secretary and Acting Assistant Secretary for Energy Efficiency and Renewable Energy, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on October 21, 2021.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

For the reasons stated in the preamble, DOE is proposing to amend part 430 of Chapter II of Title 10, Code of Federal Regulations as set forth below:

PART 430—ENERGY CONSERVATION PROGRAM FOR CONSUMER PRODUCTS

■ 1. The authority citation for part 430 continues to read as follows:

Authority: 42 U.S.C. 6291–6309; 28 U.S.C. 2461 note.

§ 430.2 [Amended]

■ 2. Section 430.2 is amended by removing the definition of "Convertible cooking appliance."

■ 3. Section 430.3 is amended by:

■ a. Redesignating paragraphs (o)(3) through (9) as paragraphs (o)(4) through (10);

■ b. Adding a new paragraph (o)(3); and

■ c. Revising newly redesignated paragraphs (o)(6) and (7).

The addition and revisions read as follows:

§ 430.3 Materials incorporated by reference.

* * * * *

(o) * * *

(3) IEC Standard 60350–2:2017, ("IEC 60350–2"), *Household electric cooking appliances Part 2: Hobs—Methods for*

measuring performance, (August 2017), IBR approved for appendix I1 to subpart B.

* * * * *

(6) International Electrotechnical Commission (IEC) Standard 62301 (“IEC 62301”), *Household electrical appliances—Measurement of standby power* (first edition, June 2005), IBR approved for appendices F, I, and I1 to subpart B.

(7) IEC 62301 (“IEC 62301”), *Household electrical appliances—Measurement of standby power*, (Edition 2.0, 2011–01), IBR approved for appendices C1, D1, D2, G, H, I, I1, J2, N, O, P, Q, X, X1, Y, Z, BB, and CC to subpart B.

* * * * *

■ 4. Section 430.23 is amended by revising paragraph (i) to read as follows:

§ 430.23 Test procedures for the measurement of energy and water consumption.

* * * * *

(i) *Cooking products.* (1) Determine the standby power for microwave ovens, excluding any microwave oven component of a combined cooking product, according to section 3.2.3 of appendix I to this subpart. Round standby power to the nearest 0.1 watt.

(2)(i) The integrated annual energy consumption of a conventional electric cooking top, including any conventional cooking top component of a combined cooking product, is determined according to section 4.3.1 of appendix I1 to this subpart. Round the result to the nearest 1 kilowatt-hours (kWh) per year.

(ii) The integrated annual energy consumption of a conventional gas cooking top, including any conventional cooking top component of a combined cooking product, is determined according to section 4.3.2 of appendix I1 to this subpart. Round the result to the nearest 1 kilo-British thermal units (kBtu) per year.

(3) The total annual gas energy consumption of a conventional gas cooking top, including any conventional cooking top component of a combined cooking product, is determined according to section 4.1.2.2.1 of appendix I1 to this subpart. Round the result to the nearest 1 kBtu per year.

(4)(i) The total annual electrical energy consumption of a conventional electric cooking top, including any conventional cooking top component of a combined cooking product, is equal to the integrated annual energy consumption of the conventional electric cooking top, as determined in paragraph (i)(2)(i) of this section.

(ii) The total annual electrical energy consumption of a conventional gas

cooking top, including any conventional cooking top component of a combined cooking product, is determined as the sum of the conventional gas cooking top annual active mode electrical energy consumption (E_{AGE}) as defined in section 4.1.2.2.2 of appendix I1 to this subpart, and the combined low-power mode energy consumption (E_{TLP}) as defined in section 4.1 of appendix I1 to this subpart. Round the result to the nearest 1 kWh per year.

(5) The estimated annual operating cost corresponding to the energy consumption of a conventional cooking top, including any conventional cooking top component of a combined cooking product, shall be the sum of the following products, rounded to the nearest dollar per year:

(i) The total annual electrical energy consumption for any electric energy usage, in kilowatt-hours (kWh) per year, as determined in accordance with paragraph (i)(4) of this section, times the representative average unit cost for electricity, in dollars per kWh, as provided pursuant to section 323(b)(2) of the Act; plus

(ii) The total annual gas energy consumption, in kBtu per year, as determined in accordance with paragraph (i)(3) of this section, times:

(A) For conventional gas cooking tops that operate with natural gas, the representative average unit cost for natural gas, in dollars per kBtu, as provided pursuant to section 323(b)(2) of the Act; or

(B) For conventional gas cooking tops that operate with LP-gas, the representative average unit cost for propane, in dollars per kBtu, as provided pursuant to section 323(b)(2) of the Act.

(6) Other useful measures of energy consumption for conventional cooking tops shall be the measures of energy consumption that the Secretary determines are likely to assist consumers in making purchasing decisions and that are derived from the application of appendix I1 to this subpart.

* * * * *

■ 5. Appendix I to Subpart B of Part 430 is amended by revising the heading to read as follows:

Appendix I to Subpart B of Part 430

Uniform Test Method for Measuring the Energy Consumption of Microwave Ovens

* * * * *

■ 6. Appendix I1 to subpart B of part 430 is added to read as follows:

Appendix I1 to Subpart B of Part 430

Uniform Test Method for Measuring the Energy Consumption of Conventional Cooking Products

Note: Any representation related to energy consumption of conventional cooking tops, including the conventional cooking top component of combined cooking products, made after [180 days after publication of the final rule in the **Federal Register**] must be based upon results generated under this test procedure. Upon the compliance date(s) of any energy conservation standard(s) for conventional cooking tops, including the conventional cooking top component of combined cooking products, use of the applicable provisions of this test procedure to demonstrate compliance with the energy conservation standard is required.

0. Incorporation by Reference

DOE incorporated by reference in § 430.3, the entire test standard for IEC 60350–2 (2017) “Household electric cooking appliances—Part 2: Hobs—Methods for measuring performance;” IEC 62301 “Household electrical appliances—Measurement of standby power” (first edition June 2005); and IEC 62301 “Household electrical appliances—Measurement of standby power” (Second Edition). However, only enumerated provisions of those documents are applicable to appendix I1, as follows. In cases in which there is a conflict, the language of the test procedure in this appendix takes precedence over the referenced test standards.

(1) IEC 60350–2 (2017)

(i) Section 5.1 as referenced in section 2.4.1 of this appendix;

(ii) Section 5.3 as referenced in sections 2.7.1.1, 2.7.3.1, 2.7.3.3, 2.7.3.4, 2.7.4, and 2.7.5 of this appendix;

(iii) Section 5.5 as referenced in section 2.5.1 of this appendix;

(iv) Section 5.6.1 as referenced in section 2.6.1 of this appendix;

(v) Section 5.6.1.5 as referenced in section 3.1.1.2 of this appendix;

(vi) Section 6.3 as referenced in section 3.1.1.1.1 of this appendix;

(vii) Section 6.3.1 as referenced in section 3.1.1.1.1 of this appendix;

(viii) Section 7.5.1 as referenced in section 2.6.2 of this appendix;

(ix) Section 7.5.2 as referenced in section 3.1.4.4 of this appendix;

(x) Section 7.5.2.1 as referenced in section 3.1.4.2 of this appendix;

(xi) Section 7.5.2.2 as referenced in section 3.1.4.4 of this appendix;

(xii) Section 7.5.4.1 as referenced in sections 1 and 3.1.4.5 of this appendix;

(xiii) Annex A as referenced in section 3.1.1.2 of this appendix;

(xiv) Annex B as referenced in sections 2.6.1 and 2.8.3 of this appendix; and

(xv) Annex C as referenced in section 3.1.4.1 of this appendix.

(2) IEC 62301 (First Edition)

(i) Paragraph 5.3 as referenced in section 3.2 of this appendix; and

(ii) Paragraph 5.3.2 as referenced in section 3.2 of this appendix.

(3) IEC 62301 (Second Edition)

- (i) Paragraph 4.2 as referenced in section 2.4.2 of this appendix;
- (ii) Paragraph 4.3.2 as referenced in section 2.2.1.1.2 of this appendix;
- (iii) Paragraph 4.4 as referenced in section 2.7.1.2 of this appendix;
- (iv) Paragraph 5.1 as referenced in section 3.2 of this appendix; and
- (v) Paragraph 5.3.2 as referenced in section 3.2 of this appendix.

1. Definitions

The following definitions apply to the test procedures in this appendix, including the test procedures incorporated by reference:

Active mode means a mode in which the product is connected to a mains power source, has been activated, and is performing the main function of producing heat by means of a gas flame, electric resistance heating, or electric inductive heating.

Built-in means the product is enclosed in surrounding cabinetry, walls, or other similar structures on at least three sides, and can be supported by surrounding cabinetry or the floor.

Combined cooking product means a household cooking appliance that combines a cooking product with other appliance functionality, which may or may not include another cooking product. Combined cooking products include the following products: Conventional range, microwave/conventional cooking top, microwave/conventional oven, and microwave/conventional range.

Combined low-power mode means the aggregate of available modes other than active mode, but including the delay start mode portion of active mode.

Cooking area means an area on a conventional cooking top surface heated by an inducted magnetic field where cookware is placed for heating, where more than one cookware item can be used simultaneously and controlled separately from other cookware placed on the cooking area, and that is either—

- (1) An area where no clear limitative markings for cookware are visible on the surface of the cooking top; or
- (2) An area with limitative markings.

Cooking top control means a part of the conventional cooking top used to adjust the power and the temperature of the cooking zone or cooking area for one cookware item.

Cooking zone means a part of a conventional cooking top surface that is either a single electric resistance heating element, multiple concentric sizes of electric resistance heating elements, an inductive heating element, or a gas surface unit that is defined by limitative markings on the surface of the cooking top and can be controlled independently of any other cooking area or cooking zone.

Cycle finished mode means a standby mode in which a conventional cooking top provides continuous status display following operation in active mode.

Drop-in means the product is supported by horizontal surface cabinetry.

Freestanding means the product is supported by the floor and is not specified in the manufacturer's instructions as able to be installed such that it is enclosed by surrounding cabinetry, walls, or other similar structures.

IEC 60350-2:2017 means the test standard published by the International Electrotechnical Commission, titled "Household electric cooking appliances—Part 2: Hobs—Methods for measuring performance," Publication 60350-2 (2017).

IEC 62301 (First Edition) means the test standard published by the International Electrotechnical Commission, titled "Household electrical appliances—Measurement of standby power," Publication 62301 (First Edition 2005-06).

IEC 62301 (Second Edition) means the test standard published by the International Electrotechnical Commission, titled "Household electrical appliances—Measurement of standby power," Publication 62301 (Edition 2.0 2011-01).

Inactive mode means a standby mode that facilitates the activation of active mode by remote switch (including remote control), internal sensor, or timer, or that provides continuous status display.

Infinite power settings means a cooking zone control without discrete power settings, allowing for selection of any power setting below the maximum power setting.

Maximum-below-threshold power setting means the power setting on a conventional cooking top that is the highest power setting that results in smoothened water temperature data that does not meet the evaluation criteria specified in Section 7.5.4.1 of IEC 60350-2:2017.

Maximum power setting means the maximum possible power setting if only one cookware item is used on the cooking zone or cooking area of a conventional cooking top, including any optional power boosting features. For conventional electric cooking tops with multi-ring cooking zones or cooking areas, the maximum power setting is the maximum power corresponding to the concentric heating element with the largest diameter, which may correspond to a power setting which may include one or more of the smaller concentric heating elements. For conventional gas cooking tops with multi-ring cooking zones, the maximum power setting is the maximum heat input rate when the maximum number of rings of the cooking zone are ignited.

Minimum-above-threshold power setting means the power setting on a conventional cooking top that is the lowest power setting that results in smoothened water temperature data that meet the evaluation criteria specified in Section 7.5.4.1 of IEC 60350-2:2017. This power setting is also referred to as the simmering setting.

Multi-ring cooking zone means a cooking zone on a conventional cooking top with multiple concentric sizes of electric resistance heating elements or gas burner rings.

Off mode means any mode in which a product is connected to a mains power source and is not providing any active mode or standby function, and where the mode may persist for an indefinite time. An indicator that only shows the user that the product is in the off position is included within the classification of an off mode.

Power setting means a setting on a cooking zone control that offers a gas flame, electric resistance heating, or electric inductive heating.

Smoothened water temperature means the 40-second moving-average temperature as calculated in Section 7.5.4.1 of IEC 60350-2:2017, rounded to the nearest 0.1 degree Celsius.

Specialty cooking zone means any cooking zone that is designed for use only with non-circular cookware, such as bridge zones, warming plates, grills, and griddles. Specialty cooking zones are not tested under this appendix.

Stable temperature means a temperature that does not vary by more than 1 °C over a 5-minute period.

Standard cubic foot of gas means the quantity of gas that occupies 1 cubic foot when saturated with water vapor at a temperature of 60 °F and a pressure of 14.73 pounds per square inch (30 inches of mercury or 101.6 kPa).

Standby mode means any mode in which a product is connected to a mains power source and offers one or more of the following user-oriented or protective functions which may persist for an indefinite time:

- (1) Facilitation of the activation of other modes (including activation or deactivation of active mode) by remote switch (including remote control), internal sensor, or timer;
- (2) Provision of continuous functions, including information or status displays (including clocks) or sensor-based functions. A timer is a continuous clock function (which may or may not be associated with a display) that allows for regularly scheduled tasks and that operates on a continuous basis.

Thermocouple means a device consisting of two dissimilar metals which are joined together and, with their associated wires, are used to measure temperature by means of electromotive force.

2. Test Conditions and Instrumentation

2.1 Installation. Install the conventional cooking top or combined cooking product in accordance with the manufacturer's instructions. If the manufacturer's instructions specify that the product may be used in multiple installation conditions, install the product according to the built-in configuration. Completely assemble the product with all handles, knobs, guards, and similar components mounted in place. Position any electric resistance heaters, gas burners, and baffles in accordance with the manufacturer's instructions. If the product can communicate through a network (e.g., Bluetooth® or internet connection), disable the network function, if it is possible to disable it by means provided in the manufacturer's user manual, for the duration of testing. If the network function cannot be disabled, or if means for disabling the function are not provided in the manufacturer's user manual, the product shall be tested in the factory default setting or in the as-shipped condition.

2.1.1 Freestanding combined cooking product. Install a freestanding combined cooking product with the back directly against, or as near as possible to, a vertical wall which extends at least 1 foot above the product and 1 foot beyond both sides of the product, and with no side walls.

2.1.2 Drop-in or built-in combined cooking product. Install a drop-in or built-in

combined cooking product in a test enclosure in accordance with manufacturer's instructions.

2.1.3 Conventional cooking top. Install a conventional cooking top with the back directly against, or as near as possible to, a vertical wall which extends at least 1 foot above the product and 1 foot beyond both sides of the product.

2.2 Energy supply.

2.2.1 Electrical supply.

2.2.1.1 Supply voltage.

2.2.1.1.1 Active mode supply voltage.

During active mode testing, maintain the electrical supply to the product at either 240 volts ± 1 percent or 120 volts ± 1 percent, according to the manufacturer's instructions, except for products which do not allow for a mains electrical supply.

2.2.1.1.2 Standby mode and off mode supply voltage. During standby mode and off mode testing, maintain the electrical supply to the product at either 240 volts ± 1 percent, or 120 volts ± 1 percent, according to the manufacturer's instructions. Maintain the electrical supply voltage waveform specified in Section 4, Paragraph 4.3.2 of IEC 62301 (Second Edition), disregarding the provisions regarding batteries and the determination, classification, and testing of relevant modes. If the power measuring instrument used for testing is unable to measure and record the total harmonic content during the test measurement period, total harmonic content may be measured and recorded immediately before and after the test measurement period.

2.2.1.2 Supply frequency. Maintain the electrical supply frequency for all tests at 60 hertz ± 1 percent.

2.2.2 Gas supply.

2.2.2.1 Natural gas. Maintain the natural gas pressure immediately ahead of all controls of the unit under test at 7 to 10 inches of water column, except as specified in section 3.1.3 of this appendix. The natural gas supplied should have a higher heating value (dry-basis) of approximately 1,025 Btu per standard cubic foot. Obtain the higher heating value on a dry basis of gas, H_n , in Btu per standard cubic foot, for the natural gas to be used in the test either from measurements made by the manufacturer conducting the test using equipment that meets the requirements described in section 2.7.2.2 of this appendix or by the use of bottled natural gas whose gross heating value is certified to be at least as accurate a value that meets the requirements in section 2.7.2.2 of this appendix.

2.2.2.2 Propane. Maintain the propane pressure immediately ahead of all controls of the unit under test at 11 to 13 inches of water column, except as specified in section 3.1.3 of this appendix. The propane supplied should have a higher heating value (dry-basis) of approximately 2,500 Btu per standard cubic foot. Obtain the higher heating value on a dry basis of gas, H_p , in Btu per standard cubic foot, for the propane to be used in the test either from measurements made by the manufacturer conducting the test using equipment that meets the requirements described in section 2.7.2.2 of this appendix, or by the use of bottled propane whose gross heating value is certified to be at least as accurate a value that

meets the requirements described in section 2.7.2.2 of this appendix.

2.3 Air circulation. Maintain air circulation in the room sufficient to secure a reasonably uniform temperature distribution, but do not cause a direct draft on the unit under test.

2.4 Ambient room test conditions.

2.4.1 Active mode ambient conditions.

During active mode testing, maintain the ambient room air pressure specified in Section 5.1 of IEC 60350-2:2017, and maintain the ambient room air temperature at 25 ± 5 °C with a target temperature of 25 °C.

2.4.2 Standby mode and off mode ambient conditions. During standby mode and off mode testing, maintain the ambient room air temperature conditions specified in Section 4, Paragraph 4.2 of IEC 62301 (Second Edition).

2.5 Product temperature.

2.5.1 Product temperature stability. Prior to any testing, the product must achieve a stable temperature meeting the ambient room air temperature specified in section 2.4 of this appendix. For all conventional cooking tops, forced cooling may be used to assist in reducing the temperature of the product between tests, as specified in Section 5.5 of IEC 60350-2:2017. Forced cooling must not be used during the period of time used to assess temperature stability.

2.5.2 Product temperature measurement. Measure the product temperature in degrees Celsius using the equipment specified in section 2.7.3.3 of this appendix at the following locations.

2.5.2.1 Measure the product temperature at the center of the cooking zone under test for any gas burner adjustment in section 3.1.3 of this appendix and per-cooking zone energy consumption test in section 3.1.4 of this appendix, except that the product temperature measurement is not required for any potential simmering setting pre-selection test in section 3.1.4.3 of this appendix. For a conventional gas cooking top, the product temperature must be measured inside the burner body of the cooking zone under test, after temporarily removing the burner cap.

2.5.2.2 Measure the temperature at the center of each cooking zone for the standby mode and off mode power test in section 3.2 of this appendix. For a conventional gas cooking top, the temperature must be measured inside the burner body of each cooking zone, after temporarily removing the burner cap. Calculate the product temperature as the average of the temperatures at the center of each cooking zone.

2.6 Test loads.

2.6.1 Test vessels. The test vessels for active mode testing must meet the specifications in Section 5.6.1 and Annex B of IEC 60350-2:2017.

2.6.2 Water load. The water used to fill the test vessels for active mode testing must meet the specifications in Section 7.5.1 of IEC 60350-2:2017. The water temperature at the start of each test, except for the gas burner adjustment in section 3.1.3 of this appendix and the potential simmering setting pre-selection test in section 3.1.4.3 of this appendix, must have an initial temperature equal to 25 ± 0.5 °C.

2.7 Instrumentation. Perform all test measurements using the following instruments, as appropriate:

2.7.1 Electrical measurements.

2.7.1.1 Active mode watt-hour meter. The watt-hour meter for measuring the active mode electrical energy consumption must have a resolution as specified in Table 1 of Section 5.3 of IEC 60350-2:2017. Measurements shall be made as specified in Table 2 of Section 5.3 of IEC 60350-2:2017.

2.7.1.2 Standby mode and off mode watt meter. The watt meter used to measure standby mode and off mode power must meet the specifications in Section 4, Paragraph 4.4 of IEC 62301 (Second Edition). If the power measuring instrument used for testing is unable to measure and record the crest factor, power factor, or maximum current ratio during the test measurement period, measure the crest factor, power factor, and maximum current ratio immediately before and after the test measurement period to determine whether these characteristics meet the specifications in Section 4, Paragraph 4.4 of IEC 62301 (Second Edition).

2.7.2 Gas measurements.

2.7.2.1 Gas meter. The gas meter used for measuring gas consumption must have a resolution of 0.01 cubic foot or less and a maximum error no greater than 1 percent of the measured value for any demand greater than 2.2 cubic feet per hour.

2.7.2.2 Standard continuous flow calorimeter. The calorimeter must have an operating range of 750 to 3,500 Btu per cubic foot. The maximum error of the basic calorimeter must be no greater than 0.2 percent of the actual heating value of the gas used in the test. The indicator readout must have a maximum error no greater than 0.5 percent of the measured value within the operating range and a resolution of 0.2 percent of the full-scale reading of the indicator instrument.

2.7.2.3 Gas line temperature. The incoming gas temperature must be measured at the gas meter. The instrument for measuring the gas line temperature shall have a maximum error no greater than ± 2 °F over the operating range.

2.7.2.4 Gas line pressure. The incoming gas pressure must be measured at the gas meter. The instrument for measuring the gas line pressure must have a maximum error no greater than 0.1 inches of water column.

2.7.3 Temperature measurements.

2.7.3.1 Active mode ambient room temperature. The room temperature indicating system must meet the specifications in Table 1 of Section 5.3 of IEC 60350-2:2017. Measurements shall be made as specified in Table 2 of Section 5.3 of IEC 60350-2:2017.

2.7.3.2 Standby mode and off mode ambient room temperature. The room temperature indicating system must have an error no greater than ± 1 °F (± 0.6 °C) over the range 65° to 90 °F (18 °C to 32 °C).

2.7.3.3 Product temperature. The temperature indicating system must have an error no greater than ± 1 °F (± 0.6 °C) over the range 65° to 90 °F (18 °C to 32 °C). Measurements shall be made as specified in Table 2 of Section 5.3 of IEC 60350-2:2017.

2.7.3.4 Water temperature. Measure the test vessel water temperature with a

thermocouple that meets the specifications in Table 1 of Section 5.3 of IEC 60350–2:2017. Measurements shall be made as specified in Table 2 of Section 5.3 of IEC 60350–2:2017.

2.7.4 Room air pressure. The room air pressure indicating system must meet the specifications in Table 1 of Section 5.3 of IEC 60350–2:2017.

2.7.5 Water mass. The scale used to measure the mass of the water load must meet the specifications in Table 1 of Section 5.3 of IEC 60350–2:2017.

2.8 Power settings.

2.8.1 On a multi-ring cooking zone on a conventional gas cooking top, all power settings are considered, whether they ignite all rings of orifices or not.

2.8.2 On a multi-ring cooking zone on a conventional electric cooking top, only power settings corresponding to the concentric heating element with the largest diameter are considered, which may correspond to operation with one or more of the smaller concentric heating elements energized.

2.8.3 On a cooking zone with infinite power settings where the available range of rotation from maximum to minimum is more than 150 rotational degrees, evaluate power settings that are spaced by 10 rotational

degrees. On a cooking zone with infinite power settings where the available range of rotation from maximum to minimum is less than or equal to 150 rotational degrees, evaluate power settings that are spaced by 5 rotational degrees. Polar coordinate paper, as provided in Annex B of IEC 60350–2:2017 may be used to mark power settings.

3. Test Methods and Measurements

3.1. Active mode. Perform the following test methods for conventional cooking tops and the conventional cooking top component of a combined cooking product.

3.1.1 Test vessel and water load selection.

3.1.1.1 Conventional electric cooking tops.

3.1.1.1.1 For cooking areas with limitative markings, measure the diameter of each cooking zone, not including any specialty cooking zones as defined in section 1 of this appendix. The outer diameter of the cooking zone printed marking must be used for the measurement, as specified in Section 6.3 of IEC 60350–2:2017. For cooking areas without limitative markings, determine the number of cooking zones as specified in Section 6.3.1 of IEC 60350–2:2017.

3.1.1.1.2 Determine the test vessel diameter in millimeters (mm) and water load

mass in grams (g) for each measured cooking zone, based on cooking zone size as specified in Table 3 in Section 5.6.1.5 of IEC 60350–2:2017 for cooking areas with limitative markings and in Annex A of IEC 60350–2:2017 for cooking areas without limitative markings. If a selected test vessel cannot be centered on the cooking zone due to interference with a structural component of the cooking top, the test vessel with the largest diameter that can be centered on the cooking zone shall be used. The allowable tolerance on the water load weight is ± 0.5 g.

