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Presidential Documents

Title 3—

The President

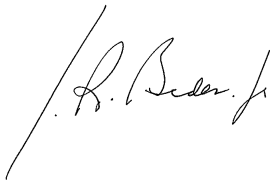
Memorandum of July 1, 2022

Delegation of Authority Under Section 506(a)(1) of the Foreign Assistance Act of 1961

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 621 of the Foreign Assistance Act of 1961 (FAA), I hereby delegate to the Secretary of State the authority under section 506(a)(1) of the FAA to direct the drawdown of up to $50 million in defense articles and services of the Department of Defense, and military education and training, to provide assistance to Ukraine and to make the determinations required under such section to direct such a drawdown.

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



THE WHITE HOUSE,
Washington, July 1, 2022

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Rules and Regulations

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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 HOMELAND SECURITY

U.S. Customs and Border Protection

8 CFR Parts 103, 212, 214, and 274a

[CBP Dec. 22–10]

RIN 1651–AB42

Conforming Amendments Related to Temporary Entry of Business Persons Under the Agreement Between the United States of America, the United Mexican States, and Canada (USMCA)

AGENCY: U.S. Customs and Border Protection, DHS.

ACTION: Final rule.

SUMMARY: This final rule amends the Department of Homeland Security (DHS) regulations relating to the temporary entry of Canadian and Mexican citizen business persons into the United States by replacing references to the North American Free Trade Agreement (NAFTA) with references to the Agreement Between the United States of America, the United Mexican States, and Canada (USMCA). The USMCA superseded NAFTA and its related provisions on July 1, 2020. Chapter 16 of the USMCA generally maintains the same treatment as provided under NAFTA with respect to the temporary entry of Canadian and Mexican citizen business persons, so substantive changes to the regulations are not needed. This document simply updates the relevant regulations to replace all references to NAFTA, including references to its appendices and annexes, with the corresponding USMCA references. This document also makes other minor, non-substantive conforming amendments and stylistic changes and corrects typographical errors.

DATES: This final rule is effective on July 11, 2022.

FOR FURTHER INFORMATION CONTACT: Paul Minton, CBP Officer (Program Manager), Office of Field Operations, U.S. Customs and Border Protection, (202) 344–1581 or *Paul.A.Minton@cbp.dhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On November 30, 2018, the Office of the United States Trade Representative (USTR) signed the ''Protocol Replacing the North American Free Trade Agreement with the Agreement Between the United States of America, the United Mexican States, and Canada'' (the Protocol) to replace the North American Free Trade Agreement (NAFTA).[1] The Agreement Between the United States of America, the United Mexican States (Mexico), and Canada (the USMCA)[2] is attached as an annex to the Protocol and was subsequently amended to reflect certain modifications and technical corrections in the ''Protocol of Amendment to the Agreement Between the United States of America, the United Mexican States, and Canada'' (the Amended Protocol), which USTR signed on December 10, 2019.

A. The USMCA and Its Effect on NAFTA

Pursuant to section 106 of the Bipartisan Congressional Trade Priorities and Accountability Act of 2015 (19 U.S.C. 4205) and section 151 of the Trade Act of 1974 (19 U.S.C. 2191), the United States adopted the USMCA through Congress' enactment of the United States-Mexico-Canada Agreement Implementation Act (USMCA Implementation Act), Public Law 116–113, 134 Stat. 11 (19 U.S.C. Chapter 29), on January 29, 2020. Section 103(a)(1)(B) of the USMCA Implementation Act (19 U.S.C. 4513(b)(1)) provides authority for new or amended regulations to be issued as necessary or appropriate to implement the USMCA.

Mexico, Canada, and the United States certified their preparedness to implement the USMCA on December 12, 2019, March 13, 2020, and April 24, 2020, respectively. Pursuant to paragraph 2 of the Protocol, the USMCA was to take effect on the first day of the third month after the last signatory party provides written notification of the completion of the domestic implementation of the USMCA through the enactment of implementing legislation. As a result, the USMCA entered into force on July 1, 2020.

On its entry into force date, the USMCA superseded NAFTA and its related provisions. *See* Protocol, paragraph 1. NAFTA entered into force on January 1, 1994. Pursuant to section 1103 of the Omnibus Trade and Competitiveness Act of 1988 (19 U.S.C. 2903) and section 151 of the Trade Act of 1974 (19 U.S.C. 2191), the United States adopted NAFTA through the enactment of the North American Free Trade Agreement Implementation Act (NAFTA Implementation Act), Public Law. 103–182, 107 Stat. 2057 (19 U.S.C. 3301 *et seq.*), on December 8, 1993. Section 601 of the USMCA Implementation Act repealed the NAFTA Implementation Act, as of the date that the USMCA entered into force. *See* 19 U.S.C. 3301.

B. The Temporary Entry of Canadian and Mexican Citizen Business Persons

On December 30, 1993, the legacy Immigration and Naturalization Service (INS)[3] published an interim rule in the **Federal Register** (58 FR 69205) to implement the provisions of NAFTA by amending its regulations to establish procedures for the temporary entry of Canadian and Mexican citizen business persons into the United States. On January 9, 1998, the final rule was published in the **Federal Register** (63 FR 1331).

Chapter 16 of the USMCA sets forth the provisions for the temporary entry of Canadian and Mexican business persons. As stated in its Statement of Administrative Action, the USMCA maintains the same treatment as provided under NAFTA for the temporary entry of business visitors, traders and investors, intra-corporate transferees, and professionals.[4] Further,

[1] Protocol Replacing the North American Free Trade Agreement with the Agreement Between the United States of America, the United Mexican States, and Canada, available at *https://ustr.gov/sites/default/files/files/agreements/FTA/USMCA/Text/USMCA_Protocol.pdf* (last visited Apr. 19, 2022).