3.1.1.2 Conventional gas cooking tops.

3.1.1.2.1 Record the nominal heat input rate for each cooking zone, not including any specialty cooking zones as defined in section 1 of this appendix.

3.1.1.2.2 Determine the test vessel diameter in mm and water load mass in g for each measured cooking zone according to Table 3.1 of this appendix. If a selected test vessel cannot be centered on the cooking zone due to interference with a structural component of the cooking top, the test vessel with the largest diameter that can be centered on the cooking zone shall be used. The allowable tolerance on the water load weight is ± 0.5 g.

TABLE 3.1—TEST VESSEL SELECTION FOR CONVENTIONAL GAS COOKING TOPS

	Nominal gas burner input rate (Btu/h)		Test vessel diameter (mm)	Water load mass (g)
	Minimum (>)	Maximum ($\leq$)		
5,600		5,600	210	2,050
8,050		8,050	240	2,700
14,300		14,300	270	3,420
14,300			300	4,240

3.1.2 Unit Preparation. Before the first measurement is taken, all cooking zones must be operated simultaneously for at least 10 minutes at maximum power. This step shall be conducted once per product.

3.1.3 Gas burner adjustment. Prior to active mode testing of each tested burner of a conventional gas cooking top, the burner average heat input rate must be adjusted, if necessary, to within 2 percent of the nominal heat input rate of the burner as specified by the manufacturer. Prior to ignition and any adjustment of the burner heat input rate, the conventional cooking top must achieve the product temperature specified in section 2.5 of this appendix. Ignite and operate the gas burner under test with the test vessel and water mass specified in section 3.1.1 of this appendix. Measure the heat input rate of the gas burner under test starting 5 minutes after ignition. If the average input rate of the gas burner under test is within 2 percent of the nominal heat input rate of the burner as specified by the manufacturer, no adjustment of the average heat input rate shall be made.

3.1.3.1 Conventional gas cooking tops with an adjustable internal pressure regulator. If the measured average heat input rate of the burner under test is not within 2 percent of the nominal heat input rate of the burner as specified by the manufacturer, adjust the product's internal pressure

regulator such that the average heat input rate of the burner under test is within 2 percent of the nominal heat input rate of the burner as specified by the manufacturer. Adjust the burner with sufficient air flow to prevent a yellow flame or a flame with yellow tips. Complete section 3.1.4 of this appendix while maintaining the same gas pressure regulator adjustment.

3.1.3.2 Conventional gas cooking tops with a non-adjustable internal pressure regulator or without an internal pressure regulator. If the measured average heat input rate of the burner under test is not within 2 percent of the nominal heat input rate of the burner as specified by the manufacturer, remove the product's internal pressure regulator, or block it in the open position, and initially maintain the gas pressure ahead of all controls of the unit under test approximately equal to the manufacturer's recommended manifold pressure. Adjust the gas supply pressure such that the average heat input rate of the burner under test is within 2 percent of the nominal heat input rate of the burner as specified by the manufacturer. Adjust the burner with sufficient air flow to prevent a yellow flame or a flame with yellow tips. Complete section 3.1.4 of this appendix while maintaining the same gas pressure regulator adjustment.

3.1.4 Per-cooking zone energy consumption test. Establish the test conditions set forth in section 2 of this appendix. Turn off the gas flow to the conventional oven(s), if so equipped. The product temperature must meet the specifications in section 2.5 of this appendix.

3.1.4.1 Test vessel placement. Position the test vessel with water load for the cooking zone under test, selected and prepared as specified in section 3.1.1 of this appendix, in the center of the cooking zone, and as specified in Annex C to IEC 60350–2:2017.

3.1.4.2 Overshoot test. Use the test methods set forth in Section 7.5.2.1 of IEC 60350–2:2017 to determine the target turndown temperature for each cooking zone, T_{Ctarget} , in degrees Celsius, as follows.

$$T_{\text{Ctarget}} = 93^{\circ}\text{C} - (T_{\text{max}} - T_{70})$$

Where:

T_{max} is highest recorded temperature value, in degrees Celsius; and

T_{70} is the average recorded temperature between the time 10 seconds before the power is turned off and the time 10 seconds after the power is turned off.

If T_{70} is within the tolerance of $70 \pm 0.5^{\circ}\text{C}$, the target turndown temperature is the highest of 80°C and the calculated T_{Ctarget} , rounded to the nearest integer. If T_{70} is

outside of the tolerance, the overshoot test is considered invalid and must be repeated after allowing the product to return to ambient conditions.

3.1.4.3 *Potential simmering setting pre-selection test.* The potential simmering setting for each cooking zone may be determined using the potential simmering setting pre-selecting test. If a potential simmering setting is already known, it may

be used instead of completing sections 3.1.4.3.1 through 3.1.4.3.4 of this appendix.

3.1.4.3.1 Use the test vessel with water load for the cooking zone under test, selected, prepared, and positioned as specified in sections 3.1.1 and 3.1.4.1 of this appendix. The temperature of the conventional cooking top is not required to meet the specification for the product temperature in section 2.5 of this appendix

for the potential simmering setting pre-selection test. Operate the cooking zone under test with the lowest available power setting. Measure the energy consumption for 10 minutes ± 2 seconds.

3.1.4.3.2 Calculate the power density of the power setting, j , on a conventional electric cooking top, Qe_j , in watts per square centimeter, as:

$$Qe_j = \frac{6 \times E_j}{a}$$

Where:

a = the surface area of the test vessel bottom, in square centimeters; and

E_j = the electrical energy consumption during the 10-minute test, in Wh.

3.1.4.3.3 Calculate the power density of the power setting, j , on a conventional gas cooking top, Qg_j , in Btu/h per square centimeter, as:

$$Qg_j = \frac{6 \times (V_j \times CF \times H + Ee_j \times K_e)}{a}$$

Where:

a = the surface area of the test vessel bottom, in square centimeters;

V_j = the volume of gas consumed during the 10-minute test, in cubic feet;

CF = the gas correction factor to standard temperature and pressure, as calculated in section 4.1.1.2.1 of this appendix;

H = either H_n or H_p , the heating value of the gas used in the test as specified in sections 2.2.2.1 and 2.2.2.2 of this appendix, in Btu per standard cubic foot of gas;

Ee_j = the electrical energy consumption of the conventional gas cooking top during the 10-minute test, in Wh; and

K_e = 3.412 Btu/Wh, conversion factor of watt-hours to Btu.

3.1.4.3.4 Repeat the measurement for each successively higher power setting until Qe_j exceeds 0.8 W/cm² for conventional electric cooking tops or Qg_j exceeds 4.0 Btu/h-cm² for conventional gas cooking tops. For conventional cooking tops with rotating knobs for selecting the power setting, the

selection knob shall be turned to the maximum power setting in between each test, to avoid hysteresis. The selection knob shall be turned in the direction from higher power to lower power to select the power setting for the test. If the appropriate power setting is passed, the selection knob shall be turned to the maximum power setting again before repeating the power setting selection. Of the last two power settings tested, the potential simmering setting is the power setting that produces a power density closest to 0.8 W/cm² for conventional electric cooking tops or 4.0 Btu/h-cm² for conventional gas cooking tops. The closest power density may be higher or lower than the applicable threshold value.

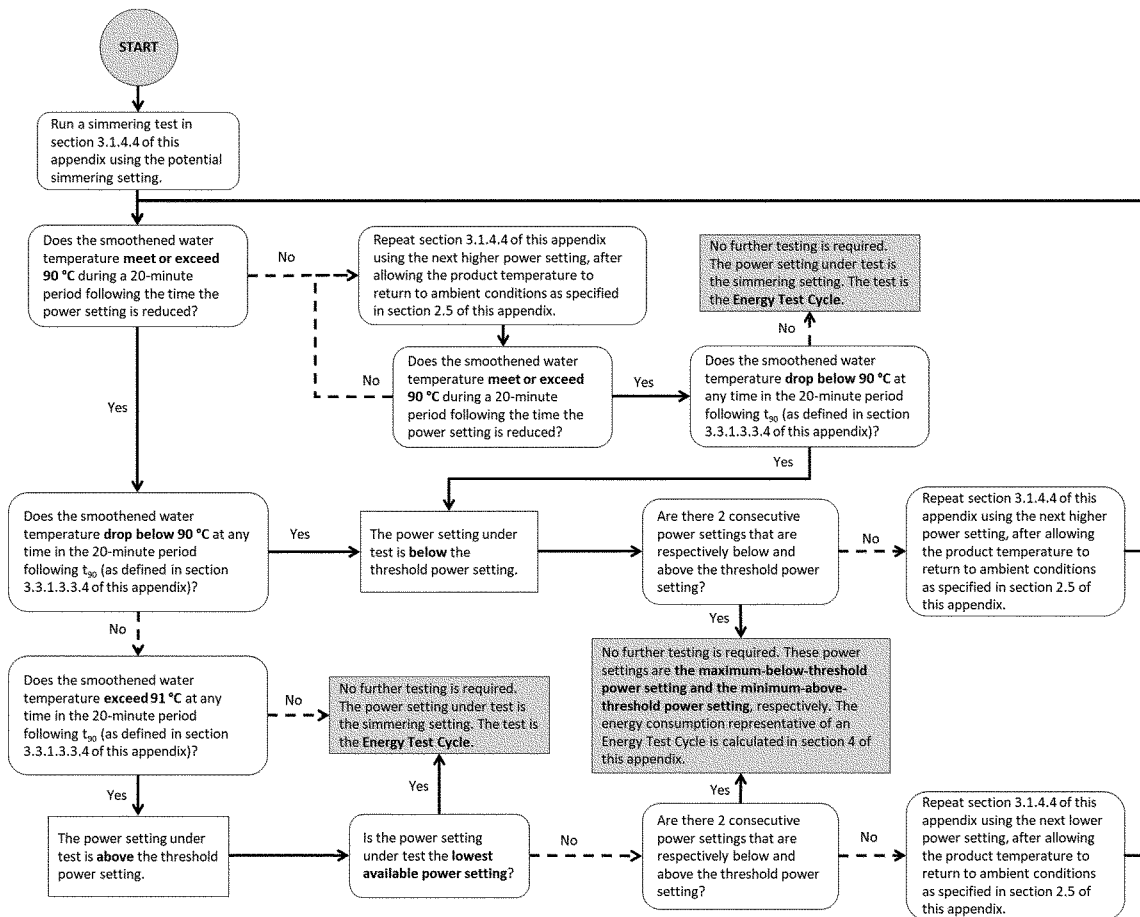
3.1.4.4 *Simmering test.* The product temperature must meet the specifications in section 2.5 of this appendix at the start of each simmering test. For each cooking zone, conduct the test method specified in Section 7.5.2 of IEC 60350–2:2017, using the potential simmering setting identified in section 3.1.4.3 of this appendix for the initial

simmering setting used in Section 7.5.2.2 of IEC 60350–2:2017. For conventional cooking tops with rotating knobs for selecting the power setting, the selection knob shall be turned in the direction from higher power to lower power to select the potential simmering setting for the test, to avoid hysteresis. If the appropriate setting is passed, the test is considered invalid and must be repeated after allowing the product to return to ambient conditions.

3.1.4.5 *Evaluation of the simmering test.* Evaluate the test conducted under section 3.1.4.4 of this appendix as set forth in Section 7.5.4.1 of IEC 60350–2:2017 according to Figure 3.1.4.5 of this appendix. If the measured water temperature at the time the power setting is reduced, T_c , is not within -0.5 °C and $+1$ °C of the target turndown temperature, $T_{c,target}$, the test is considered invalid and must be repeated after allowing the product to return to ambient conditions.

BILLING CODE 6450–01–P

Figure 3.1.4.5 Evaluation of the Simmering Test



BILLING CODE 6450-01-C

3.2 *Standby mode and off mode power.* Establish the standby mode and off mode testing conditions set forth in section 2 of this appendix. For products that take some time to enter a stable state from a higher power state as discussed in Section 5, Paragraph 5.1, Note 1 of IEC 62301 (Second Edition), allow sufficient time for the product to reach the lower power state before proceeding with the test measurement. Follow the test procedure as specified in Section 5, Paragraph 5.3.2 of IEC 62301 (Second Edition) for testing in each possible mode as described in sections 3.2.1 and 3.2.2 of this appendix. For units in which power varies as a function of displayed time in standby mode, set the clock time to 3:23 at the end of an initial stabilization period, as specified in Section 5, Paragraph 5.3 of IEC 62301 (First Edition). After an additional 10 minute stabilization period, measure the power use for a single test period of 10 minutes +0/- 2 seconds that starts when the clock time first reads 3:33. Use the average power approach described in Section 5, Paragraph 5.3.2(a) of IEC 62301 (First Edition).

3.2.1 If the product has an inactive mode, as defined in section 1 of this appendix, measure the average inactive mode power, P_{IA} , in watts.

3.2.2 If the product has an off mode, as defined in section 1 of this appendix, measure the average off mode power, P_{OM} , in watts.

3.3 *Recorded values.*3.3.1 *Active mode.*

3.3.1.1 For a conventional gas cooking top tested with natural gas, record the natural gas higher heating value in Btu per standard cubic foot, H_n , as determined in section 2.2.2.1 of this appendix for the natural gas supply. For a conventional gas cooking top tested with propane, record the propane higher heating value in Btu per standard cubic foot, H_p , as determined in section 2.2.2.2 of this appendix for the propane supply.

3.3.1.2 Record the test room temperature in degrees Celsius and relative air pressure in hectopascals (hPa) during each test.

3.3.1.3 *Per-cooking zone energy consumption test.*

3.3.1.3.1 Record the product temperature in degrees Celsius, T_p , prior to the start of each overshoot test or simmering test, as determined in section 2.5 of this appendix.

3.3.1.3.2 *Overshoot test.* For each cooking zone, record the initial temperature of the water in degrees Celsius, T_i ; the average water temperature between the time 10 seconds before the power is turned off and the time 10 seconds after the power is turned off in degrees Celsius, T_{70} ; the highest

recorded water temperature in degrees Celsius, T_{max} ; and the target turndown temperature in degrees Celsius, $T_{Ctarget}$.

3.3.1.3.3 *Simmering test.* For each cooking zone, record the temperature of the water throughout the test, in degrees Celsius, and the values in sections 3.3.1.3.3.1 through 3.3.1.3.3.7 of this appendix for the Energy Test Cycle, if an Energy Test Cycle is measured in section 3.1.4.5 of this appendix, otherwise for both the maximum-below-threshold power setting and the minimum-above-threshold power setting. Because t_{90} may not be known until completion of the simmering test, water temperature, any electrical energy consumption, and any gas volumetric consumption measurements may be recorded for several minutes after the water temperature first reaches 90 °C to ensure that 20 minutes of the simmering period are recorded.

3.3.1.3.3.1 The power setting under test.

3.3.1.3.3.2 The initial temperature of the water, in degrees Celsius, T_i .

3.3.1.3.3.3 The time at which the power setting is reduced, to the nearest second, t_c and the water temperature when the power setting is reduced, in degrees Celsius, T_c .

3.3.1.3.3.4 The time at which the simmering period starts, to the nearest second, t_{90} , which is defined as the time at which the smoothened water temperature first meets or exceeds 90 °C.

3.3.1.3.3.5 The time, to the nearest second, at the end of a 20-minute simmering period following t_{90} , t_s and the smoothened water temperature at the end of the 20-minute simmering period, in degrees Celsius, T_s .

3.3.1.3.3.6 For a conventional electric cooking top, the electrical energy consumption from the start of the test to t_s , E , in watt-hours.

3.3.1.3.3.7 For a conventional gas cooking top, the volume of gas consumed from the start of the test to t_s , V , in cubic feet of gas; and any electrical energy consumption of the cooking top from the start of the test to t_s , E_e , in watt-hours.

3.3.2 *Standby mode and off mode.* Make measurements as specified in section 3.2 of

this appendix. If the product is capable of operating in inactive mode, as defined in section 1 of this appendix, record the average inactive mode power, P_{IA} , in watts as specified in section 3.2.1 of this appendix. If the product is capable of operating in off mode, as defined in section 1 of this appendix, record the average off mode power, P_{OM} , in watts as specified in section 3.2.2 of this appendix.

4. Calculation of Derived Results From Test Measurements

4.1. Active mode energy consumption of conventional cooking tops and any conventional cooking top component of a combined cooking product.

4.1.1 Per-cycle active mode energy consumption of a conventional cooking top and any conventional cooking top component of a combined cooking product.

4.1.1.1 Conventional electric cooking top per-cycle active mode energy consumption.

4.1.1.1.1 Conventional electric cooking top per-cooking zone normalized active mode energy consumption. For each cooking zone, calculate the per-cooking zone normalized active mode energy consumption of a conventional electric cooking top, E , in watt-hours, using the following equation:

$$E = E_{ETC}$$

for cooking zones where an Energy Test Cycle was measured in section 3.1.4.5 of this appendix, and

$$E = E_{MAT} - \frac{E_{MAT} - E_{MBT}}{T_{S,MAT} - T_{S,MBT}} \times (T_{S,MAT} - 90)$$

for cooking zones where a minimum-above-threshold cycle and a maximum-below-threshold cycle were measured in section 3.1.4.5 of this appendix.

Where:

E_{ETC} = the electrical energy consumption of the Energy Test Cycle from the start of the test to the end of the test for the cooking zone, as determined in section 3.1.4.5 of this appendix, in watt-hours;

E_{MAT} = the electrical energy consumption of the minimum-above-threshold power

setting from the start of the test to the end of the test for the cooking zone, as determined in section 3.1.4.5 of this appendix, in watt-hours;

E_{MBT} = the electrical energy consumption of the maximum-below-threshold power setting from the start of the test to the end of the test for the cooking zone, as determined in section 3.1.4.5 of this appendix, in watt-hours;

$T_{S,MAT}$ = the smoothened water temperature at the end of the minimum-above-

threshold power setting test for the cooking zone, in degrees Celsius; and $T_{S,MBT}$ = the smoothened water temperature at the end of the maximum-below-threshold power setting test for the cooking zone, in degrees Celsius.

4.1.1.1.2 Calculate the per-cycle active mode total energy consumption of a conventional electric cooking top, E_{CET} , in watt-hours, using the following equation:

$$E_{CET} = \frac{2853g}{n} \times \sum_{z=1}^n \frac{E_z}{m_z}$$

Where:

n = the total number of cooking zones tested on the conventional cooking top;

E_z = the normalized energy consumption representative of the Energy Test Cycle for each cooking zone, as calculated in section 4.1.1.1.1 of this appendix, in

watt-hours; m_z is the mass of water used for each cooking zone, in grams; and 2853 = the representative water load mass, in grams.

4.1.1.2 Conventional gas cooking top per-cycle active mode energy consumption.

$$CF = \frac{P_{gas} + P_{atm}}{P_{base}} \times \frac{T_{base}}{T_{gas}}$$

Where:

P_{gas} = the measured line gas gauge pressure, in inches of water;

P_{atm} = the measured atmospheric pressure, in inches of water;

P_{base} = 408.13 inches of water, the standard sea level air pressure;

T_{base} = 519.67 degrees Rankine (or 288.7 Kelvin); and

T_{gas} = the measured line gas temperature, in degrees Rankine (or Kelvin).

4.1.1.2.2 Conventional gas cooking top per-cooking zone normalized active mode gas consumption. For each cooking zone, calculate the per-cooking zone normalized

4.1.1.2.1 Gas correction factor to standard temperature and pressure. Calculate the gas correction factor to standard temperature and pressure, which converts between standard cubic feet and measured cubic feet of gas for a given set of test conditions:

active mode gas consumption of a conventional gas cooking top, V , in cubic feet, using the following equation:

$$V = V_{ETC}$$

for cooking zones where an Energy Test Cycle was measured in section 3.1.4.5 of this appendix, and

$$V = V_{MAT} - \frac{V_{MAT} - V_{MBT}}{T_{S,MAT} - T_{S,MBT}} \times (T_{S,MAT} - 90)$$

for cooking zones where a minimum-above-threshold cycle and a maximum-below-threshold cycle were measured in section 3.1.4.5 of this appendix.

Where:

V_{ETC} = the gas consumption of the Energy Test Cycle from the start of the test to the end of the test for the cooking zone, as determined in section 3.1.4.5 of this appendix, in cubic feet;

V_{MAT} = the gas consumption of the minimum-above-threshold power setting from the start of the test to the end of the test for the cooking zone, as determined

in section 3.1.4.5 of this appendix, in cubic feet;

V_{MBT} = the gas consumption of the maximum-below-threshold power setting from the start of the test to the end of the test for the cooking zone, as determined in section 3.1.4.5 of this appendix, in cubic feet;

$T_{S,MAT}$ = the smoothened water temperature at the end of the minimum-above-threshold power setting test for the cooking zone, in degrees Celsius; and

$T_{S,MBT}$ = the smoothened water temperature at the end of the maximum-below-

threshold power setting test for the cooking zone, in degrees Celsius.

4.1.1.2.3 Conventional gas cooking top per-cooking zone active mode normalized electrical energy consumption. For each cooking zone, calculate the per-cooking zone normalized active mode electrical energy consumption of a conventional gas cooking top, E_e , in watt-hours, using the following equation:

$$E_e = E_{e,ETC}$$

for cooking zones where an Energy Test Cycle was measured in section 3.1.4.5 of this appendix, and

$$E_e = E_{e,MAT} - \frac{E_{e,MAT} - E_{e,MBT}}{T_{S,MAT} - T_{S,MBT}} \times (T_{S,MAT} - 90)$$

for cooking zones where a minimum-above-threshold cycle and a maximum-below-threshold cycle were measured in section 3.1.4.5 of this appendix.

Where:

$E_{e,ETC}$ = the electrical energy consumption of the Energy Test Cycle from the start of the test to the end of the test for the cooking zone, as determined in section 3.1.4.5 of this appendix, in watt-hours;

$E_{e,MAT}$ = the electrical energy consumption of the minimum-above-threshold power

setting from the start of the test to the end of the test for the cooking zone, as determined in section 3.1.4.5 of this appendix, in watt-hours;

$E_{e,MBT}$ = the electrical energy consumption of the maximum-below-threshold power setting from the start of the test to the end of the test for the cooking zone, as determined in section 3.1.4.5 of this appendix, in watt-hours;

$T_{S,MAT}$ = the smoothened water temperature at the end of the minimum-above-

threshold power setting test for the cooking zone, in degrees Celsius; and
 $T_{S,MBT}$ = the smoothened water temperature at the end of the maximum-below-threshold power setting test for the cooking zone, in degrees Celsius.

4.1.1.2.4 Conventional gas cooking top per-cycle active mode gas energy consumption. Calculate the per-cycle active mode gas energy consumption of a conventional gas cooking top, E_{CGG} , in Btu, using the following equation:

$$E_{CGG} = \frac{2853g}{n} \times \sum_{z=1}^n \frac{V_z \times CF \times H}{m_z}$$

Where:

n , m_z , and 2853 are defined in section 4.1.1.1.2 of this appendix;

V_z = the normalized gas consumption representative of the Energy Test Cycle for each cooking zone, as calculated in section 4.1.1.2.2 of this appendix, in cubic feet; and

CF = the gas correction factor to standard temperature and pressure, as calculated in section 4.1.1.2.1 of this appendix

H = either H_n or H_p , the heating value of the gas used in the test as specified in sections 2.2.2.1 and 2.2.2.2 of this appendix, expressed in Btu per standard cubic foot of gas.

4.1.1.2.5 Conventional gas cooking top per-cycle active mode electrical energy consumption. Calculate the per-cycle active mode electrical energy consumption of a conventional gas cooking top, E_{CGE} , in watt-hours, using the following equation:

$$E_{CGE} = \frac{2853g}{n} \times \sum_{z=1}^n \frac{E_{ez}}{m_z}$$

Where:

n , m_z , and 2853 are defined in section 4.1.1.1.2 of this appendix; and

E_{ez} = the normalized electrical energy consumption representative of the Energy Test Cycle for each cooking zone, as calculated in section 4.1.1.2.3 of this appendix, in watt-hours.

4.1.1.2.6 Conventional gas cooking top per-cycle active-mode total energy consumption. Calculate the per-cycle active mode total energy consumption of a conventional gas cooking top, E_{CGT} , in Btu, using the following equation:

$$E_{CGT} = E_{CGG} + (E_{CGE} \times K_e)$$

Where:

E_{CGG} = the per-cycle active mode gas energy consumption of a conventional gas cooking top as determined in section 4.1.1.2.4 of this appendix, in Btu;

E_{CGE} = the per-cycle active mode electrical energy consumption of a conventional gas cooking top as determined in section 4.1.1.2.5 of this appendix, in watt-hours; and $K_e = 3.412$ Btu/Wh, conversion factor of watt-hours to Btu.

4.1.2 Annual active mode energy consumption of a conventional cooking top and any conventional cooking top component of a combined cooking product.

4.1.2.1 Conventional electric cooking top annual active mode energy consumption. Calculate the annual active mode total energy

consumption of a conventional electric cooking top, E_{AET} , in kilowatt-hours per year, using the following equation:

$$E_{AET} = E_{CET} \times K \times N_C$$

Where:

E_{CET} = the conventional electric cooking top per-cycle active mode total energy consumption, as determined in section 4.1.1.1.2 of this appendix, in watt-hours;

$K = 0.001$ kWh/Wh conversion factor for watt-hours to kilowatt-hours; and

$N_C = 418$ cooking cycles per year, the average number of cooking cycles per year normalized for duration of a cooking event estimated for conventional cooking tops.

4.1.2.2 Conventional gas cooking top annual active mode energy consumption.

4.1.2.2.1 Conventional gas cooking top annual active mode gas energy consumption. Calculate the annual active mode gas energy consumption of a conventional gas cooking top, E_{AGG} , in kBtu per year, using the following equation:

$$E_{AGG} = E_{CGG} \times K \times N_C$$

Where:

K and N_C are defined in section 4.1.2.1 of this appendix; and

E_{CGG} = the conventional gas cooking top per-cycle active mode gas energy consumption, as determined in section 4.1.1.2.4 of this appendix, in Btu.

4.1.2.2.2 Conventional gas cooking top annual active mode electrical energy consumption. Calculate the annual active mode electrical energy consumption of a conventional gas cooking top, E_{AGE} , in kilowatt-hours per year, using the following equation:

$$E_{AGE} = E_{CGE} \times K \times N_C$$

Where:

K and N_C are defined in section 4.1.2.1 of this appendix; and

E_{CGE} = the conventional gas cooking top per-cycle active mode electrical energy consumption, as determined in section 4.1.1.2.5 of this appendix, in watt-hours.

4.1.2.2.3 Conventional gas cooking top annual active mode total energy consumption. Calculate the annual active mode total energy consumption of a conventional gas cooking top, E_{AGT} , in kBtu per year, using the following equation:

$$E_{AGT} = E_{AGG} + (E_{AGE} \times K_e)$$

Where:

E_{AGG} = the conventional gas cooking top annual active mode gas energy consumption as determined in section 4.1.2.2.1 of this appendix, in kBtu per year;

E_{AGE} = the conventional gas cooking top annual active mode electrical energy consumption as determined in section 4.1.2.2.2 of this appendix, in kilowatt-hours per year; and

K_e is defined in section 4.1.1.2.6 of this appendix.

4.2 Annual combined low-power mode energy consumption of a conventional cooking top and any conventional cooking top component of a combined cooking product.

4.2.1 Conventional cooking top annual combined low-power mode energy

consumption. Calculate the annual combined low-power mode energy consumption for a conventional cooking top, E_{TLP} , in kilowatt-hours per year, using the following equation:

$$E_{TLP} = [(P_{IA} \times F_{IA}) + (P_{OM} \times F_{OM})] \times K \times S_T$$

Where:

P_{IA} = inactive mode power, in watts, as measured in section 3.2.1 of this appendix;

P_{OM} = off mode power, in watts, as measured in section 3.2.2 of this appendix;

F_{IA} and F_{OM} are the portion of annual hours spent in inactive mode and off mode hours respectively, as defined in Table 4.2.1 of this appendix;

K = 0.001 kWh/Wh conversion factor for watt-hours to kilowatt-hours; and

S_T = 8,544, total number of inactive mode and off mode hours per year for a conventional cooking top.

TABLE 4.2.1—ANNUAL HOUR MULTIPLIERS

Types of low-power mode(s) available	F_{IA}	F_{OM}
Both inactive and off mode ..	0.5	0.5
Inactive mode only	1	0
Off mode only	0	1

4.2.2 Conventional cooking top component of a combined cooking product annual combined low-power mode energy consumption. Calculate the annual combined low-power mode energy consumption for the conventional cooking top component of a combined cooking product, E_{TLP} , in kilowatt-hours per year, using the following equation:

$$E_{TLP} = [(P_{IA} \times F_{IA}) + (P_{OM} \times F_{OM})] \times K \times S_{TOT} \times H_C$$

Where:

P_{IA} , P_{OM} , F_{IA} , F_{OM} , and K are defined in section 4.2.1 of this appendix;

S_{TOT} = the total number of inactive mode and off mode hours per year for a combined cooking product, as defined in Table 4.2.2 of this appendix; and

H_C = the percentage of hours per year assigned to the conventional cooking top component of a combined cooking product, as defined in Table 4.2.2 of this appendix.

TABLE 4.2.2—COMBINED COOKING PRODUCT USAGE FACTORS

Type of combined cooking product	S_{TOT}	H_C (%)
Cooking top and conventional oven (conventional range)	8,392	60
Cooking top and microwave oven	8,481	77
Cooking top, conventional oven, and microwave oven	8,329	51

4.3 Integrated annual energy consumption of a conventional cooking top and any conventional cooking top component of a combined cooking product.

4.3.1 Conventional electric cooking top integrated annual energy consumption. Calculate the integrated annual energy consumption, $IAEC$, of a conventional electric cooking top, in kilowatt-hours per year, using the following equation:

$$IAEC = E_{AET} + E_{TLP}$$

Where:

E_{AET} = the conventional electric cooking top annual active mode energy consumption, as determined in section 4.1.2.1 of this appendix; and

E_{TLP} = the annual combined low-power mode energy consumption of a conventional cooking top or any conventional cooking top component of a combined cooking product, as determined in section 4.2 of this appendix.

4.3.2 Conventional gas cooking top integrated annual energy consumption. Calculate the integrated annual energy consumption, $IAEC$, of a conventional gas cooking top, in kBtu per year, defined as:

$$IAEC = E_{AGT} + (E_{TLP} \times K_e)$$

Where:

E_{AGT} = the conventional gas cooking top annual active mode total energy consumption, as determined in section 4.1.2.2.3 of this appendix;

E_{TLP} = the annual combined low-power mode energy consumption of a conventional cooking top or any conventional cooking top component of a combined cooking product, as determined in section 4.2 of this appendix; and

K_e is defined in section 4.1.1.2.6 of this appendix.

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Department of Defense

General Services Administration

National Aeronautics and Space Administration

48 CFR Chapter 1

Federal Acquisition Regulations; Final Rules

DEPARTMENT OF DEFENSE**GENERAL SERVICES
ADMINISTRATION****NATIONAL AERONAUTICS AND
SPACE ADMINISTRATION****48 CFR Chapter 1**

[Docket No. FAR–2021–0051, Sequence No. 5]

**Federal Acquisition Regulation;
Federal Acquisition Circular 2022–01;
Introduction****AGENCY:** Department of Defense (DoD),
General Services Administration (GSA),and National Aeronautics and Space
Administration (NASA).**ACTION:** Summary presentation of final
rules.**SUMMARY:** This document summarizes
the Federal Acquisition Regulation
(FAR) rules agreed to by the Civilian
Agency Acquisition Council and the
Defense Acquisition Regulations
Council (Councils) in this Federal
Acquisition Circular (FAC) 2022–01. A
companion document, the *Small Entity
Compliance Guide* (SECG), follows this
FAC.**DATES:** For effective dates see the
separate documents, which follow.**ADDRESSES:** The FAC, including the
SECG, is available via the internet at
<https://www.regulations.gov>.**FOR FURTHER INFORMATION CONTACT:** The
analyst whose name appears in the table
below in relation to the FAR case. For
information pertaining to status or
publication schedules, contact the
Regulatory Secretariat Division at 202–
501–4755 or GSARegSec@gsa.gov.**RULES LISTED IN FAC 2022–01**

Item	Subject	FAR case	Analyst
I	Revision of Definition of “Commercial Item”	2018–018	Delgado.
II	Consolidation and Substantial Bundling	2019–003	Bowman.
III	Maximum Award Price for Certain Sole Source Manufacturing Contracts	2021–007	Jackson.

SUPPLEMENTARY INFORMATION:

Summaries for each FAR rule follow.
For the actual revisions and/or
amendments made by these FAR rules,
refer to the specific item numbers and
subjects set forth in the documents
following these item summaries. FAC
2022–01 amends the FAR as follows:

**Item I—Revision of Definition of
“Commercial Item” (FAR Case 2018–
018)**

This final rule removes the definition
of “commercial item” and replaces it
with the definitions of “commercial
product” and “commercial service”.
The rule makes numerous conforming
changes throughout the FAR. The rule
implements section 836 of the John S.
McCain National Defense Authorization
Act for Fiscal Year 2019 (Pub. L. 115–
232). This final rule will not have a
significant economic impact on a
substantial number of small entities.

**Item II—Consolidation and Substantial
Bundling (FAR Case 2019–003)**

This final rule amends the FAR to
implement section 863 of the National
Defense Authorization Act for Fiscal
Year 2016, as implemented in the Small
Business Administration (SBA) final
rule published at 84 FR 65647 on
November 29, 2019. Section 863
requires publication of public notices of
determinations for consolidation and
substantial bundling of contract
requirements. Specifically, section 863
requires the head of an agency to
publish a notice on a public website
within 7 days of making the

determination that an acquisition plan
involves a substantial bundling of
contract requirements. Section 863 also
requires the Senior Procurement
Executive or Chief Acquisition Officer
to publish a notice on a public website
that consolidation of contract
requirements is necessary and justified.
In both cases, the agency may not issue
the solicitation any earlier than 7 days
after publication of the notices. The
agency must also publish the
justification along with the solicitation.

**Item III—Maximum Award Price for
Certain Sole Source Manufacturing
Contracts (FAR Case 2021–007)**

This final rule amends the FAR to
implement section 864 of the William
M. (Mac) Thornberry National Defense
Authorization Act for Fiscal Year 2021
(Pub. L. 116–283, January 1, 2021).
Section 864 amends the Small Business
Act to modify the maximum award
price for manufacturing contracts to \$7
million for 8(a) program participants,
Women-Owned Small Business (WOSB)
program participants, Historically
Underutilized Business Zone
(HUBZone) small business concerns,
and Service-Disabled Veteran-Owned
Small Business (SDVOSB) concerns.

William F. Clark,

*Director, Office of Government-wide
Acquisition Policy, Office of Acquisition
Policy, Office of Government-wide Policy.*

Federal Acquisition Circular (FAC)
2022–01 is issued under the authority of
the Secretary of Defense, the
Administrator of General Services, and

the Administrator of National
Aeronautics and Space Administration.

Unless otherwise specified, all
Federal Acquisition Regulation (FAR)
and other directive material contained
in FAC 2022–01 is effective November
4, 2021 except for Items I through III,
which are effective December 6, 2021.

John M. Tenaglia,

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DEPARTMENT OF DEFENSE**GENERAL SERVICES
ADMINISTRATION****NATIONAL AERONAUTICS AND
SPACE ADMINISTRATION**

48 CFR Parts 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 18, 19, 22, 23, 25, 26, 27, 28, 29, 30, 31, 32, 37, 38, 39, 42, 43, 44, 46, 47, 49, 52, and 53

[FAC 2022–01; FAR Case 2018–018; Item I; Docket No. FAR–2018–0018, Sequence No. 1]

RIN 9000–AN76

**Federal Acquisition Regulation:
Revision of Definition of “Commercial
Item”**

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Final rule.

SUMMARY: DoD, GSA, and NASA are issuing a final rule amending the Federal Acquisition Regulation (FAR) to implement a section of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 to change the definition of “commercial item.”

DATES: Effective December 6, 2021.

FOR FURTHER INFORMATION CONTACT: Ms. Zenaida Delgado, Procurement Analyst, at 202–969–7207 or by email at zenaida.delgado@gsa.gov, for clarification of content. For information pertaining to status or publication schedules, contact the Regulatory Secretariat Division at 202–501–4755 or GSARegSec@gsa.gov. Please cite FAC 2022–01, FAR Case 2018–018.

SUPPLEMENTARY INFORMATION:**I. Background**

DoD, GSA, and NASA published a proposed rule at 85 FR 65610 on October 15, 2020, to amend the FAR definition of “commercial item” to implement section 836 of the John S. McCain National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2019 (Pub. L. 115–232). Section 836 separates the definition of “commercial item” at 41 U.S.C. 103 into the definitions of “commercial product” and “commercial service,” at 41 U.S.C. 103 and 103a.

Splitting the definition of “commercial item” into the definitions of “commercial product” and “commercial service” was a recommendation made by the independent panel created by section 809 of the NDAA for FY 2016 (Pub. L. 114–92). The panel was created to

review and improve the functioning of the defense acquisition system and eliminate any regulations found unnecessary to achieve such improvements. The panel recommended the splitting of the definition of “commercial item” to better “reflect the significant roles services and commercial services play today in the DoD procurement budget.” See recommendation on pages 29 to 30 of Volume 1 of 3 dated January 2018 of the Report of the Advisory Panel on Streamlining and Codifying Acquisition Regulations, available at https://section809panel.org/wp-content/uploads/2018/04/Sec809Panel_Vol1-Report_Jan18_REVISED_2018-03-14.pdf.

The change in this final rule resolves the issue the Section 809 Panel cites, which is that the “acquisition workforce has faced issues with inconsistent interpretations of policy, confusion over how to identify eligible commercial products and services”. Bifurcating the definition of “commercial item” into “commercial product” and “commercial service” is a way to provide clarity for the acquisition workforce, which may result in greater engagement with the commercial marketplace.

It is important to note that the amendment to separate “commercial item” into “commercial product” and “commercial service” does not expand or shrink the universe of products or services the Government may procure using FAR part 12, nor does it change the terms and conditions with which contractors must comply.

The following summarizes the changes made to the FAR:

1. Removed from FAR part 2 the definition of “commercial item” and replaced it with the definitions of “commercial product” and “commercial service” in accordance with the NDAA with only minor revisions for clarification to align with that which is currently in the FAR. The clarification in paragraph 3(ii) of the definition of “commercial product” has been in FAR part 2 since the definition of “commercial item” was incorporated by FAR case 94–790, Acquisition of Commercial Items, in 1995. Paragraphs 2(i) and 2(ii) of the definition of “commercial service” are also long standing; they stem from a FAR change published October 22, 2001, which was revised slightly in a FAR change published June 18, 2004.

2. Replaced all instances of “non-commercial” and “noncommercial” with “other than commercial” as it relates to this rule. This editorial change provides consistent language throughout the FAR.

3. Removed FAR 12.102(g), and a corresponding reference at FAR 37.601(c), as obsolete. FAR 12.102(g) only applied to contracts or orders entered into before November 23, 2013.

4. Added the definition of “established price” at FAR 16.001 to be consistent with the term as defined at the FAR clauses at FAR 52.216–2, Economic Price Adjustment—Standard Supplies, and 52.216–3, Economic Price Adjustment—Semistandard Supplies. This is an editorial change for consistency to have the definition in both the clause and the corresponding FAR part.

5. Made conforming changes to cross references, and the following Standard Forms (SF): SF 294, Subcontracting Report for Individual Contracts; SF 1443, Contractor’s Request for Progress Payment; and SF 1449, Solicitation/Contract/Order for Commercial Products and Commercial Services. Also, minor editorial changes were made as needed throughout the FAR. These revisions do not impact terms and conditions of commercial contracts or how the Government procures commercial products or commercial services.

Three respondents submitted comments on the proposed rule.

II. Discussion and Analysis

The Civilian Agency Acquisition Council and the Defense Acquisition Regulations Council (the Councils) reviewed the public comments in the development of the final rule. A discussion of the comments and the changes made to the rule as a result of those comments are provided as follows:

A. Summary of Significant Changes

There are no significant changes from the proposed rule.

B. Analysis of Public Comments

Of the three responses received, none provided negative comments on the rule, although they suggested changes as described below. No changes resulted from the public comments.

Comment: A respondent expressed that paragraph (1) of the commercial product definition in the proposed rule is not consistent with the language in 41 U.S.C. 103(1). This respondent stated that while the wording for both definitions is very similar, the structure of the definition as promulgated in current law indicates it was the intent of Congress that for a product to meet the definition of a commercial product under paragraph (1), it must have been sold, leased, or licensed, or offered for sale, lease, or license, to the general public.

Response: The Councils note that the respondent's quoted definition is similar to the statutory definition, and to the definition used in the proposed rule. No change is necessary.

Comment: Two respondents suggested to explicitly include commercial services under the definition of commercial-off-the-shelf ("COTS") items to provide the Government access to the broadest range of service providers. One respondent pointed to the following benefits: increase competition and allow Government customers quicker access to required commercial services. A respondent suggested to, at least, clarify that commercial wireless telecommunications offerings constitute a "commercial product" and thus can satisfy all definitional elements of COTS items.

Response: The Councils cannot accept the suggestions because they are not consistent with the statute being implemented. Section 836 of the NDAA for FY 2019 did not modify the definition of COTS item.

C. Other Changes

Other changes made in the final rule are as follows:

- Revisions were made to account for additional instances of the term "commercial item" in the FAR after the proposed rule was published in the following sections: FAR 9.110–4(b), 9.110–5, 9.405–1, 39.205(a)(3) and (c)(3), 43.105(c), 52.209–14(d)(1), 52.229–13(c), and 52.229–14(c).

- Three changes missed in the proposed rule were added as follows: the heading of FAR subpart 12.1, the word "commercial" at FAR 15.601, and the inclusion of "commercial products" in 52.212–5(b)(36).

- Prescriptive language was relocated from the introductory text for the FAR clauses at 52.216–2, 52.216–3, and 52.216–4 to FAR 16.203–4(a)(4), (b)(6), and (c)(5), respectively, to be consistent with FAR drafting conventions.

III. Applicability to Contracts at or Below the Simplified Acquisition Threshold (SAT) and for Commercial Products (Including Commercially Available Off-the-Shelf (COTS) Items), or for Commercial Services

This rule does not create new solicitation provisions or contract clauses. This rule merely replaces the term "commercial item(s)" with "commercial product(s)," "commercial service(s)," "commercial product(s) or commercial service(s)," or "commercial product(s) and commercial service(s)" in the FAR including in part 52, as appropriate. This rule does not impose

any new requirements on contracts at or below the SAT or for commercial products, including COTS items, or for commercial services.

IV. Executive Orders 12866 and 13563

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

V. Congressional Review Act

As required by the Congressional Review Act (5 U.S.C. 801–808) before an interim or final rule takes effect, DoD, GSA, and NASA will send the rule and the "Submission of Federal Rules Under the Congressional Review Act" form to each House of the Congress and to the Comptroller General of the United States. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. The Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget has determined that this is not a major rule under 5 U.S.C. 804.

VI. Regulatory Flexibility Act

DoD, GSA, and NASA have prepared a Final Regulatory Flexibility Analysis (FRFA) consistent with the Regulatory Flexibility Act, 5 U.S.C. 601–612. The FRFA is summarized as follows:

This final rule amends the FAR to change the definition of "commercial item" by splitting it into the definitions of "commercial product" and "commercial service".

The objective is to implement section 836 of the John S. McCain NDAA for FY19 (Pub. L. 115–232). This is consistent with the recommendations by the independent panel created by section 809 of the NDAA for FY 2016 (Pub. L. 114–92). This case implements amendments to 41 U.S.C. 103 and 103a. The legal basis for this rule is 40 U.S.C. 121(c), 10 U.S.C. chapter 137, and 51 U.S.C. 20113.

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

The final rule impacts all entities that do business with the Federal Government, including the over 327,458 small business registrants in the System for Award Management. However, the rule does not implement any requirements with which

small entities must comply. This rule splits the definition of "commercial item" into the definitions of "commercial product" and "commercial service".

The final rule does not include additional reporting or record keeping requirements.

There are no available alternatives to the final rule to accomplish the desired objective of the statute.

Interested parties may obtain a copy of the FRFA from the Regulatory Secretariat Division. The Regulatory Secretariat Division has submitted a copy of the FRFA to the Chief Counsel for Advocacy of the Small Business Administration.

VII. Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C 3501–3521) applies; however, the changes to the FAR and the updates to the information collections do not impose new information collection burden. The changes do not impose additional, or change any existing, information collection requirements to the paperwork burden previously approved under the following OMB Control Numbers: 9000–0007, Subcontracting Plans; 9000–0018, Federal Acquisition Regulation Part 3: Improper Business Practices and Personal Conflicts of Interest; 9000–0193, FAR Part 9 Responsibility Matters; 9000–0097, Federal Acquisition Regulation Part 4 Requirements; 9000–0136, Commercial Item Acquisitions; 9000–0034, Examination of Records by Comptroller General and Contract Audit; 9000–0013, Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data; 9000–0048, Authorized Negotiators and Integrity of Unit Prices; 9000–0010, Progress Payments, SF 1443; 9000–0024, Buy American, Trade Agreements, and Duty-Free Entry; 9000–0061, Transportation Requirements; 9000–0068, Economic Price Adjustment; 9000–0070, Payments; 9000–0138, Contract Financing; 9000–0188, Combating Trafficking in Persons; 9000–0197, Use of Products and Services of Kaspersky Lab; 9000–0198, Violations of Arms Control Treaties or Agreements; and 1615–0092, E-Verify Program.

List of Subjects in 48 CFR Parts 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 18, 19, 22, 23, 25, 26, 27, 28, 29, 30, 31, 32, 37, 38, 39, 42, 43, 44, 46, 47, 49, 52, and 53

Government procurement.

William F. Clark,

Director, Office of Government-wide Acquisition Policy, Office of Acquisition Policy, Office of Government-wide Policy.

Therefore, DoD, GSA, and NASA amend 48 CFR parts 1, 2, 3, 4, 5, 6, 7,

8, 9, 10, 11, 12, 13, 14, 15, 16, 18, 19, 22, 23, 25, 26, 27, 28, 29, 30, 31, 32, 37, 38, 39, 42, 43, 44, 46, 47, 49, 52, and 53 as set forth below:

■ 1. The authority citation for 48 CFR parts 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 18, 19, 22, 23, 25, 26, 27, 28, 29, 30, 31, 32, 37, 38, 39, 42, 43, 44, 46, 47, 49, 52, and 53 continues to read as follows:

Authority: 40 U.S.C. 121(c); 10 U.S.C. chapter 137; and 51 U.S.C. 20113.

PART 1—FEDERAL ACQUISITION REGULATIONS SYSTEM

1.102 [Amended]

■ 2. Amend section 1.102 by removing from paragraph (b)(1)(i) the phrase “commercial products and services;” and adding the phrase “commercial products and commercial services;” in its place.

1.102–2 [Amended]

■ 3. Amend section 1.102–2 by removing from paragraph (a)(4) the phrase “commercial products and services” and adding the phrase “commercial products and commercial services” in its place.

PART 2—DEFINITIONS OF WORDS AND TERMS

■ 4. Amend section 2.101 in paragraph (b)(2) by—

■ a. In the defined term “Biobased product”, removing the phrase “commercial or industrial product” and adding the phrase “commercial product or industrial product” in its place;

■ b. In the defined term “Commercial component”, removing the words “commercial item” and adding the words “commercial product” in its place;

■ c. In the defined term “Commercial computer software”, removing the words “commercial item” and adding the words “commercial product or commercial service” in its place.

■ d. Removing the defined term “Commercial item”;

■ e. Adding the defined terms “Commercial product” and “Commercial service” in alphabetical order; and

■ f. In the defined term “Commercially available off-the-shelf (COTS) item”, removing from paragraph (1)(i) “commercial item” and “definition in this section” and adding “commercial product” and “definition of “commercial product” in this section” in their places, respectively.

The additions read as follows:

2.101 Definitions.

* * * * *

(b) * * *

(2) * * *

Commercial product means—

(1) A product, other than real property, that is of a type customarily used by the general public or by nongovernmental entities for purposes other than governmental purposes, and—

(i) Has been sold, leased, or licensed to the general public; or

(ii) Has been offered for sale, lease, or license to the general public;

(2) A product that evolved from a product described in paragraph (1) of this definition through advances in technology or performance and that is not yet available in the commercial marketplace, but will be available in the commercial marketplace in time to satisfy the delivery requirements under a Government solicitation;

(3) A product that would satisfy a criterion expressed in paragraph (1) or (2) of this definition, except for—

(i) Modifications of a type customarily available in the commercial marketplace; or

(ii) Minor modifications of a type not customarily available in the commercial marketplace made to meet Federal Government requirements. “Minor modifications” means modifications that do not significantly alter the nongovernmental function or essential physical characteristics of an item or component, or change the purpose of a process. Factors to be considered in determining whether a modification is minor include the value and size of the modification and the comparative value and size of the final product. Dollar values and percentages may be used as guideposts, but are not conclusive evidence that a modification is minor;

(4) Any combination of products meeting the requirements of paragraph (1), (2), or (3) of this definition that are of a type customarily combined and sold in combination to the general public;

(5) A product, or combination of products, referred to in paragraphs (1) through (4) of this definition, even though the product, or combination of products, is transferred between or among separate divisions, subsidiaries, or affiliates of a contractor; or

(6) A nondevelopmental item, if the procuring agency determines the product was developed exclusively at private expense and sold in substantial quantities, on a competitive basis, to multiple State and local governments or to multiple foreign governments.

Commercial service means—

(1) Installation services, maintenance services, repair services, training services, and other services if—

(i) Such services are procured for support of a commercial product as defined in this section, regardless of whether such services are provided by the same source or at the same time as the commercial product; and

(ii) The source of such services provides similar services contemporaneously to the general public under terms and conditions similar to those offered to the Federal Government;

(2) Services of a type offered and sold competitively in substantial quantities in the commercial marketplace based on established catalog or market prices for specific tasks performed or specific outcomes to be achieved and under standard commercial terms and conditions. For purposes of these services—

(i) *Catalog price* means a price included in a catalog, price list, schedule, or other form that is regularly maintained by the manufacturer or vendor, is either published or otherwise available for inspection by customers, and states prices at which sales are currently, or were last, made to a significant number of buyers constituting the general public; and

(ii) *Market prices* means current prices that are established in the course of ordinary trade between buyers and sellers free to bargain and that can be substantiated through competition or from sources independent of the offerors; or

(3) A service referred to in paragraph (1) or (2) of this definition, even though the service is transferred between or among separate divisions, subsidiaries, or affiliates of a contractor.

* * * * *

PART 3—IMPROPER BUSINESS PRACTICES AND PERSONAL CONFLICTS OF INTEREST

3.104–1 [Amended]

■ 5. In section 3.104–1 amend the definition of “Contractor bid or proposal information” in paragraph (1) by removing “10 U.S.C. 2306a(h)” and adding in its place “10 U.S.C. 2306a(h)(1)” and removing “41 U.S.C. 3501(a)(2)” and adding “41 U.S.C. 3501(a)(1)” in its place.

■ 6. Amend section 3.104–9 by revising the introductory text to read as follows:

3.104–9 Contract clauses.

In solicitations and contracts that exceed the simplified acquisition threshold, other than those for commercial products or commercial services, insert the clauses at—

* * * * *

3.404 [Amended]

- 7. Amend section 3.404 by removing “commercial items” and adding “commercial products or commercial services” in its place.
- 8. Amend section 3.502–2 by revising paragraph (i) introductory text to read as follows:

3.502–2 Subcontractor kickbacks.

* * * * *

(i) Requires each contracting agency to include in each prime contract, other than for commercial products or commercial services, exceeding \$150,000, a requirement that the prime contractor shall—

* * * * *

3.502–3 [Amended]

- 9. Amend section 3.502–3 by removing “commercial items” and adding “commercial products or commercial services” in its place.

3.503–2 [Amended]

- 10. Amend section 3.503–2 by removing “commercial items” and adding “commercial products or commercial services” in its place.

3.1004 [Amended]

- 11. Amend section 3.1004 by removing from paragraph (b)(1) “commercial item” and “FAR 52.203–14” and adding “commercial product or commercial service” and “52.203–14” in their places, respectively.

PART 4—ADMINISTRATIVE AND INFORMATION MATTERS**4.203 [Amended]**

- 12. Amend section 4.203 by removing from paragraph (a) the term “Commercial Items” and adding the term “Commercial Products and Commercial Services” in its place.

4.605 [Amended]

- 13. Amend section 4.605 by removing from paragraph (b) the term “Commercial Items” and adding the term “Commercial Products and Commercial Services” in its place.

4.1103 [Amended]

- 14. Amend section 4.1103 by removing from paragraph (a)(3) the term “Commercial Items” and adding the term “Commercial Products and Commercial Services” in its place.

4.1201 [Amended]

- 15. Amend section 4.1201 by removing from paragraph (d) the term “commercial items” and adding the term “commercial products or commercial services” in its place.

4.1202 [Amended]

- 16. Amend section 4.1202 by removing from paragraph (a) introductory text the terms “commercial item solicitations” and “FAR part 12” and adding the terms “solicitations for commercial products or commercial services” and “part 12” in their places, respectively.

4.1902 [Amended]

- 17. Amend section 4.1902 by removing the text “commercial items” and adding “commercial products or commercial services,” in its place.

PART 5—PUBLICIZING CONTRACT ACTIONS**5.202 [Amended]**

- 18. Amend section 5.202 by removing from paragraph (a)(10) “commercial items” and adding “commercial products” in its place.

5.203 [Amended]

- 19. Amend section 5.203 by removing from paragraphs (a) introductory text, (b), and (c) the term “commercial items” and adding “commercial products or commercial services” in their places, respectively.

PART 6—COMPETITION REQUIREMENTS**6.001 [Amended]**

- 20. Amend section 6.001 by removing from paragraph (a) “commercial items” and adding “commercial products or commercial services” in its place.

6.302–5 [Amended]

- 21. Amend section 6.302–5 by:
 - a. Removing from paragraph (a)(2)(ii) “commercial item” and adding “commercial product” in its place; and
 - b. Removing from paragraph (c)(3) “brand-name commercial items” and adding “brand name commercial products” in its place.
- 22. Amend section 6.502 by—
 - a. Revising paragraph (a);
 - b. Removing from paragraph (b)(1)(i) the term “commercial items” and adding “commercial products and commercial services” in its place;
 - c. Removing from paragraph (b)(1)(iv) the term “commercial items or” and adding “commercial products or commercial services or unnecessarily restricting” in its place;
 - d. Removing from paragraph (b)(2)(ii) the term “commercial items” and adding “commercial products and commercial services” in its place; and
 - e. Removing from paragraphs (b)(2)(v) and (vi) the term “commercial items”

and adding “commercial products, commercial services,” in its place.

The revision reads as follows:

6.502 Duties and responsibilities.

(a) Agency and procuring activity advocates for competition are responsible for—

- (1) Promoting the acquisition of commercial products and commercial services;
- (2) Promoting full and open competition;
- (3) Challenging requirements that are not stated in terms of functions to be performed, performance required, or essential physical characteristics;
- (4) Challenging barriers to the acquisition of commercial products and commercial services; and
- (5) Challenging barriers to full and open competition such as unnecessarily restrictive statements of work, unnecessarily detailed specifications, and unnecessarily burdensome contract clauses.

* * * * *

PART 7—ACQUISITION PLANNING**7.102 [Amended]**

- 23. Amend section 7.102 by removing from paragraph (a)(1) the phrase “commercial items or, to the extent that commercial items suitable” and adding “commercial products or commercial services, or to the extent that commercial products suitable” in its place.

7.103 [Amended]

- 24. Amend section 7.103 by removing from paragraph (b) the phrase “commercial items, or to the extent that commercial items suitable” and adding “commercial products or commercial services, or to the extent that commercial products suitable” in its place.

7.105 [Amended]

- 25. Amend section 7.105 by removing from paragraph (b)(14)(i) the term “commercial items” and adding “commercial products or commercial services” in its place.

PART 8—REQUIRED SOURCES OF SUPPLIES AND SERVICES**8.402 [Amended]**

- 26. Amend section 8.402 by—
 - a. Removing from paragraph (a) the term “commercial supplies and services” and adding “commercial supplies and commercial services” in its place; and
 - b. Removing from paragraph (f)(1) the phrase “commercial items (part 12),”

and adding “commercial products or commercial services (part 12),” in its place.

PART 9—CONTRACTOR QUALIFICATIONS

9.106–1 [Amended]

■ 27. Amend section 9.106–1 by removing from paragraph (a) the term “commercial items” and adding “commercial products or commercial services” in its place.

9.109–5 [Amended]

■ 28. Amend section 9.109–5 by removing the text “commercial items” and adding “commercial products or commercial services” in its place.

9.110–4 [Amended]

■ 29. Amend section 9.110–4 by removing from paragraph (b) “commercial items” and adding “commercial products and commercial services” in its place.

9.110–5 [Amended]

■ 30. Amend section 9.110–5 by removing the term “commercial items” and adding “commercial products and commercial services” in its place.

9.405–1 [Amended]

■ 31. Amend section 9.405–1 by removing from paragraph (b) the term “commercial items” and adding “commercial products and commercial services” in its place.

9.405–2 [Amended]

■ 32. Amend section 9.405–2 in paragraph (b) introductory text, in the fourth sentence, by removing “commercial items” and adding “commercial products” in its place.

PART 10—MARKET RESEARCH

■ 33. Amend section 10.001 by—
 ■ a. Removing from paragraph (a)(2)(v) the phrase “for a noncommercial item” and adding “for other than a commercial product or commercial service” in its place;
 ■ b. Removing from paragraph (a)(3)(ii) introductory text the phrase “commercial items or, to the extent commercial items suitable” and adding “commercial products or commercial services, or, to the extent commercial products suitable” in its place;
 ■ c. Removing from paragraph (a)(3)(iii) the term “commercial items” and adding “commercial products” in its place;
 ■ d. Removing from paragraph (a)(3)(iv) the term “commercial items” and adding “commercial products or commercial services” in its place; and

■ e. Revising paragraph (d).
 The revision reads as follows:

10.001 Policy.

* * * * *

(d) See 10.003 for the requirement for a prime contractor to perform market research in contracts in excess of \$6 million, other than contracts for the acquisition of commercial products or commercial services (section 826 of Pub. L. 110–181).

10.002 [Amended]

■ 34. Amend section 10.002 by—
 ■ a. Removing from paragraph (b) introductory text the term “commercial items” and adding “commercial products, commercial services,” in its place;
 ■ b. Removing from paragraph (b)(1) introductory text the word “item” and adding “product or service” in its place;
 ■ c. Removing from paragraphs (b)(1)(i)(A), (B), and (C) the word “Items” and adding “Products or services” in its place;
 ■ d. Removing from paragraph (b)(1)(ii) the word “items” and adding “products or services” in its place;
 ■ e. Removing from paragraph (c) the phrases “indicates commercial” and “permit commercial” and adding “indicates commercial products, commercial services,” and “permit commercial products, commercial services,” in their places, respectively; and
 ■ f. Removing from paragraph (d)(1) the phrases “item or” and “commercial item” and adding “product or” and “commercial product or commercial service” in their places, respectively.
 ■ 35. Revise section 10.003 to read as follows:

10.003 Contract clause.

The contracting officer shall insert the clause at 52.210–1, Market Research, in solicitations and contracts over \$6 million, other than solicitations and contracts for the acquisition of commercial products or commercial services.

PART 11—DESCRIBING AGENCY NEEDS

11.002 [Amended]

■ 36. Amend section 11.002 by—
 ■ a. Removing from paragraph (a)(2)(ii) the phrase “commercial items, or, to the extent that commercial items suitable” and adding “commercial products or commercial services or, to the extent that commercial products suitable” in its place;
 ■ b. Removing from paragraphs (a)(2)(iii) and (iv) the term “commercial

items” and adding “commercial products, commercial services,” in its place; and

■ c. Removing from paragraph (a)(2)(v) the terms “commercial items or,” and “commercial items suitable” and adding “commercial products or commercial services or,” and “commercial products suitable” in their places, respectively.

11.302 [Amended]

■ 37. Amend section 11.302 by—
 ■ a. Removing from paragraph (b)(1) the terms “acquiring other” and “commercial items” and adding “acquiring products other” and “commercial products as defined in 2.101” in their places, respectively;
 ■ b. Removing from paragraph (b)(2) the terms “commercial items” and “the item” and adding “commercial products” and “the product” in their places, respectively; and
 ■ c. Removing from paragraph (c)(1) the term “commercial items” and adding “commercial products” in its place.

11.304 [Amended]

■ 38. Amend section 11.304 by removing the text “commercial items” and adding “commercial products” in its place.

PART 12—ACQUISITION OF COMMERCIAL PRODUCTS AND COMMERCIAL SERVICES

■ 39. Revise the part heading to read as set forth above.

12.000 [Amended]

■ 40. Amend section 12.000 by—
 ■ a. In the first sentence, removing the term “commercial items” and adding “commercial products, including commercial components, and commercial services” in its place; and
 ■ b. In the second sentence, removing the terms “commercial items” and “commercial items and components” and adding “commercial products and commercial services” in their place.

12.001 [Amended]

■ 41. Amend section 12.001 by removing the term “commercial items” and adding “commercial products or commercial services” in its place.
 ■ 42. Revise the heading of subpart 12.1 to read as follows:

Subpart 12.1—Acquisition of Commercial Products and Commercial Services

12.101 [Amended]

■ 43. Amend section 12.101 by removing the term “commercial items” wherever it appears and adding

“commercial products, commercial services,” in its place.

12.102 [Amended]

- 44. Amend section 12.102 by—
- a. Removing from paragraph (a) the phrase “the definition of commercial items” and adding “the definitions of “commercial product” or “commercial service” in its place;
- b. Removing from paragraph (c) the term “commercial items” wherever it appears and adding “commercial products or commercial services” in its place;
- c. Removing from paragraph (d) the phrase “commercial item in section 2.101” and adding “commercial product” in its place;
- d. Removing from paragraphs (e) and (f)(1) the term “commercial items” and adding “commercial products or commercial services” in its place;
- e. In paragraph (f)(2) introductory text:
 - i. Removing the term “for an item” and adding “for a product” in its place; and
 - ii. Removing the term “commercial item” wherever it appears and adding “commercial product or commercial service” in its place;
- f. Removing from paragraph (f)(2)(i) “see Subpart 30.2” and adding “see subpart 30.2” in its place; and
- g. Removing paragraph (g).

12.103 [Amended]

- 45. Amend section 12.103 by removing the text “commercial items” and “12.504;” and adding “commercial products” and “12.504.” in their places, respectively.
- 46. Revise the heading of subpart 12.2 to read as follows:

Subpart 12.2—Special Requirements for the Acquisition of Commercial Products and Commercial Services

12.201 [Amended]

- 47. Amend section 12.201 by removing “commercial items” wherever it appears and adding “commercial products and commercial services” in its place.

12.202 [Amended]

- 48. Amend section 12.202 by—
- a. Removing from paragraph (a) the term “commercial items” and adding “commercial products and commercial services” in its place; and
- b. In paragraph (b):
 - i. Removing in the first sentence the terms “commercial items” and “products or services” and adding “commercial products or commercial services” and “products or commercial services” in their places, respectively; and

- ii. Removing in the second sentence the terms “commercial item” and “type of product or service” and adding “commercial product or commercial service” and “type of commercial product or commercial service” in their places, respectively.

12.203 [Amended]

- 49. Amend section 12.203 in paragraph (a) by:
 - a. In the first sentence, removing the term “commercial items” and adding in its place the phrase “commercial products and commercial services”; and
 - b. In the second and third sentences, removing the term “commercial items” wherever it appears and adding in its place the phrase “commercial products or commercial services”.
- 50. Amend section 12.204 by revising paragraph (a) to read as follows:

12.204 Solicitation/contract form.

(a)(1) The contracting officer shall use the Standard Form 1449, Solicitation/Contract/Order for Commercial Products and Commercial Services, if—

- (i) The acquisition is expected to exceed the simplified acquisition threshold;
- (ii) A paper solicitation or contract is being issued; and
- (iii) Procedures at 12.603 are not being used.

(2) Use of the SF 1449 is nonmandatory but encouraged for commercial acquisitions not exceeding the simplified acquisition threshold.

* * * * *

12.205 [Amended]

- 51. Amend section 12.205 by—
- a. In paragraph (a):
 - i. In the first sentence, removing the word “product”; and
 - ii. In the second sentence, removing the phrase “product literature from offerors of commercial items” and adding “product or service literature from offerors of commercial products or commercial services” in its place;
- b. In paragraph (b):
 - i. In the first sentence, removing the phrases “more than one product” and “commercial items” and adding “multiple offers” and “commercial products or commercial services” in their places, respectively; and
 - ii. In the second sentence, removing the phrase “product as a separate offer” and adding “offer separately” in its place; and
- c. Removing from paragraph (c) the words “commercial items” and adding “commercial products or commercial services” in their place.

12.206 [Amended]

- 52. Amend section 12.206 by removing the text “commercial items” and adding “commercial products and commercial services” in its place.

12.207 [Amended]

- 53. Amend section 12.207 by removing from paragraphs (a) and (e) the words “commercial items” and adding “commercial products or commercial services” in their places.
- 54. Revise section 12.208 to read as follows:

12.208 Contract quality assurance.

Contracts for commercial products shall rely on contractors’ existing quality assurance systems as a substitute for Government inspection and testing before tender for acceptance unless customary market practices for the commercial product being acquired include in-process inspection. Any in-process inspection by the Government shall be conducted in a manner consistent with commercial practice. The Government shall rely on the contractor to accomplish all inspection and testing needed to ensure that commercial services acquired conform to contract requirements before they are tendered to the Government.

12.209 [Amended]

- 55. Amend section 12.209 by removing the words “commercial items” and “Commercial item” and adding “commercial products and commercial services” and “Commercial product and commercial service” in their places, respectively.

12.210 [Amended]

- 56. Amend section 12.210 by removing the text “commercial items” and adding “commercial products and commercial services” in its place.

12.211 [Amended]

- 57. Amend section 12.211 by:
 - a. Removing the text “commercial item” and adding “commercial product” in its place; and
 - b. Removing the text “commercial items” wherever it appears and adding “commercial products” in its place.

12.214 [Amended]

- 58. Amend section 12.214 by—
- a. Removing from the first sentence “commercial items” and adding “commercial products or commercial services” in its place;
- b. Removing from the second sentence “See 48 CFR 30.201–1” and adding “See 30.201–1” and “commercial products or

commercial services” in their places, respectively; and

■ c. Removing from the last sentence “in 48 CFR 30.201” and adding “in 30.201” in its place.

■ 59. Revise the heading of subpart 12.3 to read as follows:

Subpart 12.3—Solicitation Provisions and Contract Clauses for the Acquisition of Commercial Products and Commercial Services

12.300 [Amended]

■ 60. Amend section 12.300 by removing the text “commercial items” and adding “commercial products and commercial services” in its place.

■ 61. Amend section 12.301 by—

■ a. Revising the section heading;

■ b. Removing from paragraphs (a) introductory text and (a)(1) the text “commercial items” and adding “commercial products or commercial services” in its place;

■ c. Removing from paragraph (b) introductory text the text “commercial items” wherever it appears and adding “commercial products or commercial services” in its place;

■ d. In paragraphs (b)(1) and (2):

■ i. Removing in the headings the text “*Commercial Items*” and adding “*Commercial Products and Commercial Services*” in its place; and

■ ii. Removing the text “commercial items” and adding “commercial products or commercial services” in its place; and

■ e. Removing in the third sentence of paragraph (b)(2) the text “Subpart 1.4” and adding “subpart 1.4” in its place;

■ f. Removing from paragraph (b)(3) heading the text “*Commercial Items*” and adding “*Commercial Products and Commercial Services*” in its place;

■ g. In paragraph (b)(4):

■ i. In the heading, removing the text “*Commercial Items*” and adding “*Commercial Products and Commercial Services*” in its place;

■ ii. Removing the text “commercial items” wherever it appears and adding “commercial products or commercial services” in its place; and

■ iii. Removing the text “Part 15” and adding “part 15” in its place;

■ h. In paragraph (c)(1):

■ i. Removing the term “Commercial Items” and adding “Commercial Products and Commercial Services” in its place; and

■ ii. Removing the term “commercial items” and adding “commercial products or commercial services” in its place;

■ i. Removing from paragraph (d) introductory text the text “commercial

items” wherever it appears and adding “commercial products or commercial services” in its place; and

■ j. Removing from paragraph (f) the text “commercial items” and adding “commercial products or commercial services” in its place.

The revision reads as follows:

12.301 Solicitation provisions and contract clauses for the acquisition of commercial products and commercial services.

* * * * *

■ 62. Amend section 12.302 by—

■ a. Revising the section heading;

■ b. In paragraph (a):

■ i. Removing the text “commercial items” wherever it appears and adding “commercial products and commercial services” in its place; and

■ ii. Removing the text “Commercial Items” wherever it appears and adding “Commercial Products and Commercial Services” in its place;

■ c. In paragraph (b):

■ i. Removing the text “*Commercial Items*” and adding “*Commercial Products and Commercial Services*” in its place; and

■ ii. Removing the text “Commercial Items” and adding “Commercial Products and Commercial Services” in its place; and

■ d. Removing from paragraph (c) “commercial items” and adding “commercial products or commercial services” in its place.

The revision reads as follows:

12.302 Tailoring of provisions and clauses for the acquisition of commercial products and commercial services.

* * * * *

12.303 [Amended]

■ 63. Amend section 12.303 by—

■ a. Removing from the introductory text the term “commercial items” and adding “commercial products or commercial services” in its place;

■ b. Removing from paragraph (c)(1) the text “Commercial Items” and adding “Commercial Products and Commercial Services” in its place;

■ c. Removing from paragraph (c)(3) the text “and Executive Orders” and adding “or Executive Orders—Commercial Products and Commercial Services” in its place; and

■ d. Removing from paragraphs (e)(1), (3), and (4) the term “Commercial Items” and adding “Commercial Products and Commercial Services” in its place.

■ 64. Revise the heading for subpart 12.4 to read as follows:

Subpart 12.4—Unique Requirements Regarding Terms and Conditions for Commercial Products and Commercial Services

12.401 [Amended]

■ 65. Amend section 12.401 by—

■ a. In paragraph (a), removing the term “Commercial Items” and adding “Commercial Products and Commercial Services” in its place; and

■ b. In paragraph (b), removing the text “commercial items” and adding “commercial products or commercial services” in its place.

12.402 [Amended]

■ 66. Amend 12.402 by—

■ a. In paragraph (a):

■ i. Removing the text “commercial item” and adding “commercial product or commercial service” in its place; and

■ ii. Removing the text “commercial items” wherever it appears and adding “commercial products or commercial services” in its place;

■ b. Removing from paragraph (b) the phrase “complex commercial items or commercial items used” and adding “complex commercial products or commercial services, or commercial products or commercial services used” in its place; and

■ c. Removing from paragraph (c) “commercial items” and adding “commercial products or commercial services” in its place.

12.403 [Amended]

■ 67. Amend section 12.403 by removing from paragraphs (a), (b), and (d) the text “commercial items” wherever it appears and adding “commercial products or commercial services” in its place.

12.404 [Amended]

■ 68. Amend section 12.404 by removing from paragraph (b) introductory text the term “commercial items” and adding “commercial products” in its place.

■ 69. Revise the heading of subpart 12.5 to read as follows:

Subpart 12.5—Applicability of Certain Laws to the Acquisition of Commercial Products, Commercial Services and Commercially Available Off-the-Shelf Items

12.500 [Amended]

■ 70. Amend section 12.500 by—

■ a. Removing from paragraphs (a)(1) and (2) the term “commercial items” and adding “commercial products or commercial services” in its place;

■ b. Removing from paragraph (a)(3) the text “of COTS items” and adding “of

commercially available off-the-shelf (COTS) items” in its place; and

■ c. Removing from paragraph (b) the term “commercial items” and adding “commercial products or commercial services” in its place.

12.501 [Amended]

■ 71. Amend section 12.501 by removing from paragraphs (a) and (b) the term “commercial items” and adding “commercial products or commercial services” in its place.

12.502 [Amended]

■ 72. Amend section 12.502 by—

■ a. Removing from paragraph (a) the text “commercial items” and adding “commercial products or commercial services” in its place; and

■ b. Revising paragraph (b).

The revision reads as follows:

12.502 Procedures.

* * * * *

(b) For subcontracts for the acquisition of commercial products or commercial services, the clauses at 52.212–5, Contract Terms and Conditions Required to Implement Statutes or Executive Orders—Commercial Products and Commercial Services, and 52.244–6, Subcontracts for Commercial Products and Commercial Services, reflect the applicability of the laws listed in 12.504 by identifying the only provisions and clauses that are required to be included in a subcontract at any tier for the acquisition of commercial products or commercial services.

* * * * *

■ 73. Amend section 12.503 by—

■ a. Revising the section heading;

■ b. Removing from paragraph (a) the text “commercial items” and adding “commercial products or commercial services” in its place;

■ c. Removing from paragraph (b) the text “commercial items” and adding “commercial products and commercial services” in its place; and

■ d. Removing from paragraph (c) the words “regards” and “commercial items” and adding “regard” and “commercial products and commercial services” in their places, respectively.

The revision reads as follows:

12.503 Applicability of certain laws to Executive agency contracts for the acquisition of commercial products and commercial services.

* * * * *

■ 74. Amend section 12.504 by—

■ a. Revising the section heading;

■ b. Removing from paragraph (a) the phrase “commercial items or commercial components” and adding

“commercial products or commercial services” in its place;

■ c. Removing from paragraph (b) the terms “Subpart 22.3” and “commercial items or commercial components” and adding “subpart 22.3” and “commercial products or commercial services” in their places, respectively; and

■ d. Removing from paragraph (c) the words “regards” and “commercial items or commercial components” and adding “regard” and “commercial products or commercial services” in their places, respectively.

The revision reads as follows:

12.504 Applicability of certain laws to subcontracts for the acquisition of commercial products and commercial services.

* * * * *

12.505 [Amended]

■ 75. Amend section 12.505 by removing from the introductory text the words “commercial items” and adding “commercial products” in its place.

■ 76. Revise the heading of subpart 12.6 to read as follows:

Subpart 12.6—Streamlined Procedures for Evaluation and Solicitation for Commercial Products and Commercial Services

■ 77. Revise section 12.601 to read as follows:

12.601 General.

(a) This subpart provides optional procedures for—

(1) Streamlined evaluation of offers for commercial products or commercial services; and

(2) Streamlined solicitation of offers for commercial products or commercial services for use where appropriate.

(b) These procedures are intended to simplify the process of preparing and issuing solicitations and evaluating offers for commercial products or commercial services consistent with customary commercial practices.

■ 78. Amend section 12.602 by—

■ a. Removing from paragraph (a):

■ i. The term “Commercial Items” and adding “Commercial Products and Commercial Services” in its place; and

■ ii. The term “commercial items” and adding “commercial products or commercial services” in its place; and

■ b. Revising paragraph (b).

The revision reads as follows:

12.602 Streamlined evaluation of offers.

* * * * *

(b) Offers shall be evaluated in accordance with the criteria contained in the solicitation. For many commercial products or commercial

services, the criteria need not be more detailed than technical (capability of the item offered to meet the agency need), price, and past performance. Technical capability may be evaluated by how well the proposed products or services meet the Government requirement instead of predetermined subfactors. Solicitations for commercial products or commercial services do not have to contain subfactors for technical capability when the solicitation adequately describes the intended use of the commercial product or commercial service. A technical evaluation would normally include examination of such things as product or service literature, product samples (if requested), technical features, and warranty provisions. Past performance shall be evaluated in accordance with the procedures in section 13.106 or subpart 15.3, as applicable. The contracting officer shall ensure the instructions provided in the provision at 52.212–1, Instructions to Offerors—Commercial Products and Commercial Services, and the evaluation criteria provided in the provision at 52.212–2, Evaluation—Commercial Products and Commercial Services, are in agreement.

* * * * *

■ 79. Amend section 12.603 by—

■ a. Revising the section heading;

■ b. Removing from paragraph (a) the term “commercial items” and adding “commercial products or commercial services” in its place;

■ c. Removing from paragraph (c)(2)(i) the terms “commercial items” and “Subpart 12.6” and adding “commercial products or commercial services” and “subpart 12.6” in their places, respectively;

■ d. Removing from paragraph (c)(2)(viii) the text “Commercial” and adding “Commercial Products and Commercial Services” in its place;

■ e. Removing from paragraphs (c)(2)(ix), (x), and (xi) the text “Commercial Items” and adding “Commercial Products and Commercial Services” in its place; and

■ f. Removing from paragraph (c)(2)(xii) the phrase “Or Executive Orders—Commercial Items” and adding “or Executive Orders—Commercial Products and Commercial Services” in its place.

The revision reads as follows:

12.603 Streamlined solicitation for commercial products or commercial services.

* * * * *

PART 13—SIMPLIFIED ACQUISITION PROCEDURES**13.000 [Amended]**

- 80. Amend section 13.000 by:
 - i. Removing the text “and commercial items” and adding “commercial products, and commercial services”; and
 - ii. Removing the text “of commercial items” wherever it appears and adding “of commercial products and commercial services” in its place.

13.003 [Amended]

- 81. Amend section 13.003 by—
 - a. Removing from paragraph (c)(1)(ii) the phrase “commercial items using Subpart” and adding “commercial products or commercial services using subpart” in its place;
 - b. Removing from paragraph (c)(2) introductory text the phrase “commercial items, the threshold in Subpart” and adding “commercial products and commercial services, the threshold in subpart” in its place;
 - c. Removing from paragraph (g)(1) the phrase “threshold for other than commercial items” and adding “threshold when acquiring other than commercial products or commercial services” in its place; and
 - d. Removing from paragraph (g)(2) the text “commercial items” and “in Parts” and adding “commercial products or commercial services” and “in parts” in their places, respectively.
- 82. Amend section 13.005 by revising paragraph (b) to read as follows:

13.005 List of laws inapplicable to contracts and subcontracts at or below the simplified acquisition threshold.

* * * * *

(b) The Federal Acquisition Regulatory Council (FAR Council) will include any law enacted after October 13, 1994, that sets forth policies, procedures, requirements, or restrictions for the acquisition of property or services, on the list set forth in paragraph (a) of this section. The FAR Council may make exceptions when it determines in writing that it is in the best interest of the Government that the enactment should apply to contracts or subcontracts not greater than the simplified acquisition threshold.

* * * * *

13.105 [Amended]

- 83. Amend section 13.105 by removing from paragraph (b) the words “commercial items” and adding “commercial products or commercial services,” in its place.

13.106–1 [Amended]

- 84. Amend section 13.106–1 by removing from paragraph (b)(2) the term “commercial items” and adding “commercial products and commercial services” in its place.

13.302–1 [Amended]

- 85. Amend section 13.302–1 by removing from paragraph (a) the term “commercial items” and adding “commercial products and commercial services” in its place.

13.302–4 [Amended]

- 86. Amend section 13.302–4 by—
 - a. Removing from paragraph (a)(1) “commercial items” and adding “commercial products and commercial services” in its place; and
 - b. Removing from paragraph (a)(2) “commercial items” and adding “commercial products or commercial services” in its place.

13.302–5 [Amended]

- 87. Amend section 13.302–5 by removing from paragraph (d)(1) the text “Commercial Items” and “commercial items” and adding “Commercial Products and Commercial Services” and “commercial products or commercial services” in their places, respectively.

13.303–5 [Amended]

- 88. Amend section 13.303–5 by removing from paragraph (b)(2) the terms “commercial item” and “Subpart 13.5” and adding “commercial product and commercial service” and “subpart 13.5” in their places, respectively.

13.303–8 [Amended]

- 89. Amend section 13.303–8 by removing “Commercial Items” and adding “Commercial Products and Commercial Services” in its place.

13.307 [Amended]

- 90. Amend section 13.307 by—
 - a. In paragraph (a):
 - i. In the paragraph heading, removing “*Commercial items*” and adding “*Commercial products and commercial services*” in its place; and
 - ii. Removing the text “Commercial Items” and adding “Commercial Products and Commercial Services” in its place; and
 - b. In paragraphs (b) and (c), removing the text “*commercial items*” and adding “*commercial products and commercial services*” in its place.
- 91. Revise the heading for subpart 13.5 to read as follows:

Subpart 13.5—Simplified Procedures for Certain Commercial Products and Commercial Services**13.500 [Amended]**

- 92. Amend section 13.500 by—
 - a. In paragraph (a), removing the terms “commercial items” and “commercial item acquisitions” and adding the terms “commercial products or commercial services” and “commercial acquisitions” in their places, respectively;
 - b. In paragraph (b), removing the text “commercial items” and adding “commercial products or commercial services” in its place; and
 - c. In paragraphs (c)(1) and (2), removing the term “commercial items” and adding in its place the term “commercial products or commercial services”.

PART 14—SEALED BIDDING**14.201–1 [Amended]**

- 93. Amend section 14.201–1 by removing from paragraph (c) the phrase “(see 4.1202(b)) or for acquisitions of commercial items” and adding “(see 4.1202(b)), or for acquisitions of commercial products and commercial services” in its place.

PART 15—CONTRACTING BY NEGOTIATION**15.204–1 [Amended]**

- 94. Amend section 15.204–1 by removing from paragraph (b) the text “commercial items” and adding “commercial products and commercial services” in its place.

15.209 [Amended]

- 95. Amend section 15.209 by removing from paragraph (b)(1)(iii) the term “commercial items” and adding “commercial products or commercial services” in its place.
- 96. Amend section 15.306 by revising paragraph (e)(2) to read as follows:

15.306 Exchanges with offerors after receipt of proposals.

* * * * *

(e) * * *

(2) Reveals an offeror’s technical solution, including—

- (i) Unique technology;
- (ii) Innovative and unique uses of commercial products or commercial services; or
- (iii) Any information that would compromise an offeror’s intellectual property to another offeror;

* * * * *

15.401 [Amended]

■ 97. Amend section 15.401 in the definition of “Subcontract” by removing the terms “commercial items” and “41 U.S.C. 3501(a)(3)” and adding “commercial products or commercial services” and “41 U.S.C. 3501(a)(2)” in their places, respectively.

■ 98. Amend section 15.403–1 by—

■ a. In paragraph (b)(3), removing the terms “commercial item” and “subsection” and adding “commercial product or commercial service” and “section” in their places, respectively;

■ b. In paragraph (b)(5), removing the terms “commercial items” and “subsection” and adding “commercial products or commercial services” and “section” in their places, respectively;

■ c. Revising the heading of paragraph (c)(3) and revising paragraph (c)(3)(i);

■ d. Removing from paragraphs (c)(3)(ii)(A) and (B) the term “commercial items” and adding “commercial services” in their places, respectively;

■ e. Revising paragraph (c)(3)(iii) introductory text;

■ f. Removing from paragraphs (c)(3)(iii)(A), (B), and (C) the text “commercial item” and adding “commercial product” in their places, respectively; and

■ g. Removing from paragraph (c)(3)(iv) the phrase “for noncommercial supplies or services treated as commercial items” and adding “for other than commercial products or services treated as commercial products or commercial services” in its place.

The revisions read as follows:

15.403–1 Prohibition on obtaining certified cost or pricing data (10 U.S.C. 2306a and 41 U.S.C. chapter 35).

* * * * *

(c) * * *

(3) *Commercial products and commercial services.* (i) Any acquisition that the contracting officer determines meets the commercial product or commercial service definition in 2.101, or any modification, as defined in paragraph (3)(i) of the commercial product definition, that does not change a commercial product to other than commercial, is exempt from the requirement for certified cost or pricing data. If the contracting officer determines that a product or service claimed to be commercial is not, and that no other exception or waiver applies (e.g., the acquisition is not based on adequate price competition; the acquisition is not based on prices set by law or regulation; and the acquisition exceeds the threshold for the submission of certified cost or pricing data at 15.403–4(a)(1)), the contracting

officer shall require submission of certified cost or pricing data.

* * * * *

(iii) The following requirements apply to minor modifications defined in paragraph (3)(ii) of the definition of a commercial product at 2.101 that do not change the commercial product to other than commercial:

* * * * *

15.403–3 [Amended]

■ 99. Amend section 15.403–3 by—

■ a. Revising the heading of paragraph (c);

■ b. Removing from paragraph (c)(1) the term “commercial item” and adding “commercial product or commercial service” in its place;

■ c. Removing from the heading of paragraph (c)(2) the term “*commercial items*” and adding “*commercial products or commercial services*” in its place; and

■ d. Removing from paragraphs (c)(2)(i), (ii), and (iii) the term “commercial items” and adding “commercial products or commercial services” in its place.

The revision reads as follows:

15.403–3 Requiring data other than certified cost or pricing data.

* * * * *

(c) *Commercial products and commercial services.* * * *

* * * * *

■ 100. Amend section 15.404–1 by—

■ a. Removing from paragraph (a)(4) the phrase “for commercial or non-commercial items”;

■ b. Revising the heading of paragraph (b);

■ c. Removing from the last sentence in paragraph (b)(1) the word “item”;

■ d. Removing from paragraph (b)(2)(ii) introductory text the phrase “commercial items including those “of a type” or requiring minor modifications” and adding “commercial products or commercial services including those “of a type” or when requiring minor modifications for commercial products” in its place;

■ e. Removing from paragraphs (b)(2)(ii)(C) and (e)(3) the phrase “commercial items that are “of a type” or requiring minor modifications” and adding “commercial products or commercial services that are “of a type”, or requiring minor modifications for commercial products” in its place; and

■ f. Removing from paragraph (f)(2) the term “commercial items” and adding “commercial products” in its place.

The revision reads as follows:

15.404–1 Proposal analysis techniques.

* * * * *

(b) *Price analysis.* * * *

* * * * *

15.404–2 [Amended]

■ 101. Amend section 15.404–2 in paragraph (a)(2)(iii)(E) by removing the term “for an item” and adding its place the term “for a product or service” and removing the term “commercial item” and adding in its place the phrase “commercial product or commercial service”.

15.407–2 [Amended]

■ 102. Amend section 15.407–2 by removing from paragraph (e)(1) the text “commercial items” and adding “commercial products, commercial services” in its place.

15.408 [Amended]

■ 103. Amend section 15.408 by—

■ a. Removing from paragraph (f)(1)(v) the text “commercial items” and adding “commercial products and commercial services” in its place;

■ b. Removing from paragraphs (n)(2)(i)(B)(2)(iii), (iv), and (vi) the term “commercial item” and adding “commercial product or commercial service” in its place; and

■ c. In table 15–2:

■ i. Revising the section I heading;

■ ii. Revising the section II heading;

■ iii. In paragraph (II)(A)(2), in the second sentence, removing the term “commercial items” and adding “commercial products or commercial services” in its place;

■ iv. In paragraph (II)(A)(2), in the ninth sentence, removing the term “commercial items” and adding “commercial products” in its place; and

■ v. Revising the section III heading.

The revisions read as follows:

15.408 Solicitation provisions and contract clauses.

* * * * *

Table 15–2—Instructions for Submitting Cost/Price Proposals When Certified Cost or Pricing Data Are Required

* * * * *

I. General Instructions

* * * * *

II. Cost Elements

* * * * *

III. Formats for Submission of Line Item Summaries

* * * * *

15.506 [Amended]

■ 104. Amend section 15.506 by removing from paragraph (d)(5) the phrase “commercial items, the make

and model of the item” and adding “commercial products, the make and model of the product” in its place.

■ 105. Amend section 15.601 by revising the definition of “Commercial item offer” to read as follows:

15.601 Definitions.

* * * * *

Commercial product or commercial service offer means an offer of a commercial product or commercial service that the vendor wishes to see introduced in the Government’s supply system as an alternate or a replacement for an existing supply item. This term does not include innovative or unique configurations or uses of commercial products or commercial services that are being offered for further development and that may be submitted as an unsolicited proposal.

* * * * *

15.603 [Amended]

■ 106. Amend section 15.603 by removing from paragraph (b) the term “commercial item” and adding “commercial product or commercial service” in its place.

PART 16—TYPES OF CONTRACTS

■ 107. Amend section 16.001 by adding in alphabetical order the definition of “Established price” to read as follows:

16.001 Definitions.

* * * * *

Established price means a price that—

(1) Is an established catalog or market price for a commercial product sold in substantial quantities to the general public; and

(2) Is the net price after applying any standard trade discounts offered by the contractor.

* * * * *

16.201 [Amended]

■ 108. Amend section 16.201 by removing from paragraph (a) the term “commercial items” and adding “commercial products and commercial services” in its place.

16.202–2 [Amended]

■ 109. Amend section 16.202–2 by removing from the introductory text the term “commercial items” and adding “commercial products or commercial services” in its place.

■ 110. Amend section 16.203–4 by adding paragraphs (a)(4), (b)(6), and (c)(5) to read as follows:

16.203–4 Contract clauses.

(a) * * *

(4) The contracting officer may modify the clause by increasing the 10 percent limit on aggregate increases specified in 52.216–2(c)(1), upon approval by the chief of the contracting office.

(b) * * *

(6) The contracting officer may modify the clause by increasing the 10 percent limit on aggregate increases specified in 52.216–3(c)(1), upon approval by the chief of the contracting office.

(c) * * *

(5) The contracting officer may modify the clause by increasing the 10 percent limit on aggregate increases specified in 52.216–4(c)(4), upon approval by the chief of the contracting office.

* * * * *

16.301–3 [Amended]

■ 111. Amend section 16.301–3 by removing from paragraph (b) the term “commercial items” and adding “commercial products and commercial services” in its place.

16.307 [Amended]

■ 112. Amend section 16.307 by removing from paragraph (a)(1) the term “commercial item” and adding “commercial product or commercial service” in its place.

16.506 [Amended]

■ 113. Amend section 16.506 by removing from paragraph (h) the words “See” and “commercial items” and adding “See” and “commercial products or commercial services” in their places, respectively.

■ 114. Amend section 16.601 by—

■ a. Removing from paragraph (c)(2)(ii) the term “noncommercial items” and adding “other than commercial products or commercial services” in its place;

■ b. Removing from paragraph (c)(2)(iv) the phrase “the definition of commercial item at 2.101” and adding “the definition of “commercial service”” in its place;

■ c. Removing from paragraph (d)(2) the term “commercial items” and adding “commercial products and commercial services” in its place; and

■ d. Revising the first sentence of paragraph (f)(1) and revising paragraphs (f)(2) and (3).

The revisions read as follows:

16.601 Time-and-materials contracts.

* * * * *

(f) * * * (1) The contracting officer shall insert the provision at 52.216–29, Time-and-Materials/Labor-Hour

Proposal Requirements—Other Than Commercial Acquisition With Adequate Price Competition, in solicitations contemplating use of a time-and-materials or labor-hour type of contract for the acquisition of other than commercial products or commercial services, if the price is expected to be based on adequate price competition.

* * *

(2) The contracting officer shall insert the provision at 52.216–30, Time-and-Materials/Labor-Hour Proposal Requirements—Other Than Commercial Acquisition Without Adequate Price Competition, in solicitations for the acquisition of other than commercial products or commercial services contemplating use of a time-and-materials or labor-hour type of contract if the price is not expected to be based on adequate price competition.

(3) The contracting officer shall insert the provision at 52.216–31, Time-and-Materials/Labor-Hour Proposal Requirements—Commercial Acquisition, in solicitations contemplating use of a commercial time-and-materials or labor-hour contract.

PART 18—EMERGENCY ACQUISITIONS

18.201 [Amended]

■ 115. Amend section 18.201 by removing from paragraph (e) the term “commercial items” and adding “commercial products and commercial services” in its place.

■ 116. Amend section 18.202 by—

■ a. Revising the heading for paragraph (c);

■ b. Removing from paragraph (c) the term “commercial items” and adding “commercial products or commercial services” in its place; and

■ c. Removing from paragraph (d) the term “commercial items” and adding “commercial products and commercial services” in its place.

The revision reads as follows:

18.202 Defense or recovery from certain events.

* * * * *

(c) *Commercial product or commercial service treatment.* * * *

* * * * *

PART 19—SMALL BUSINESS PROGRAMS

19.304 [Amended]

■ 117. Amend section 19.304 by removing from paragraph (b) the term “Certifications—Commercial Items” and adding “Certifications—Commercial

Products and Commercial Services” in its place.

19.701 [Amended]

■ 118. Amend section 19.701 by removing from the definition of “Commercial plan” the term “commercial items” and adding “commercial products and performance of commercial services” in its place.

19.704 [Amended]

■ 119. Amend section 19.704 by removing from paragraph (d) the terms “commercial items” and “commercial item” and adding “commercial products and commercial services” and “commercial product or commercial service” in their places, respectively.

PART 22—APPLICATION OF LABOR LAWS TO GOVERNMENT ACQUISITIONS

22.305 [Amended]

■ 120. Amend section 22.305 by removing from paragraph (b) the term “commercial items” and adding “commercial products and commercial services” in its place.

22.604–1 [Amended]

■ 121. Amend section 22.604–1 by removing from paragraph (a) the term “commercial items” and adding “commercial products and commercial services” in its place.

22.1302 [Amended]

■ 122. Amend section 22.1302 by removing from paragraph (b) the term “commercial items” and adding “commercial products or commercial services,” in its place.

22.1310 [Amended]

■ 123. Amend section 22.1310 by removing from paragraph (c) the term “commercial items” and adding “commercial products or commercial services” in its place.

22.1505 [Amended]

■ 124. Amend section 22.1505 by removing from paragraph (a) the terms “commercial items” and “Certifications—Commercial Items” and adding “commercial products or commercial services” and “Certifications—Commercial Products and Commercial Services” in their places, respectively.

22.1605 [Amended]

■ 125. Amend section 22.1605 by removing from paragraph (a) “commercial items” and adding “commercial products, commercial services,” in its place.

22.1801 [Amended]

■ 126. Amend section 22.1801 in the definition of “Commercially available off-the-shelf (COTS) item” by removing in paragraph (1)(i) the phrase “commercial item (as defined in paragraph (1) of the definition at 2.101” and adding “commercial product (as defined in paragraph (1) of the definition of “commercial product” at 2.101” in its place.

22.1802 [Amended]

■ 127. Amend section 22.1802 by removing from paragraph (b)(4)(i) the term “Commercial or noncommercial services” and adding “Services” in its place.

22.1803 [Amended]

■ 128. Amend section 22.1803 by removing from paragraph (c)(2) the phrase “definition of “commercial item” at 2.101” and adding “definition of “commercial product” at 2.101” in its place.

PART 23—ENVIRONMENT, ENERGY AND WATER EFFICIENCY, RENEWABLE ENERGY TECHNOLOGIES, OCCUPATIONAL SAFETY, AND DRUG-FREE WORKPLACE

23.501 [Amended]

■ 129. Amend section 23.501 by removing from paragraph (b) the term “commercial items” and adding “commercial products and commercial services” in its place.

PART 25—FOREIGN ACQUISITION

25.103 [Amended]

■ 130. Amend section 25.103 by removing from paragraph (e) the terms “commercial item”, “commercial item”, and “Section” and adding “commercial product”, “commercial product”, and “section” in their places, respectively.

25.202 [Amended]

■ 131. Amend section 25.202 by removing from paragraph (a)(4) the terms “commercial item”, “commercial item”, and “Section” and adding “commercial product”, “commercial product”, and “section” in their places, respectively.

25.703–2 [Amended]

■ 132. Amend section 25.703–2 by—
■ a. Removing from paragraph (b) introductory text the phrase “of this subsection” and adding “of this section” in its place; and
■ b. Removing from paragraph (b)(1) the term “commercial items” and adding

“commercial products and commercial services” in its place.

25.1001 [Amended]

■ 133. Amend section 25.1001 by removing from paragraph (a) the text “Executive Orders—Commercial Items” and adding “Executive Orders—Commercial Products and Commercial Services” in its place.

25.1101 [Amended]

■ 134. Amend section 25.1101 by—
■ a. In paragraph (a)(1)(i), removing the word “Subpart” and adding “subpart” in its place;
■ b. In paragraph (a)(1)(ii), removing the term “commercial item” and adding “commercial product” in its place; and
■ c. In paragraph (b)(1)(i)(B), removing the term “commercial item” and adding “commercial product” in its place.
■ 135. Amend section 25.1103 by revising paragraph (d) to read as follows:

25.1103 Other provisions and clauses.

* * * * *

(d) The contracting officer shall include in each solicitation for the acquisition of other than commercial products or commercial services the provision at 52.225–20, Prohibition on Conducting Restricted Business Operations in Sudan—Certification.

* * * * *

PART 26—OTHER SOCIOECONOMIC PROGRAMS

26.206 [Amended]

■ 136. Amend section 26.206 by removing from paragraph (a) the term “commercial items” and adding “commercial products and commercial services” in its place.

PART 27—PATENTS, DATA, AND COPYRIGHTS

27.102 [Amended]

■ 137. Amend section 27.102 by removing from paragraph (c) the term “commercial items” and adding “commercial products and commercial services” in its place.

27.201–1 [Amended]

■ 138. Amend section 27.201–1 by removing from paragraph (d) the term “commercial items” and adding “commercial products or commercial services” in its place, and by removing “FAR”.

27.201–2 [Amended]

■ 139. Amend section 27.201–2 by—
■ a. Removing from paragraph (c)(1) the term “commercial items” and adding

“commercial products or the provision of commercial services” in its place; and

■ b. Removing from paragraph (c)(2)(i) the term “commercial items” and adding “commercial products or the provision of services that are not commercial services” in its place.

PART 28—BONDS AND INSURANCE

28.106–4 [Amended]

■ 140. Amend section 28.106–4 by removing from paragraph (b) the words “Section”, “Pub. L.” wherever it appears, “Sections”, and “commercial items as defined in Subpart” and adding “section”, “Public Law”, “sections”, and “commercial products or commercial services as defined in subpart” in their places, respectively.

28.106–6 [Amended]

■ 141. Amend section 28.106–6 in paragraph (d) introductory text by:

■ a. Removing the term “Pub. L.” wherever it appears and adding in its place “Public Law”;

■ b. Removing the word “Sections” and adding in its place “sections”; and

■ c. Removing the phrase “commercial items as defined in Subpart” and adding in its place “commercial products or commercial services as defined in subpart”.

PART 29—TAXES

29.402–3 [Amended]

■ 142. Amend section 29.402–3 by removing from paragraph (a) introductory text the terms “FAR part 12” and “commercial items” and adding “part 12” and “commercial products and commercial services” in their places, respectively.

PART 30—COST ACCOUNTING STANDARDS ADMINISTRATION

30.201–5 [Amended]

■ 143. Amend section 30.201–5 by:

■ a. In paragraph (b)(1) introductory text, removing the text “\$15,000,000” and adding “\$15 million” in its place; and

■ b. In paragraph (b)(1)(i), removing the term “commercial items” and adding in its place “commercial products or commercial services”.

PART 31—CONTRACT COST PRINCIPLES AND PROCEDURES

31.205–26 [Amended]

■ 144. Amend section 31.205–26 by removing from paragraph (f) introductory text the phrases “commercial item” and “subsection is transferred” and adding “commercial

product or commercial service” and “section is sold or transferred” in their places, respectively.

PART 32—CONTRACT FINANCING

32.000 [Amended]

■ 145. Amend section 32.000 by removing from paragraph (g) the term “commercial items” and adding “commercial products and commercial services” in its place.

32.002 [Amended]

■ 146. Amend section 32.002 by—

■ a. Removing from paragraph (b) the terms “Commercial Item” and “commercial items” and adding “Commercial Product and Commercial Service” and “commercial products and commercial services” in their places, respectively;

■ b. Removing from paragraph (c)(1) the term “Non-Commercial Item Purchase Financing” and adding “Financing for Other Than a Commercial Purchase” in its place; and

■ c. Removing from paragraph (c)(2) the words “For Non-Commercial Items” and adding “for Other Than Commercial Acquisitions” in its place.

32.005 [Amended]

■ 147. Amend section 32.005 by removing from paragraph (c) the term “for Non-Commercial Items” and adding “for Other Than Commercial Acquisitions” in its place.

■ 148. Revise the heading of subpart 32.1 to read as follows:

Subpart 32.1 Financing for Other Than a Commercial Purchase

32.100 [Amended]

■ 149. Amend section 32.100 by removing the text “commercial items” and adding “commercial products or commercial services” in its place.

32.110 [Amended]

■ 150. Amend section 32.110 by removing from paragraph (a) the term “commercial item” and adding “commercial product or commercial service” in its place.

32.112 [Amended]

■ 151. Amend section 32.112 by revising the section heading to read as follows:

32.112 Nonpayment of subcontractors under contracts other than for commercial products and commercial services.

* * * * *

■ 152. Amend section 32.112–2 by revising paragraph (a) introductory text to read as follows:

32.112–2 Subcontractor requests for information.

(a) In accordance with section 806(a)(1) of Public Law 102–190, as amended by sections 2091 and 8105 of Public Law 103–355 (10 U.S.C. 2302 note), upon the request of a subcontractor or supplier under a Federal contract other than for a commercial product or commercial service, the contracting officer shall promptly advise the subcontractor or supplier as to—

* * * * *

■ 153. Revise the heading of subpart 32.2 to read as follows:

Subpart 32.2 Commercial Product and Commercial Service Purchase Financing

32.201 [Amended]

■ 154. Amend section 32.201 by removing the text “commercial items” and adding “commercial products or commercial services” in its place.

32.202–1 [Amended]

■ 155. Amend section 32.202–1 by—

■ a. Removing from paragraph (a) the term “commercial items” and adding “commercial products or commercial services” in its place; and

■ b. In paragraph (c):

■ i. Removing the term “non-commercial” and adding “other than commercial” in its place; and

■ ii. Removing the term “non-commercial” wherever it appears and adding “other than commercial” in its place.

32.202–2 [Amended]

■ 156. Amend section 32.202–2 by—

■ a. Revising the section heading; and

■ b. Removing from the definition of “Commercial advance payment” the word “subsection” and the term “for Non-Commercial Items” and adding “section” and “for Other Than Commercial Acquisitions” in their places, respectively.

The revision reads as follows:

32.202–2 Types of payments for commercial product and commercial service purchases.

* * * * *

32.202–4 [Amended]

■ 157. Amend section 32.202–4 by removing from paragraph (a)(2) the term “Commercial Items” and adding “Commercial Products and Commercial Services” in its place.

32.206 [Amended]

■ 158. Amend section 32.206 by—

■ a. Removing the term “Commercial Items” wherever it appears and adding

“Commercial Products and Commercial Services” in its place;

■ b. Removing from paragraph (f) “non-commercial” and adding “other than commercial” in its place; and

■ c. Removing from paragraph (g) heading “*commercial items*” and adding “*commercial products and commercial services*” in its place.

■ 159. Revise the heading of subpart 32.4 to read as follows:

Subpart 32.4 Advance Payments for Other Than Commercial Acquisitions

32.504 [Amended]

■ 160. Amend section 32.504 by removing from paragraphs (a), (b), and (g) the term “commercial item” and adding “commercial product or commercial service” in its place.

32.601 [Amended]

■ 161. Amend section 32.601 by removing from paragraphs (b)(3) and (10) the term “commercial item financing” and adding “financing of commercial products or commercial services” in its place.

32.904 [Amended]

■ 162. Amend section 32.904 by removing from paragraph (b)(1)(ii)(B)(4) the phrase “commercial item, including a brand-name commercial item for” and adding “commercial product or commercial service, including a brand-name commercial product for” in its place.

32.908 [Amended]

■ 163. Amend section 32.908 by—
■ a. Removing from paragraph (c) introductory text the term “Commercial Items” and adding “Commercial Products and Commercial Services” in its place; and

■ b. Removing from paragraph (c)(1) the terms “commercial item” and “commercial item for” and adding “commercial product or commercial service” and “commercial product for” in their places, respectively.

PART 37—SERVICE CONTRACTING

37.601 [Amended]

■ 164. Amend section 37.601 by removing paragraph (c).

PART 38—FEDERAL SUPPLY SCHEDULE CONTRACTING

38.101 [Amended]

■ 165. Amend section 38.101 by removing from paragraph (a) the phrase “commercial supplies and services” and adding “commercial supplies and commercial services” in its place.

PART 39—ACQUISITION OF INFORMATION TECHNOLOGY

■ 166. Amend section 39.203 by revising paragraph (d) to read as follows:

39.203 Applicability.

* * * * *

(d) *Commercial products and commercial services.* When acquiring commercial products and commercial services, an agency must comply with those ICT accessibility standards that can be met with supplies or services that are available in the commercial marketplace and that best address the agency’s needs, but see 39.205(a)(3).

* * * * *

■ 167. Amend section 39.205 by revising paragraphs (a)(3) and (c)(3) introductory text to read as follows:

39.205 Exemptions.

(a) * * *

(3) *Nonavailability of conforming commercial products and commercial services.* Where there are no commercial products and commercial services that fully conform to the ICT accessibility standards, the agency shall procure the supplies or service available in the commercial marketplace that best meets the ICT accessibility standards consistent with the agency’s needs.

* * * * *

(c) * * *

(3) *Nonavailability of conforming commercial products and commercial services.* A determination of commercial products and commercial services nonavailability shall include—

* * * * *

PART 42—CONTRACT ADMINISTRATION AND AUDIT SERVICES

42.709–1 [Amended]

■ 168. Amend section 42.709–1 by removing from paragraph (b) the term “commercial items” and adding “commercial products or commercial services” in its place.

42.709–7 [Amended]

■ 169. Amend section 42.709–7 by removing the text “commercial items” and adding “commercial products or commercial services” in its place.

42.1305 [Amended]

■ 170. Amend section 42.1305 by removing from paragraph (c) the text “modified-commercial items” wherever it appears and adding “modified-commercial products” in its place.

PART 43—CONTRACT MODIFICATIONS

43.105 [Amended]

■ 171. Amend section 43.105 by removing from paragraph (c) the phrase “commercial items, including commercially available off-the-shelf items” and adding “commercial products, including commercially available off-the-shelf items, and commercial services” in its place.

PART 44—SUBCONTRACTING POLICIES AND PROCEDURES

44.000 [Amended]

■ 172. Amend section 44.000 by removing from paragraph (b) the term “commercial items” and adding “commercial products or commercial services” in its place.

44.302 [Amended]

■ 173. Amend section 44.302 by removing from paragraph (a) the terms “commercial items” and “Part 12” and adding “commercial products and commercial services” and “part 12” in their places, respectively.

44.303 [Amended]

■ 174. Amend section 44.303 by removing from the introductory text the term “commercial items” and adding “commercial products and commercial services” in its place.

■ 175. Revise the heading for subpart 44.4 to read as follows:

Subpart 44.4 Subcontracts for Commercial Products and Commercial Services

44.400 [Amended]

■ 176. Amend section 44.400 by removing the text “commercial items or commercial components” and adding “commercial products, including commercial components, or commercial services” in its place.

44.402 [Amended]

■ 177. Amend section 44.402 by—
■ a. Removing from paragraph (a)(1) the words “commercial items” and adding “commercial products, commercial services,” in its place;

■ b. Removing from paragraph (a)(2) introductory text the phrase “commercial items or commercial components” and adding “commercial products or commercial services” in its place;

■ c. Removing from paragraph (a)(2)(i) the phrase “executive orders applicable to subcontractors furnishing commercial items or commercial components” and adding “Executive orders applicable to

subcontractors furnishing commercial products or commercial services” in its place;

■ d. Removing from paragraph (b) the terms “Commercial Items” and “commercial items or commercial components” and adding “Commercial Products and Commercial Services” and “commercial products or commercial services” in their places, respectively; and

■ e. Removing from paragraph (c) the words “commercial items” and adding “commercial products and commercial services” in its place.

44.403 [Amended]

■ 178. Amend section 44.403 by removing the terms “Commercial Items” and “commercial items” and adding “Commercial Products and Commercial Services” and “commercial products or commercial services” in their places, respectively.

PART 46—QUALITY ASSURANCE

46.102 [Amended]

■ 179. Amend section 46.102 by—
■ a. Removing from paragraph (b) the phrase “services tendered” and adding “services (including commercial services) tendered” in its place; and
■ b. Removing from paragraph (f) the phrases “commercial items shall” and “commercial item” and adding “commercial products” and “commercial product” in their places, respectively.

■ 180. Revise section 46.202–1 to read as follows:

46.202–1 Contracts for commercial products and commercial services.

When acquiring commercial products (see part 12), the Government shall rely on contractors’ existing quality assurance systems as a substitute for Government inspection and testing before tender for acceptance unless customary market practices for the commercial product being acquired include in-process inspection. Any in-process inspection by the Government shall be conducted in a manner consistent with commercial practice. The Government shall rely on the contractor to accomplish all inspection and testing needed to ensure that commercial services acquired conform to contract requirements before they are tendered to the Government.

46.317 [Amended]

■ 181. Amend section 46.317 by removing from paragraph (b)(1) the term “Commercial items” and adding “Commercial products and commercial services” in its place.

■ 182. Amend section 46.706 by—

■ a. Removing from paragraph (b)(1)(iii) the term “commercial items” and adding “commercial products and commercial services” in its place; and
■ b. Revising paragraph (b)(5).

The revision reads as follows:

46.706 Warranty terms and conditions.

* * * * *

(b) * * *

(5) *Markings.* (i) The packaging and preservation requirements of the contract shall require the contractor to stamp or mark the supplies delivered or otherwise furnish notice with the supplies of the existence of the warranty. The purpose of the markings or notice is to inform Government personnel who store, stock, or use the supplies that the supplies are under warranty. Markings may be brief but should include—

(A) A brief statement that a warranty exists;

(B) The substance of the warranty;

(C) Its duration; and

(D) Who to notify if the supplies are found to be defective.

(ii) For commercial products (see 46.709), the contractor’s trade practice in warranty marking is acceptable if sufficient information is presented for supply personnel and users to identify warranted supplies.

* * * * *

■ 183. Amend section 46.709 by:

■ a. Revising the section heading; and

■ b. Removing the term “commercial items” and adding “commercial products and commercial services” in its place.

The revision reads as follows:

46.709 Warranties of commercial products and commercial services.

* * * * *

46.710 [Amended]

■ 184. Amend section 46.710 by removing from the introductory text the term “commercial items” and adding “commercial products and commercial services” in its place.

■ 185. Amend section 46.801 by revising paragraph (a) to read as follows:

46.801 Applicability.

(a) This subpart does not apply to commercial products and commercial services. This subpart applies to contracts other than those for—

(1) Information technology, including telecommunications;

(2) Construction;

(3) Architect-engineer services; and

(4) Maintenance and rehabilitation of real property.

* * * * *

PART 47—TRANSPORTATION

47.405 [Amended]

■ 186. Amend section 47.405 by removing the quote marks in the first sentence, and by removing in the second sentence “commercial items” and adding “commercial products” in its place.

47.504 [Amended]

■ 187. Amend section 47.504 by:

■ a. In paragraph (d) introductory text, removing the phrase “commercial items or commercial components” and adding “commercial products, including commercial components, or commercial services” in its place; and

■ b. In paragraph (d)(4) introductory text, removing the term “commercial items” and adding “commercial products” in its place.

47.507 [Amended]

■ 188. Amend section 47.507 by removing from paragraph (a)(3) the terms “*Alternate II*” and “commercial items” and adding “*Alternate II*” and “commercial products” in their places, respectively.

PART 49—TERMINATION OF CONTRACTS

49.002 [Amended]

■ 189. Amend section 49.002 in paragraph (a)(2) by:

■ a. Removing the term “commercial item” and adding in its place “commercial product and commercial service”;

■ b. Removing the term “commercial items” wherever it appears and adding in its place “commercial products and commercial services”; and

■ c. Removing the term “Commercial Items” and adding “Commercial Products and Commercial Services” in its place.

49.501 [Amended]

■ 190. Amend section 49.501 by removing the text “Commercial Items” and adding “Commercial Products and Commercial Services” in its place.

PART 52—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 191. Amend section 52.203–6 by:

■ a. Revising the date of Alternate I; and

■ b. Removing from paragraph (b) of Alternate I the terms “commercial items” and “commercial item(s)” and adding “commercial products or commercial services” and “commercial product(s) and commercial service(s)” in their places, respectively.

The revision reads as follows:

52.203–6 Restrictions on Subcontractor Sales to the Government.

* * * * *

Alternate I (NOV 2021). * * *

* * * * *

- 192. Amend section 52.203–13 by:
- a. Revising the date of the clause; and
- b. Removing from paragraph (c) the term “commercial item” and adding “commercial product or commercial service” in its place.

The revision reads as follows:

52.203–13 Contractor Code of Business Ethics and Conduct.

* * * * *

Contractor Code of Business Ethics and Conduct (NOV 2021)

* * * * *

- 193. Amend section 52.203–14 by:
- a. Revising the date of the clause; and
- b. Removing from paragraph (d)(1) the term “commercial item” and adding “commercial product or commercial service” in its place.

The revision reads as follows:

52.203–14 Display of Hotline Poster(s).

* * * * *

Display of Hotline Poster(s) (NOV 2021)

* * * * *

- 194. Amend section 52.204–8 by:
- a. Revising the date of the provision; and
- b. Removing from paragraph (c)(1)(xvi) the term “commercial items” and adding “commercial products or commercial services” in its place.

The revision reads as follows:

52.204–8 Annual Representations and Certifications.

* * * * *

Annual Representations and Certifications (NOV 2021)

* * * * *

- 195. Amend section 52.204–21 by:
- a. Revising the date of the clause; and
- b. Removing from paragraph (c) the term “commercial items” and adding “commercial products or commercial services” in its place.

The revision reads as follows:

52.204–21 Basic Safeguarding of Covered Contractor Information Systems.

* * * * *

Basic Safeguarding of Covered Contractor Information Systems (NOV 2021)

* * * * *

- 196. Amend section 52.204–23 by:
- a. Revising the date of the clause; and
- b. Removing from paragraph (d) the phrases “in all subcontracts,” and

“commercial items” and adding “in all subcontracts” and “commercial products or commercial services” in their places, respectively.

The revision reads as follows:

52.204–23 Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities.

* * * * *

Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (NOV 2021)

* * * * *

- 197. Amend section 52.204–24 by:
- a. Revising the date of the clause; and
- b. Removing from the introductory paragraph the term “Commercial Items” and adding “Commercial Products and Commercial Services” in its place.

The revision reads as follows:

52.204–24 Representation Regarding Certain Telecommunications and Video Surveillance Services or Equipment.

* * * * *

Representation Regarding Certain Telecommunications and Video Surveillance Services or Equipment (NOV 2021)

* * * * *

- 198. Amend section 52.204–25 by:
- a. Revising the date of the clause; and
- b. Removing from paragraph (e) the term “commercial items” and adding “commercial products or commercial services” in its place.

The revision reads as follows:

52.204–25 Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment.

* * * * *

Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment (NOV 2021)

* * * * *

- 199. Amend section 52.209–6 by—
- a. Revising the date of the clause;
- b. Removing from paragraph (a) introductory text the word “item” and adding “*item*” in its place;
- c. Removing from paragraph (a)(1)(i) the phrase “commercial item (as defined in paragraph (1) of the definition in” and adding “commercial product (as defined in paragraph (1) of the definition of “commercial product” in” in its place; and
- d. Removing from paragraph (e) the term “commercial items” and adding “commercial products or commercial services” in its place.

The revision reads as follows:

52.209–6 Protecting the Government’s Interest When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment.

* * * * *

Protecting the Government’s Interest When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (NOV 2021)

* * * * *

- 200. Amend section 52.209–13 by:
- a. Revising the date of the provision; and
- b. Removing from paragraph (a) the phrase “commercial items as defined at FAR 2.101” and adding “commercial products and commercial services as defined in Federal Acquisition Regulation 2.101” in its place.

The revision reads as follows:

52.209–13 Violation of Arms Control Treaties or Agreements—Certification.

* * * * *

Violation of Arms Control Treaties or Agreements—Certification (NOV 2021)

* * * * *

- 201. Amend section 52.209–14 by:
- a. Revising the date of the clause; and
- b. Removing from paragraph (d)(1) the term “commercial items” and adding “commercial products and commercial services” in its place.

The revision reads as follows:

52.209–14 Reserve Officer Training Corps and Military Recruiting on Campus.

* * * * *

Reserve Officer Training Corps and Military Recruiting on Campus (NOV 2021)

* * * * *

- 202. Amend section 52.210–1 by—
- a. Revising the date of the clause;
- b. Revising paragraph (a);
- c. Revising the introductory text of paragraph (b);
- d. Removing from the introductory text of paragraph (b)(1) the phrase “commercial items or, to the extent commercial items” and adding “commercial products, commercial services, or, to the extent commercial products” in its place; and
- e. Removing from paragraph (b)(2) the term “commercial items” and adding “commercial products, commercial services,” in its place.

The revisions read as follows:

52.210–1 Market Research.

* * * * *

Market Research (NOV 2021)

(a) *Definition*. As used in this clause—

Commercial product, commercial service, and nondevelopmental item have the meaning contained in Federal Acquisition Regulation (FAR) 2.101.

(b) Before awarding subcontracts for other than commercial acquisitions, where the subcontracts are over the simplified acquisition threshold, as defined in FAR 2.101 on the date of subcontract award, the Contractor shall conduct market research to—

* * * * *

- 203. Amend section 52.212–1 by—
- a. Revising the section heading;
- b. Revising the heading and date of the provision;
- c. Removing from paragraph (b)(8) the term “FAR 52.212–3” and adding “Federal Acquisition Regulation (FAR) 52.212–3” in its place;
- d. Removing from paragraph (e) the phrase “subpart 4.10 of the Federal Acquisition Regulation” and “commercial items” and adding “FAR subpart 4.10” and “commercial products or commercial services” in their places, respectively; and
- e. Removing from paragraph (l)(5) the phrase “commercial items, the make and model of the item” and adding “commercial products, the make and model of the product” in its place.

The revisions read as follows:

52.212–1 Instructions to Offerors—Commercial Products and Commercial Services.

* * * * *

Instructions to Offerors—Commercial Products and Commercial Services (NOV 2021)

* * * * *

- 204. Amend section 52.212–2 by revising the section heading and the heading and date of the provision to read as follows:

52.212–2 Evaluation—Commercial Products and Commercial Services.

* * * * *

Evaluation—Commercial Products and Commercial Services (NOV 2021)

* * * * *

- 205. Amend section 52.212–3 by—
- a. Revising the section heading;
- b. Revising the heading and date of the provision; and
- c. Removing from paragraph (b)(2) the term “Commercial Items” and adding “Commercial Products and Commercial Services” in its place.

The revisions read as follows:

52.212–3 Offeror Representations and Certifications—Commercial Products and Commercial Services.

* * * * *

Offeror Representations and Certifications—Commercial Products and Commercial Services (NOV 2021)

* * * * *

- 206. Amend section 52.212–4 by—
- a. Revising the section heading;
- b. Revising the heading and date of the clause;
- c. Removing from paragraph (d) the term “FAR” and adding “Federal Acquisition Regulation (FAR)” in its place;
- d. Removing from paragraph (i)(6)(vii) the phrase “32.608–2 of the Federal Acquisition Regulation” and adding “FAR 32.608–2” in its place;
- e. Revising the date of Alternate I;
- f. Removing from the introductory text of paragraph (i)(1)(ii)(A) of Alternate I the words “commercial item at” and adding “commercial product at FAR” in its place; and
- g. Removing from paragraph (i)(6)(vii) of Alternate I the phrase “32.608–2 of the Federal Acquisition Regulation” and adding “FAR 32.608–2” in its place.

The revisions read as follows:

52.212–4 Contract Terms and Conditions—Commercial Products and Commercial Services.

* * * * *

Contract Terms and Conditions—Commercial Products and Commercial Services (NOV 2021)

* * * * *

Alternate I (NOV 2021). * * *

* * * * *

- 207. Amend section 52.212–5 by—
- a. Revising the section heading;
- b. Revising the heading and date of the clause;
- c. Removing from paragraph (a) introductory text the term “commercial items” and adding “commercial products and commercial services” in its place;
- d. Removing from paragraph (a)(2) the date “(JUL 2018)” and adding “(NOV 2021)” in its place;
- e. Removing from paragraph (a)(3) the date “(AUG 2020)” and adding “(NOV 2021)” in its place;
- f. In paragraph (b) introductory text:
- i. Removing the term “commercial items” and adding “commercial products and commercial services” in its place; and
- ii. Removing the phrase “[Contracting Officer check as appropriate.]” and adding in its place “[*Contracting Officer check as appropriate.*]”;
- g. Removing from paragraph (b)(1) the date “(OCT 1995)” and adding “(NOV 2021)” in its place;
- h. Removing from paragraph (b)(2) the date “(JUN 2020)” and adding “(NOV 2021)” in its place;

- i. Removing from paragraph (b)(8) the date “(JUN 2020)” and adding “(NOV 2021)” in its place;
- j. Removing from paragraph (b)(17)(i) the date “(SEP 2021)” and adding “(NOV 2021)” in its place;
- k. Removing from paragraph (b)(35)(i) the date “(OCT 2020)” and adding “(NOV 2021)” in its place;
- l. In paragraph (b)(36):
- i. Removing the date “(OCT 2015)”, and adding (NOV 2021) in its place; and
- ii. Removing the terms “commercial items” and “22.1803” and adding “commercial products or commercial services” and “FAR 22.1803” in their places, respectively;
- m. Removing from paragraph (b)(48) the date “(JAN 2021)” and adding “(NOV 2021)” in its place;
- n. Removing from paragraph (b)(49)(i) the date “(JAN 2021)” and adding “(NOV 2021)” in its place;
- o. Removing from paragraph (b)(56) the term “Commercial Items” and date “(FEB 2002)” and adding “Commercial Products and Commercial Services” and “(NOV 2021)” in their places, respectively;
- p. Removing from paragraph (b)(57) the term “Commercial Items” and date “(JAN 2017)” and adding “Commercial Products and Commercial Services” and “(NOV 2021)” in their places, respectively;
- q. Removing from paragraph (b)(63)(i) the date “(FEB 2006)” and adding “(NOV 2021)” in its place;
- r. Removing from paragraph (b)(63)(iii) the date “(FEB 2006)” and adding “(NOV 2021)” in its place;
- s. Removing from paragraph (c) introductory text the term “commercial items” and phrase “[Contracting Officer check as appropriate.]” and adding “commercial products and commercial services” and “[*Contracting Officer check as appropriate.*]” in their places, respectively;
- t. Removing from paragraph (e)(1) introductory text the term “commercial items” and adding “commercial products or commercial services” in its place;
- u. Removing from paragraph (e)(1)(i) the date “(JUN 2020)” and adding “(NOV 2021)” in its place;
- v. Removing from paragraph (e)(1)(iii) the date “(JUL 2018)” and adding “(NOV 2021)” in its place;
- w. Removing from paragraph (e)(1)(iv) the date “(AUG 2020)” and adding “(NOV 2021)” in its place;
- x. Removing from paragraph (e)(1)(xiii)(A) the date “(OCT 2020)” and adding “(NOV 2021)” in its place;
- y. Removing from paragraph (e)(1)(xvi) the date “(OCT 2015)” and adding “(NOV 2021)” in its place;

- z. Removing from paragraph (e)(1)(xxii) the date “(FEB 2006)” and adding “(NOV 2021)” in its place;
- aa. Removing from paragraph (e)(2) the phrase “May include in its subcontracts for commercial items” and adding “may include in its subcontracts for commercial products and commercial services” in its place;
- bb. Revising the date of Alternate II;
- cc. Removing from the introductory text of paragraph (e)(1) of Alternate II the term “commercial items” and adding “commercial products or commercial services” in its place;
- dd. Removing from paragraph (e)(1)(ii)(A) of Alternate II the date “(JUN 2020)” and adding “(NOV 2021)” in its place;
- ee. Removing from paragraph (e)(1)(ii)(C) of Alternate II the date “(JUL 2018)” and adding “(NOV 2021)” in its place;
- ff. Removing from paragraph (e)(1)(ii)(D) of Alternate II the date “(AUG 2020)” and adding “(NOV 2021)” in its place;
- gg. Removing from paragraph (e)(1)(ii)(L)(1) of Alternate II the date “(OCT 2020)” and adding “(NOV 2021)” in its place;
- hh. Removing from paragraph (e)(1)(ii)(O) of Alternate II the date “(OCT 2015)” and adding “(NOV 2021)” in its place; and
- ii. Removing from paragraph (e)(1)(ii)(U) of Alternate II the date “(FEB 2006)” and adding “(NOV 2021)” in its place.

The revisions read as follows:

52.212–5 Contract Terms and Conditions Required To Implement Statutes or Executive Orders—Commercial Products and Commercial Services.

* * * * *

Contract Terms and Conditions
Required To Implement Statutes or
Executive Orders—Commercial
Products and Commercial Services
(NOV 2021)

* * * * *

Alternate II (NOV 2021) * * *

* * * * *

- 208. Amend section 52.213–4 by—
- a. Revising the section heading;
- b. Revising the heading and date of the clause;
- c. Removing from paragraph (a)(1)(ii) the date “(JUL 2018)” and adding in its place “(NOV 2021)”;
- d. Removing from paragraph (a)(1)(iii) the date “(AUG 2020)” and adding in its place “(NOV 2021)”;
- e. Removing from paragraph (a)(2)(vi) the date “(DEC 2013)” and adding in its place “(NOV 2021)”;
- f. In paragraph (a)(2)(viii):

- i. Removing the term “Commercial Items” and adding in its place “Commercial Products and Commercial Services”; and
- ii. Removing the date “(JUL 2021)” and adding “(NOV 2021)” in its place;
- g. Removing from paragraph (b)(1)(viii)(A) the date “(OCT 2020)” and adding in its place “(NOV 2021)”;
- h. Removing from paragraph (b)(1)(xvii) the date “(JAN 2021)” and adding in its place “(NOV 2021)”;
- i. Removing from paragraph (b)(1)(xxi) the date “(FEB 2006)” and adding in its place “(NOV 2021)”;
- j. In paragraph (b)(2)(i):
- i. Removing the date “(JUN 2016)” and adding in its place “(NOV 2021)”;
- and
- ii. Removing the phrase “its information system.” and adding “its information system.” in its place; and
- k. Removing from paragraph (b)(2)(ii) the date “(JUN 2020)” and adding in its place “(NOV 2021)”.

The revisions read as follows:

52.213–4 Terms and Conditions—Simplified Acquisitions (Other Than Commercial Products and Commercial Services).

* * * * *

Terms and Conditions—Simplified
Acquisitions (Other Than Commercial
Products and Commercial Services)
(NOV 2021)

* * * * *

- 209. Amend section 52.215–1 by—
- a. Revising the heading and date of the provision; and
- b. Removing from paragraph (f)(11)(v) “commercial items, the make and model of the item” and adding “commercial products, the make and model of the product” in its place.

The revisions read as follows:

52.215–1 Instructions to Offerors—Competitive Acquisition.

* * * * *

Instructions to Offerors—Competitive
Acquisition (NOV 2021)

* * * * *

- 210. Amend section 52.215–14 by—
- a. Revising the date of the clause; and
- b. Removing from paragraph (c) the term “commercial items” and adding “commercial products and commercial services” in its place.

The revision reads as follows:

52.215–14 Integrity of Unit Prices.

* * * * *

Integrity of Unit Prices (NOV 2021)

* * * * *

- 211. Amend section 52.215–20 by—

- a. Revising the date of the provision; and
- b. Removing from paragraph (a)(1)(ii) the terms “Commercial item” and “commercial item” and adding “Commercial product and commercial service” and “commercial product and commercial service” in their places, respectively.

The revision reads as follows:

52.215–20 Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data.

* * * * *

Requirements for Certified Cost or
Pricing Data and Data Other Than
Certified Cost or Pricing Data (NOV
2021)

* * * * *

- 212. Amend section 52.215–21 by—
- a. Revising the date of the clause;
- b. Removing from the introductory text of paragraph (a)(1)(ii) the term “commercial items” and adding “commercial products or commercial services” in its place;
- c. Removing from paragraph (a)(1)(ii)(A)(1) the term “commercial item” and adding “commercial product or commercial service” in its place;
- d. Removing from paragraph (a)(1)(ii)(A)(2) the phrase “commercial item to a contract or subcontract for the acquisition of an item other than a commercial item” and adding “commercial product or commercial service, to a contract or subcontract for the acquisition of other than a commercial product or commercial service” in its place;
- e. Redesignating paragraph (a)(1)(ii)(B) as paragraph (a)(1)(ii)(B); and
- f. Removing from newly redesignated paragraph (a)(1)(ii)(B) the term “commercial item” and adding “commercial product and commercial service” in its place.

The revision reads as follows:

52.215–21 Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data—Modifications.

* * * * *

Requirements for Certified Cost or
Pricing Data and Data Other Than
Certified Cost or Pricing Data—
Modifications (NOV 2021)

* * * * *

- 213. Amend section 52.216–2 by—
- a. Revising the introductory text;
- b. Revising the date of the clause; and
- c. Removing from paragraph (a) the term “commercial item” and adding “commercial product” in its place.

The revisions read as follows:

52.216-2 Economic Price Adjustment—Standard Supplies.

As prescribed in 16.203-4(a), insert the following clause:

* * * * *

Economic Price Adjustment—Standard Supplies (NOV 2021)

* * * * *

- 214. Amend section 52.216-3 by—
- a. Revising the introductory text;
 - b. Revising the date of the clause; and
 - c. Removing from paragraph (a) the term “commercial item” and adding “commercial product” in its place.

The revisions read as follows:

52.216-3 Economic Price Adjustment—Semistandard Supplies.

As prescribed in 16.203-4(b), insert the following clause:

* * * * *

Economic Price Adjustment—Semistandard Supplies (NOV 2021)

* * * * *

- 215. Amend section 52.216-4 by revising the introductory text to read as follows:

52.216-4 Economic Price Adjustment—Labor and Material.

As prescribed in 16.203-4(c), insert the following clause:

* * * * *

- 216. Amend section 52.216-29 by revising the section heading and the heading and date of the provision to read as follows:

52.216-29 Time-and-Materials/Labor-Hour Proposal Requirements—Other Than Commercial Acquisition With Adequate Price Competition.

* * * * *

Time-and-Materials/Labor-Hour Proposal Requirements—Other Than Commercial Acquisition With Adequate Price Competition (NOV 2021)

* * * * *

- 217. Amend section 52.216-30 by—
- a. Revising the section heading;
 - b. Revising the heading and date of the provision; and
 - c. Removing from paragraph (d) the phrase “commercial item at 2.101” and adding ““commercial service” at Federal Acquisition Regulation 2.101” in its place.

The revisions read as follows:

52.216-30 Time-and-Materials/Labor-Hour Proposal Requirements—Other Than Commercial Acquisition Without Adequate Price Competition.

* * * * *

Time-and-Materials/Labor-Hour Proposal Requirements—Other Than Commercial Acquisition Without Adequate Price Competition (NOV 2021)

* * * * *

- 218. Amend section 52.216-31 by revising the section heading and the heading and date of the provision to read as follows:

52.216-31 Time-and-Materials/Labor-Hour Proposal Requirements—Commercial Acquisition.

* * * * *

Time-and-Materials/Labor-Hour Proposal Requirements—Commercial Acquisition (NOV 2021)

* * * * *

- 219. Amend section 52.219-9 by—
- a. Revising the date of the clause;
 - b. Removing from paragraph (b) the definition of “Commercial item”;
 - c. Removing from the definition of “Commercial plan” the term “commercial items” and adding “commercial products and commercial services” in its place;
 - d. Adding, in alphabetical order, the definitions “Commercial product” and “Commercial service”;
 - e. Removing from paragraph (g) the terms “commercial items” and “commercial item” and adding “commercial products and commercial services” and “commercial product or commercial service” in their places, respectively; and
 - f. In paragraph (j):
- i. Removing the term “52.212-5” and adding in its place “FAR 52.212-5”;
 - ii. Removing the term “Commercial Items” wherever it appears and adding in its place “Commercial Products and Commercial Services”;
 - iii. Removing the term “commercial item” and adding in its place “commercial product or commercial service”;
 - iv. Removing the term “52.244-6” and adding “FAR 52.244-6” in its place.

The additions and revisions read as follows:

52.219-9 Small Business Subcontracting Plan.

* * * * *

Small Business Subcontracting Plan (NOV 2021)

* * * * *

(b) * * *

Commercial product means a product that satisfies the definition of “commercial product” in Federal Acquisition Regulation (FAR) 2.101.

Commercial service means a service that satisfies the definition of “commercial service” in FAR 2.101.

* * * * *

- 220. Amend section 52.222-50 by—
- a. Revising the date of the clause; and
 - b. In paragraph (a), in the definition of “Commercially available off-the-shelf (COTS) item”:
 - i. Removing the word “means” in the introductory text; and
 - ii. Revising paragraph (1) introductory text and (1)(i).

The revisions read as follows:

52.222-50 Combating Trafficking in Persons.

* * * * *

Combating Trafficking in Persons (NOV 2021)

* * * * *

(a) * * *

Commercially available off-the-shelf (COTS) item—(1) Means any item of supply (including construction material) that is—

(i) A commercial product (as defined in paragraph (1) of the definition of “commercial product” at Federal Acquisition Regulation (FAR) 2.101;

* * * * *

- 221. Amend section 52.222-54 by—
- a. Revising the date of the clause;
 - b. In paragraph (a), in the definition of “Commercially available off-the-shelf (COTS) item”, revising paragraph (1)(i); and
 - c. Removing from paragraph (e)(1)(i) the term “Commercial or noncommercial services” and adding “Services” in its place.

The revisions read as follows:

52.222-54 Employment Eligibility Verification.

* * * * *

Employment Eligibility Verification (NOV 2021)

* * * * *

(a) * * *

Commercially available off-the-shelf (COTS) item—

(1) * * *

(i) A commercial product (as defined in paragraph (1) of the definition of “commercial product” at Federal Acquisition Regulation (FAR) 2.101;

* * * * *

- 222. Amend section 52.225-1 by—
- a. Revising the date of the clause; and
 - b. In paragraph (a), in the definition of “Commercially available off-the-shelf (COTS) item”, revising paragraph (1)(i).

The revisions read as follows:

52.225-1 Buy American—Supplies.

* * * * *

Buy American—Supplies (NOV 2021)

* * * * *

(a) * * *

Commercially available off-the-shelf (COTS) item—(1) * * *

(i) A commercial product (as defined in paragraph (1) of the definition of “commercial product” at Federal Acquisition Regulation (FAR) 2.101;

* * * * *

■ 223. Amend section 52.225–3 by—

- a. Revising the date of the clause; and
- b. In paragraph (a), in the definition of “Commercially available off-the-shelf (COTS) item”, revising paragraph (1)(i).

The revisions read as follows:

52.225–3 Buy American—Free Trade Agreements—Israeli Trade Act.

* * * * *

Buy American—Free Trade Agreements—Israeli Trade Act (NOV 2021)

* * * * *

(a) * * *

Commercially available off-the-shelf (COTS) item—(1) * * *

(i) A commercial product (as defined in paragraph (1) of the definition of “commercial product” at Federal Acquisition Regulation (FAR) 2.101;

* * * * *

■ 224. Amend section 52.225–9 by—

- a. Revising the date of the clause;
- b. In paragraph (a), in the definition of “Commercially available off-the-shelf (COTS) item”, revising paragraph (1)(i); and
- c. Removing from paragraph (b)(2) the term “commercial item” and adding “commercial product” in its place.

The revisions read as follows:

52.225–9 Buy American—Construction Materials.

* * * * *

52.225–9 Buy American—Construction Materials.

Buy American—Construction Materials (NOV 2021)

(a) * * *

Commercially available off-the-shelf (COTS) item—(1) * * *

(i) A commercial product (as defined in paragraph (1) of the definition of “commercial product” at Federal Acquisition Regulation (FAR) 2.101;

■ 225. Amend section 52.225–11 by—

- a. Revising the date of the clause;
- b. In paragraph (a), in the definition of “Commercially available off-the-shelf (COTS) item”, revising paragraph (1)(i); and
- c. Removing from paragraph (b)(3) the term “commercial item” and adding “commercial product” in its place.

The revisions read as follows:

52.225–11 Buy American—Construction Materials Under Trade Agreements.

* * * * *

Buy American—Construction Materials Under Trade Agreements (NOV 2021)

* * * * *

(a) * * *

Commercially available off-the-shelf (COTS) item—(1) * * *

(i) A commercial product (as defined in paragraph (1) of the definition of “commercial product” at Federal Acquisition Regulation (FAR) 2.101;

* * * * *

■ 226. Amend section 52.229–13 by:

- a. Revising the date of the clause; and
- b. Removing from paragraph (c) the phrases “in all subcontracts,” and “commercial items” and adding “in all subcontracts” and “commercial products or commercial services” in their places, respectively.

The revision reads as follows:

52.229–13 Taxes—Foreign Contracts in Afghanistan.

* * * * *

Taxes—Foreign Contracts in Afghanistan (NOV 2021)

* * * * *

■ 227. Amend section 52.229–14 by:

- a. Revising the date of the clause; and
- b. Removing from paragraph (c) the phrases “in all subcontracts” and “commercial items” and adding “in all subcontracts” and “commercial products or commercial services” in their places, respectively.

The revision reads as follows:

52.229–14 Taxes—Foreign Contracts in Afghanistan (North Atlantic Treaty Organization Status of Forces Agreement).

* * * * *

Taxes—Foreign Contracts in Afghanistan (North Atlantic Treaty Organization Status of Forces Agreement) (NOV 2021)

* * * * *

■ 228. Amend section 52.232–7 by—

- a. Revising the date of the clause;
- b. Removing from paragraph (b)(2) the phrase “commercial item at 2.101” and adding “commercial product or commercial service in Federal Acquisition Regulation (FAR) 2.101” in its place; and
- c. Removing from paragraph (b)(4) the phrase “Subpart 31.2 of the Federal Acquisition Regulation (FAR)” and adding “FAR subpart 31.2” in its place.

The revision reads as follows:

52.232–7 Payments under Time-and-Materials and Labor-Hour Contracts.

* * * * *

Payments under Time-and-Materials and Labor-Hour Contracts (NOV 2021)

* * * * *

■ 229. Amend section 52.232–16 by—

- a. Revising the date of the clause;
- b. Removing from paragraph (j)(5) introductory text the term “commercial item” and adding “commercial product or commercial service” in its place; and
- c. Removing from paragraph (j)(5)(i) the phrase “commercial item purchase that meets the definition and standards for acquisition of commercial items in FAR Parts” and adding “commercial product or commercial service purchase that meets the definition and standards for acquisition of commercial products and commercial services in FAR parts” in its place.

The revision reads as follows:

52.232–16 Progress Payments.

* * * * *

Progress Payments (NOV 2021)

* * * * *

■ 230. Amend section 52.232–29 by—

- a. Revising the section heading;
- b. Revising the heading and date of the clause;
- c. Removing from paragraph (b) the phrase “52.212–4, Contract Terms and Conditions—Commercial Items” and adding “Federal Acquisition Regulation (FAR) 52.212–4, Contract Terms and Conditions—Commercial Products and Commercial Services” in its place; and
- d. Removing from paragraph (h) the term “52.232–31” and adding “FAR 52.232–31” in its place.

The revisions read as follows:

52.232–29 Terms for Financing of Purchases of Commercial Products and Commercial Services.

* * * * *

Terms for Financing of Purchases of Commercial Products and Commercial Services (NOV 2021)

* * * * *

■ 231. Amend section 52.232–30 by—

- a. Revising the section heading;
- b. Revising the heading and date of the clause; and
- c. Removing from paragraph (g) the phrase “52.212–4, Contract Terms and Conditions—Commercial Items” and adding “Federal Acquisition Regulation 52.212–4, Contract Terms and Conditions—Commercial Products and Commercial Services” in its place.

The revisions read as follows:

52.232–30 Installment Payments for Commercial Products and Commercial Services.

* * * * *

Installment Payments for Commercial Products and Commercial Services (NOV 2021)

* * * * *

- 232. Amend section 52.232–31 by—
- a. Revising the date of the provision;
- b. Removing from paragraph (a) the phrase “Commercial Items, at 52.232–29” and adding “Commercial Products and Commercial Services, at Federal Acquisition Regulation (FAR) 52.232–29” in its place; and
- c. Removing from paragraph (b) the phrase “52.232–29, Terms for Financing of Purchases of Commercial Items, the terms of the clause at 52.232–29 shall govern” and adding “FAR 52.232–29, Terms for Financing of Purchases of Commercial Products and Commercial Services, the terms of the clause at FAR 52.232–29 shall govern” in its place.

The revision reads as follows:

52.232–31 Invitation To Propose Financing Terms.

* * * * *

Invitation To Propose Financing Terms
(NOV 2021)

* * * * *

- 233. Amend section 52.232–40 by—
- a. Revising the date of the clause; and
- b. Removing from paragraph (c) the term “commercial items” and adding “commercial products or commercial services” in its place.

The revision reads as follows:

52.232–40 Providing Accelerated Payments to Small Business Subcontractors.

* * * * *

Providing Accelerated Payments to
Small Business Subcontractors (NOV
2021)

* * * * *

- 234. Amend section 52.242–17 by revising the introductory text to read as follows:

52.242–17 Government Delay of Work.

As prescribed in 42.1305(c), insert the following clause:

* * * * *

- 235. Amend section 52.244–6 by—
- a. Revising the section heading;
- b. Revising the heading and date of the clause;
- c. Revising paragraph (a);
- d. Removing from paragraph (b) the term “commercial items” and adding “commercial products, commercial services,” in its place;
- e. Removing from the paragraph (c)(1) introductory text the term “commercial items” and adding “commercial products or commercial services” in its place;
- f. Removing from paragraph (c)(1)(i) the date “(Jun 2020)” and adding “(NOV 2021)” in its place;

- g. Removing from paragraph (c)(1)(iv) the date “(JUN 2016)” and adding “(NOV 2021)” in its place;
- h. Removing from paragraph (c)(1)(v) the date “(JUL 2018)” and adding “(NOV 2021)” in its place;
- i. Removing from paragraph (c)(1)(vi) the date “(AUG 2020)” and adding “(NOV 2021)” in its place;
- j. Removing from paragraph (c)(1)(xiv)(A) the date “(OCT 2020)” and adding “(NOV 2021)” in its place;
- k. Removing from paragraph (c)(1)(xix) the date “(DEC 2013)” and adding “(NOV 2021)” in its place;
- l. Removing from paragraph (c)(1)(xx) the date “(FEB 2006)” and adding “(NOV 2021)” in its place; and
- m. Removing from paragraph (c)(2) the term “commercial items” and adding “commercial products or commercial services” in its place.

The revisions read as follows:

52.244–6 Subcontracts for Commercial Products and Commercial Services.

* * * * *

Subcontracts for Commercial Products
and Commercial Services (NOV 2021)

(a) *Definitions.* As used in this clause—

Commercial product, commercial service, and commercially available off-the-shelf item have the meanings contained in Federal Acquisition Regulation (FAR) 2.101.

Subcontract includes a transfer of commercial products or commercial services between divisions, subsidiaries, or affiliates of the Contractor or subcontractor at any tier.

* * * * *

- 236. Amend section 52.246–26 by—
- a. Revising the date of the clause;
- b. Removing from paragraph (g)(1)(i) the term “FAR” and adding “Federal Acquisition Regulation (FAR)” in its place; and
- c. Removing from paragraph (g)(2)(i) the words “Commercial items” and adding “Commercial products and commercial services” in its place.

The revision reads as follows:

52.246–26 Reporting Nonconforming Items.

* * * * *

Reporting Nonconforming Items (NOV 2021)

* * * * *

- 237. Amend section 52.247–64 by—
- a. Revising the date of clause;
- b. Removing from paragraph (e)(4) introductory text the term “commercial items” and adding “commercial products or commercial services” in its place;

- c. Revising the date of Alternate II;
- d. Removing from paragraph (e)(4) introductory text of Alternate II the term “commercial items” and adding “commercial products or commercial services” in its place; and
- e. Removing from paragraph (e)(4)(ii)(C) of Alternate II the term “commercial items” and adding “commercial products” in its place.

The revisions read as follows:

52.247–64 Preference for Privately Owned U.S.-Flag Commercial Vessels.

* * * * *

Preference for Privately Owned U.S.-
Flag Commercial Vessels (NOV 2021)

* * * * *

Alternate II (NOV 2021)

* * * * *

PART 53—FORMS

53.212 [Amended]

- 238. Amend section 53.212 by—
- a. Revising the section heading;
- b. Removing the term “(Rev. 2/2012)” and adding “(Rev. NOV 2021)” in its place; and
- c. Removing the terms “*Commercial Items*” and “commercial items” and adding “Commercial Products and Commercial Services” and “commercial products and commercial services” in their places, respectively.

The revision reads as follows:

53.212 Acquisition of commercial products and commercial services.

* * * * *

53.213 [Amended]

- 239. Amend section 53.213 by—
- a. In paragraph (a):
- i. Removing the date “(Rev. 2/2012)” and adding in its place “(Rev. NOV 2021)”; and
- ii. Removing the words “*Commercial Items*” and adding “*Commercial Products and Commercial Services*” in their place; and
- b. In paragraph (f):
- i. Removing the date “(Rev. 2/2012)” and adding “(Rev. NOV 2021)” in its place; and
- ii. Removing the words “*Commercial Items*” and adding “*Commercial Products and Commercial Services*” in their place.

53.219 [Amended]

- 240. Amend section 53.219 by removing the date “(Rev. OCT 2020)” and adding “(Rev. NOV 2021)” in its place.

53.232 [Amended]

■ 241. Amend section 53.232 by removing the text “(Jul 2009)” and adding “(NOV 2021)” in its place.

■ 242. Amend section 53.300 in paragraph (a) by revising the entry for “SF 1449” to read as follows:

53.300 Listing of Standard, Optional, and Agency forms.

* * * * *

(a) * * *

TABLE 53–1—FORMS IN THE GSA FORMS LIBRARY

Form No.	Form title
* * * * *	
SF 1449	Solicitation/Contract/Order for Commercial Products and Commercial Services.
* * * * *	

[FR Doc. 2021–22144 Filed 11–3–21; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF DEFENSE**GENERAL SERVICES ADMINISTRATION****NATIONAL AERONAUTICS AND SPACE ADMINISTRATION****48 CFR Parts 5 and 7**

[FAC 2022–01; FAR Case 2019–003; Item II; Docket No. 2019–0029; Sequence No. 1]

RIN 9000–AN86

Federal Acquisition Regulation: Consolidation and Substantial Bundling

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Final rule.

SUMMARY: DoD, GSA, and NASA are issuing a final rule amending the Federal Acquisition Regulation (FAR) to implement a section of the National Defense Authorization Act for Fiscal Year 2016 that requires providing public notices of determinations for substantial bundling and consolidation of contract requirements.

DATES: Effective December 6, 2021.

FOR FURTHER INFORMATION CONTACT: Ms. Dana Bowman, Procurement Analyst, at 202–803–3188, or by email at dana.bowman@gsa.gov. For information pertaining to status or publication schedules, contact the Regulatory

Secretariat Division at 202–501–4755. Please cite FAC 2022–01, FAR Case 2019–003.

SUPPLEMENTARY INFORMATION:**I. Background**

DoD, GSA, and NASA published a proposed rule at 85 FR 23299 on April 27, 2020, to implement section 863 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2016 (Pub. L. 114–92, codified at 15 U.S.C. 644(e)(3) and 15 U.S.C. 657q(c)(2)) and the Small Business Administration (SBA) implementing regulations. SBA published a final rule to implement section 863 on November 29, 2019, at 84 FR 65647.

Section 863 requires public notification of an agency’s determination to substantially bundle or consolidate contract requirements. Specifically, publication of a notice is required when the head of a contracting agency determines that an acquisition plan for a procurement involves substantial bundling of contract requirements. The head of the contracting agency must publish a notice on a public website that such determination has been made not later than 7 days after making the determination. Any solicitation for a procurement related to the acquisition plan may not be published earlier than 7 days after such notice is published. A justification for the determination must be published with the solicitation. The justification must address the specific benefits anticipated, any alternative approaches, impediments to participation by small business concerns as prime contractors, and actions designed to maximize participation of small business concerns as subcontractors (see 15 U.S.C. 644(e)(3)(A) through (C)).

Section 863 also requires publication of a notice when the senior procurement executive (SPE) or chief acquisition officer (CAO) makes a determination that an acquisition strategy involving consolidation of contract requirements is necessary and justified under 15 U.S.C. 657q(c)(2)(A). The SPE or CAO must publish a notice on a public website that such determination has been made not later than 7 days after making the determination. Any solicitation for a procurement related to the acquisition strategy may not be published earlier than 7 days after such notice is published. A justification for the determination must be published with the solicitation. The justification must include the information in 15 U.S.C. 657q(c)(1)(A) through (E).

As a result, this final rule amends FAR 7.107–5, Notifications, to require

the publication on the Governmentwide Point of Entry of a notice of substantial bundling or of a notice of consolidation, as required in the SBA final rule. This section also contains references to the required content of the consolidation determination (at FAR 7.107–2) and the substantial bundling determination (at FAR 7.107–4).

Four respondents submitted public comments in response to the proposed rule.

II. Discussion and Analysis

The Civilian Agency Acquisition Council and the Defense Acquisition Regulations Council (the Councils) reviewed the public comments in the development of the final rule. A discussion of the comments received and any changes made to the rule as a result of the public comments are provided as follows:

A. Summary of Significant Changes From the Proposed Rule

There are no significant changes made to the final rule.

B. Analysis of Public Comments**1. Support for the Rule**

Comment: One respondent expressed support for the rule.

Response: The Councils acknowledge the respondent’s support for the rule.

2. More Time Between Publication of Notice and Solicitation Issuance

Comment: Two respondents expressed concern about the 7-day notification period, stating that it is not enough time for small businesses to plan and strategize. The respondents requested the notification posting period be extended for a longer time, at least 2 weeks.

Response: This FAR rule uses the same time period set forth in SBA’s implementation of section 863 after SBA considered the length of the notification period.

3. Location of Notices

Comment: One respondent suggested that the existing requirement to publish the notification on a “public site” is too vague and that compliance could be satisfied by posting on an agency’s social media platform. The respondent recommends that all notifications should be posted on *beta.sam* via the Governmentwide point of entry (GPE).

Response: This rule implements section 863 of the NDAA for FY 2016 (Pub. L. 114–92) and the SBA implementing regulations (13 CFR 125), which requires agencies to provide public notices on the GPE of determinations for substantial bundling

and consolidation of contract requirements. FAR 7.107–5(b)(1) currently requires annual publication on the agency website of a list of bundled contracts and rationale, because section 1312 of Public Law 111–240 requires it. Thus, this rule could not mandate that all notifications be published on SAM via the GPE.

Additionally, the FAR text is amended at 7.107–5(c) and 7.107–5(d) to require the Senior Procurement Executive or Chief Acquisition Officer to publish notifications of consolidation and substantial bundling of contract requirements in the GPE not later than 7 days after making such a determination and prior to issuance of the solicitation. The FAR does not use social media as a publication platform. No changes were made to the FAR text as a result of this comment.

4. Broader Applicability of Notice Requirement

Comment: One respondent questioned why the required notification did not apply to all bundled procurements. The respondent further stated that the definition for substantial bundling should be referenced to provide guidance to the procurement office.

Response: This rule implements section 863 of the NDAA for FY 2016 (Pub. L. 114–92) and the SBA implementing regulations, which require publication of notices when a procurement involves consolidation or substantial bundling of contract requirements. The definition for substantial bundling can be found at 7.107–4(a)(1). Neither section 863 nor the SBA regulations altered notification requirements for bundled procurements below the substantial bundling threshold; therefore, this final rule does not apply these requirements below the substantial bundling threshold.

5. Outside the Scope of the Rule

Comment: One respondent questioned whether information is being withheld from the proposed rule. Another respondent stated that SBA procurement center representatives often disagree with the bundling justification but sign form 2579 despite their opposition. The respondent further stated that small business subcontractors are not being utilized by large businesses given that there is “no punishment for a large not subcontracting” and no incentive for large businesses to comply with subcontracting goals beyond their initial proposal submission. Additionally, the respondent stated that bundling has been prohibited in Federal acquisition and recommends the following actions:

- Allow small businesses to be involved in the “crafting of bundling efforts” given that “large [businesses] are involved in the crafting of the bundling effort;” and

- Give SBA the “power to do their jobs” by allowing for a process for the procurement center representative to disagree with the bundling effort.

Response: The respondents’ comments are outside the scope of this FAR rule. The Councils note that FAR 19.502–8 addresses the process for SBA PCRs to appeal the contracting officer’s rejection of SBA’s recommendation.

III. Applicability to Contracts at or Below the Simplified Acquisition Threshold (SAT) and for Commercial Items, Including Commercially Available Off-the-Shelf (COTS) Items

This rule does not create new solicitation provisions or contract clauses or impact any existing provisions or clauses.

IV. Executive Orders 12866 and 13563

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

V. Congressional Review Act

As required by the Congressional Review Act (5 U.S.C. 801–808) before an interim or final rule takes effect, DoD, GSA, and NASA will send the rule and the “Submission of Federal Rules Under the Congressional Review Act” form to each House of the Congress and to the Comptroller General of the United States. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. The Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget has determined that this is not a major rule under 5 U.S.C. 804.

VI. Regulatory Flexibility Act

DoD, GSA, and NASA have prepared a Final Regulatory Flexibility Analysis (FRFA) consistent with the Regulatory

Flexibility Act, 5 U.S.C. 601–612. The FRFA is summarized as follows:

This rule is necessary to implement section 863 of the National Defense Authorization Act for 2016 (Pub. L. 114–92, codified at 15 U.S.C. 644(e)(3) and 15 U.S.C. 657q(c)(2)), and the Small Business Administration (SBA) implementing regulations. Section 863 requires the head of a contracting agency to publish a notice on a public website within 7 days of making the determination that an acquisition plan involves a substantial bundling of contract requirements. Additionally, section 863 requires the senior procurement executive or chief acquisition officer to publish a notice on a public website that consolidation of contract requirements is necessary and justified. For substantial bundling and for consolidation, the agency may not issue the solicitation any earlier than 7 days after publication of the notices described above. The agency must also publish the justification along with the solicitation. The objective of this rule is to amend the FAR to require that a notice of substantial bundling or of a notice of consolidation be published on the Governmentwide Point of Entry, as required in the SBA final rule. This section also contains references to the required content of the consolidation determination (at FAR 7.107–2) and the substantial bundling determination (at FAR 7.107–4).

No public comments were received in response to the initial regulatory flexibility analysis.

This rule may have a positive economic impact on any small entity that is interested in participating in Federal procurement. By posting justifications and notices of upcoming procurements that are planned to be substantially bundled or consolidated, small business concerns are made aware of potential subcontracting opportunities and possibilities for participating in joint ventures or small business teaming arrangements, which will help small businesses increase their competitiveness. The System for Award Management shows 315,655 entities that are small business concerns under at least one North American Industry Classification System code.

This rule does not include any new reporting, recordkeeping, or other compliance requirements for any small entities.

There are no known significant alternative approaches to the rule that would meet the stated objectives of the applicable statute.

Interested parties may obtain a copy of the FRFA from the Regulatory Secretariat Division. The Regulatory Secretariat Division has submitted a copy of the FRFA to the Chief Counsel for Advocacy of SBA.

VII. Paperwork Reduction Act

This rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. 3501–3521).

List of Subjects in 48 CFR Parts 5 and 7

Government procurement.

William F. Clark,

Director, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

Therefore, DoD, GSA, and NASA are amending 48 CFR parts 5 and 7 as set forth below:

- 1. The authority citation for 48 CFR parts 5 and 7 continues to read as follows:

Authority: 40 U.S.C. 121(c); 10 U.S.C. chapter 137; and 51 U.S.C. 20113.

PART 5—PUBLICIZING CONTRACT ACTIONS

- 2. Amend section 5.205 by revising paragraph (g) to read as follows:

5.205 Special Situations.

* * * * *

(g) *Notifications to the public regarding consolidation, bundling, or substantial bundling.* (1) For the requirement to publish a notification of consolidation or substantial bundling of contract requirements, see 7.107–5(c) and (d).

(2) The agency is encouraged to provide notification of the rationale for any bundled requirement to the GPE before issuing the solicitation of any bundled requirement (see 7.107–5(b)).

PART 7—ACQUISITION PLANNING**7.105 [Amended]**

- 3. Amend section 7.105 by removing from paragraph (b)(16) the term “GPE” and adding “Governmentwide point of entry (GPE)” in its place.

7.107–1 [Amended]

- 4. Amend section 7.107–1 by removing from paragraph (a) the phrase “7.107–3 and 7.107–4” and adding “7.107–3, 7.107–4, and 7.107–5” in its place.

7.107–2 [Amended]

- 5. Amend section 7.107–2 by—
 - a. Removing from paragraph (a) introductory text the phrases “senior procurement executive” and “chief acquisition officer” and adding “senior procurement executive (SPE)” and “chief acquisition officer (CAO)” in their places, respectively;
 - b. Removing from paragraph (b) the phrases “senior procurement executive or chief acquisition officer” and “subsection” and adding “SPE or CAO” and “section” in their places, respectively;

- c. Removing from paragraph (d)(3) the phrase “senior procurement executive or chief acquisition officer” and adding “SPE or CAO” in its place;

- d. Removing from paragraph (e)(1) introductory text the word “subsection” wherever it appears and adding “section” in its place;

- e. Removing from paragraph (e)(1)(i) the word “subsection” and adding “section” in its place; and

- f. Removing from paragraph (e)(2)(i) the phrase “senior procurement executive” and adding “SPE” in its place.

- 6. Amend section 7.107–5 by—

- a. Revising paragraph (b);

- b. Redesignating paragraphs (c) and (d) as paragraphs (e) and (g) and adding new paragraphs (c) and (d) and paragraph (f); and

- c. Removing from the newly redesignated paragraph (g) “*Public notification*” and adding “*Notification to public*” in its place.

The revision and additions read as follows:

7.107–5 Notifications.

* * * * *

(b) *Notification to the public of rationale for bundled requirement.* The agency is encouraged to provide notification of the rationale for any bundled requirement to the GPE, before issuance of the solicitation (see 5.201).

(c) *Notification to the public of consolidation of contract requirements.* The SPE or CAO shall publish in the GPE—

(1) A notice that the agency has determined a consolidation of contract requirements is necessary and justified (see 7.107–2) no later than 7 days after making the determination; the solicitation may not be publicized prior to 7 days after publication of the notice of the agency determination; and

(2) The determination that consolidation is necessary and justified with the publication of the solicitation. See 7.107–2 for the required content of the determination.

(d) *Notification to the public of substantial bundling of contract requirements.* The head of the agency shall publish in the GPE—

(1) A notice that the agency has determined that a procurement involves substantial bundling (see 7.107–4) no later than 7 days after such determination has been made; the solicitation may not be publicized prior to 7 days after the publication of the notice of the determination; and

(2) The rationale for substantial bundling with the publication of the solicitation. The rationale is the

information required for inclusion in the acquisition strategy at 7.107–4(b).

* * * * *

(f) *Annual notification to the public of the rationale for bundled requirements.* The agency shall publish on its website a list and rationale for any bundled requirement for which the agency solicited offers or issued an award. The notification shall be made annually within 30 days of the agency’s data certification regarding the validity and verification of data entered in the Federal Procurement Data System to the Office of Federal Procurement Policy (see 4.604).

* * * * *

[FR Doc. 2021–22145 Filed 11–3–21; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF DEFENSE**GENERAL SERVICES ADMINISTRATION****NATIONAL AERONAUTICS AND SPACE ADMINISTRATION****48 CFR Part 19**

[FAC 2022–01; FAR Case 2021–007; Item III; Docket No. FAR–2021–0007, Sequence No. 1]

RIN 9000—AO25**Federal Acquisition Regulation: Maximum Award Price for Certain Sole Source Manufacturing Contracts**

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Final rule.

SUMMARY: DoD, GSA, and NASA are issuing a final rule amending the Federal Acquisition Regulation (FAR) to implement a section of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021 that modified the Small Business Act maximum award price for manufacturing contracts to \$7 million.

DATES: Effective December 6, 2021.

FOR FURTHER INFORMATION CONTACT: Mr. Michael O. Jackson, Procurement Analyst, at 202–208–4949 or by email at michael.o.jackson@gsa.gov, for clarification of content. For information pertaining to status or publication schedules, contact the Regulatory Secretariat Division at 202–501–4755 or GSARegSec@gsa.gov. Please cite FAC 2022–01, FAR Case 2021–007.

SUPPLEMENTARY INFORMATION:

I. Background

DoD, GSA, and NASA are amending the FAR to implement section 864 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2021 (Pub. L. 116–283, January 1, 2021). Section 864 amends the Small Business Act to modify the maximum award price for manufacturing contracts to \$7 million for the 8(a), Women-Owned Small Business (WOSB), Historically Underutilized Business Zone (HUBZone), and Service-Disabled Veteran-Owned Small Business (SDVOSB) programs.

The maximum award price for manufacturing contracts at FAR 19.804–6(c)(2), 19.805–1(a)(2), 19.1306(a)(2)(i), 19.1406(a)(2)(i), and 19.1506(c)(1)(i) is subject to the inflationary adjustment required by 41 U.S.C. 1908. Section 1908 requires an adjustment every five years (on October 1 of each year evenly divisible by five) of statutory acquisition-related thresholds for inflation, using the Consumer Price Index for all urban consumers, except for the Construction Wage Rate Requirements statute (Davis-Bacon Act), Service Contract Labor Standards statute (Service Contract Act), and trade agreements thresholds (see FAR 1.109).

FAR case 2019–013 (85 FR 62485), effective on October 1, 2020, made inflationary adjustments to, amongst others, the following: Increased the \$7 million threshold at FAR 19.804–6(c)(2), 19.805–1(a)(2), and 19.1306(a)(2)(i) to \$7.5 million; increased the \$6.5 million threshold at FAR 19.1406(a)(2)(i) to \$7 million; and increased the \$6.5 million threshold at FAR 19.1506(c)(1)(i) to \$7 million.

This final rule will harmonize the maximum award price threshold for manufacturing contracts amongst the socioeconomic programs by changing the current FAR maximum award price threshold for the 8(a) sole source, 8(a) competitive, and HUBZone sole source programs from \$7.5 million to the statutory amount of \$7 million. The maximum award price threshold for the WOSB and SDVOSB programs remains unchanged at the current threshold of \$7 million, which is consistent with section 864 of the NDAA for FY 2021.

II. Publication of This Final Rule for Public Comment Is Not Required by Statute

The statute that applies to the publication of the FAR is 41 U.S.C. 1707. Subsection (a)(1) of 41 U.S.C. 1707 requires that a procurement policy, regulation, procedure, or form (including an amendment or modification thereof) must be published

for public comment if it relates to the expenditure of appropriated funds and has either a significant effect beyond the internal operating procedures of the agency issuing the policy, regulation, procedure, or form, or has a significant cost or administrative impact on contractors or offerors. This final rule is not required to be published for public comment because the rule will not have a significant cost or administrative impact on contractors or offerors. A search of the Federal Procurement Data System revealed that there were no contracts awarded for 8(a) sole source, 8(a) competitive, or HUBZone sole source manufacturing contracts in the range of \$7 million to \$7.5 million between the date of the increase in the threshold to \$7.5 million (October 1, 2020) and April 2021.

III. Applicability to Contracts at or Below the Simplified Acquisition Threshold (SAT) and for Commercial Items, Including Commercially Available Off-the-Shelf (COTS) Items

This rule does not create new solicitation provisions or contract clauses or impact any existing provisions or clauses. This rule merely modifies a threshold in accordance with statute. This rule does not impose any new requirements on contracts at or below the SAT or for commercial items, including COTS items, except for the changes in the thresholds themselves.

IV. Executive Orders 12866 and 13563

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

V. Congressional Review Act

As required by the Congressional Review Act (5 U.S.C. 801–808) before an interim or final rule takes effect, DoD, GSA, and NASA will send the rule and the “Submission of Federal Rules Under the Congressional Review Act” form to each House of the Congress and to the Comptroller General of the United States. A major rule cannot take effect until 60 days after it is published in the

Federal Register. The Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget has determined that this is not a major rule under 5 U.S.C. 804.

VI. Regulatory Flexibility Act

Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule under 41 U.S.C. 1707(a)(1) (see section II. of this preamble), the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601–612) are not applicable. Accordingly, no regulatory flexibility analysis is required, and none has been prepared.

VII. Paperwork Reduction Act

This rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. 3501–3521).

List of Subjects in 48 CFR Part 19

Government procurement.

William F. Clark,

Director, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

Therefore, DoD, GSA, and NASA amend 48 CFR part 19 as set forth below:

PART 19—SMALL BUSINESS PROGRAMS

■ 1. The authority citation for 48 CFR part 19 continues to read as follows:

Authority: 40 U.S.C. 121(c); 10 U.S.C. chapter 137; and 51 U.S.C. 20113.

19.804–6 [Amended]

■ 2. Amend section 19.804–6 by removing from paragraph (c)(2) the phrase “\$7.5 million” and adding “\$7 million” in its place.

19.805–1 [Amended]

■ 3. Amend section 19.805–1 by removing from paragraph (a)(2) the phrase “\$7.5 million” and adding “\$7 million” in its place.

19.1306 [Amended]

■ 4. Amend section 19.1306 by removing from paragraph (a)(2)(i) the phrase “\$7.5 million” and adding “\$7 million” in its place.

[FR Doc. 2021–22146 Filed 11–3–21; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF DEFENSE
GENERAL SERVICES
ADMINISTRATION

NATIONAL AERONAUTICS AND
SPACE ADMINISTRATION

48 CFR Chapter 1

[Docket No. FAR–2021–0051, Sequence No. 5]

Federal Acquisition Regulation;
Federal Acquisition Circular 2022–01;
Small Entity Compliance Guide

AGENCY: Department of Defense (DoD),
General Services Administration (GSA),

and National Aeronautics and Space
Administration (NASA).
ACTION: Small Entity Compliance Guide.

SUMMARY: This document is issued
under the joint authority of DoD, GSA,
and NASA. This *Small Entity*
Compliance Guide has been prepared in
accordance with section 212 of the
Small Business Regulatory Enforcement
Fairness Act of 1996. It consists of a
summary of the rules appearing in
Federal Acquisition Circular (FAC)
2022–01, which amends the Federal
Acquisition Regulation (FAR).
Interested parties may obtain further
information regarding these rules by

referring to FAC 2022–01, which
precedes this document.
DATES: November 4, 2021.
ADDRESSES: The FAC, including the
SECG, is available via the internet at
<https://www.regulations.gov>.
FOR FURTHER INFORMATION CONTACT: For
clarification of content, contact the
analyst whose name appears in the table
below. Please cite FAC 2022–01 and the
FAR Case number. For information
pertaining to status or publication
schedules, contact the Regulatory
Secretariat Division at 202–501–4755 or
GSARegSec@gsa.gov. An asterisk (*)
next to a rule indicates that a regulatory
flexibility analysis has been prepared.

RULES LISTED IN FAC 2022–01

Item	Subject	FAR case	Analyst
* I	Revision of Definition of “Commercial Item”	2018–018	Delgado.
* II	Consolidation and Substantial Bundling	2019–003	Bowman.
III	Maximum Award Price for Certain Sole Source Manufacturing Contracts	2021–007	Jackson.

SUPPLEMENTARY INFORMATION:
Summaries for each FAR rule follow.
For the actual revisions and/or
amendments made by these FAR rules,
refer to the specific item numbers and
subjects set forth in the documents
following these item summaries. FAC
2022–01 amends the FAR as follows:

Item I—Revision of Definition of
“Commercial Item” (FAR Case 2018–
018)

This final rule removes the definition
of “commercial item” and replaces it
with the definitions of “commercial
product” and “commercial service”.
The rule makes numerous conforming
changes throughout the FAR. The rule
implements section 836 of the John S.
McCain National Defense Authorization
Act for Fiscal Year 2019 (Pub. L. 115–
232). This final rule will not have a
significant economic impact on a
substantial number of small entities.

Item II—Consolidation and Substantial
Bundling (FAR Case 2019–003)

This final rule amends the FAR to
implement section 863 of the National
Defense Authorization Act for Fiscal
Year 2016, as implemented in the Small
Business Administration (SBA) final
rule published at 84 FR 65647 on
November 29, 2019. Section 863
requires publication of public notices of
determinations for consolidation and
substantial bundling of contract
requirements. Specifically, section 863
requires the head of an agency to
publish a notice on a public website
within 7 days of making the
determination that an acquisition plan
involves a substantial bundling of
contract requirements. Section 863 also
requires the Senior Procurement
Executive or Chief Acquisition Officer
to publish a notice on a public website
that consolidation of contract
requirements is necessary and justified.
In both cases, the agency may not issue
the solicitation any earlier than 7 days
after publication of the notices. The

agency must also publish the
justification along with the solicitation.

Item III—Maximum Award Price for
Certain Sole Source Manufacturing
Contracts (FAR Case 2021–007)

This final rule amends the FAR to
implement section 864 of the William
M. (Mac) Thornberry National Defense
Authorization Act for Fiscal Year 2021
(Pub. L. 116–283, January 1, 2021).
Section 864 amends the Small Business
Act to modify the maximum award
price for manufacturing contracts to \$7
million for 8(a) program participants,
Women-Owned Small Business (WOSB)
program participants, Historically
Underutilized Business Zone
(HUBZone) small business concerns,
and Service-Disabled Veteran-Owned
Small Business (SDVOSB) concerns.

William F. Clark,
Director, Office of Government-wide
Acquisition Policy, Office of Acquisition
Policy, Office of Government-wide Policy.
[FR Doc. 2021–22147 Filed 11–3–21; 8:45 am]
BILLING CODE 6820–EP–P

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