[2] The Agreement Between the United States of America, the United Mexican States, and Canada is the official name of the USMCA treaty. Please be aware that, in other contexts, the same document is also referred to as the United States-Mexico-Canada Agreement.

[3] The Homeland Security Act of 2002, Public Law 207–296, 116 Stat. 2135, as amended, transferred the responsibilities of the INS to the Department of Homeland Security (DHS).

[4] Statement of Administrative Action, available at *https://www.finance.senate.gov/imo/media/doc/*

Continued

Section 503 of the USMCA Implementation Act, Public Law 116–113, 134 Stat. 11, makes conforming changes to the NAFTA-specific provisions of the Immigration and Nationality Act, 8 U.S.C. 1101 *et seq.,* in order to provide the same treatment to Canada and Mexico with respect to temporary entry as was provided under NAFTA. The USMCA does not modify or expand access to visas issued or visa classifications authorized under the INA.

II. Discussion of Amendments to Regulations

This document makes conforming amendments to title 8 of the Code of Federal Regulations (CFR) in order to reflect statutory changes made in section 503 of the USMCA Implementation Act. As the immigration-related provisions of the USMCA are substantially similar to those contained within NAFTA, substantive amendments to the regulations are not required. References to NAFTA's immigration-related provisions are currently found in 8 CFR 103.7(d)(11), 212.1(l), 214.1(a)(2), 214.2(b)(4), 214.2(e)(22)(i), 214.2(l)(17), 214.6, and 274a.12(b)(19). Specific changes to 8 CFR are as follows:

In 8 CFR 103.7(d)(11), 212.1(l), 214.1(a)(2), 214.2(e)(22)(i), 214.2(l)(17), and 274a.12(b)(19), references to NAFTA are replaced with the corresponding references to the USMCA.

Similarly, in 8 CFR 214.2(b)(4), references to NAFTA, including references to its appendices and annexes, are replaced with the corresponding references to the USMCA. The word ''existing'' is removed from the first sentence in the introductory paragraph of § 214.2(b)(4), along with the entire second sentence of the introductory paragraph of § 214.2(b)(4), which referenced ''existing requirements.'' These sentences in the introductory paragraph of § 214.2(b)(4) are being amended because NAFTA Appendix 1603.A.3 (Existing Immigration Measures) and the definition of ''existing'' in NAFTA Annex 1608 do not appear in USMCA Chapter 16. The third sentence in the introductory paragraph of § 214.2(b)(4) is being removed because it is redundant with 8 CFR 214.2(b)(4)(ii). Additionally, ''existing'' is removed from § 214.2(b)(4)(ii) to conform with the introductory paragraph and the USMCA. Other amendments include minor wording, punctuation, and stylistic changes to bring the regulations in line with the text of the USMCA, as well as corrections of typographical errors. Additionally, under NAFTA, occupations in the fields of commercial transactions, public relations and advertising, tourism, tour bus operation, and translation were all grouped together under the heading entitled, ''General Service''. The USMCA moved those occupations and changed them into separate categories. To reflect this organizational change in the regulations, paragraphs (b)(4)(i)(G)(*2*) though (*7*) are removed from under the ''General Service'' heading and are set out in paragraphs (b)(4)(i)(H) through (L). Lastly, language is added to clarify the cross-reference in paragraph (b)(4)(ii).

In 8 CFR 214.6, references to NAFTA, including references to its appendices and annexes, are replaced with the corresponding references to the USMCA. Other changes include minor wording, punctuation, formatting, and stylistic changes to bring the regulations in line with the text of the USMCA, as well to correct typographical errors.

III. Statutory and Regulatory Requirements

A. Administrative Procedure Act

Under section 553 of the Administrative Procedure Act (APA) (5 U.S.C. 553), agencies generally are required to publish a notice of proposed rulemaking in the **Federal Register** that solicits public comment on the proposed regulatory amendments, consider public comments in deciding on the content of the final amendments, and publish the final amendments at least 30 days prior to their effective date. This rule is exempt from APA rulemaking requirements pursuant to 5 U.S.C. 553(a)(1) as a foreign affairs function of the United States because it is amending U.S. domestic regulations to conform to the immigration-related provisions of the USMCA, which is an international agreement negotiated between the United States, Mexico, and Canada.

CBP also has determined that there is good cause pursuant to 5 U.S.C. 553(b)(B) to publish this rule without prior public notice and comment procedures. This rule simply makes conforming amendments to existing DHS regulations to reflect the statutory changes made by section 503 of the USMCA Implementation Act, Public Law 116–113, 134 Stat. 11. Specifically, this rule replaces references to NAFTA with the USMCA, along with other minor, non-substantive stylistic changes. Chapter 16 of the USMCA provides the same treatment to Canada and Mexico regarding temporary entry that NAFTA provided. As a result, prior public notice and comment procedures for this rule are impracticable, unnecessary, and contrary to the public interest.

For the same reasons, a delayed effective date is not required under 5 U.S.C. 553(d)(3). The USMCA entered into force on July 1, 2020. A delayed effective date would be impractical, unnecessary, and contrary to the public interest.

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

Rules involving the foreign affairs function of the United States are exempt from the requirements of Executive Orders 12866 and 13563. Because this rule involves a foreign affairs function of the United States by implementing a specific trilateral agreement negotiated between the United States, Mexico, and Canada, the rule is not subject to the provisions of Executive Orders 12866 and 13563.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), as amended by the Small Business Regulatory Enforcement and Fairness Act of 1996, requires an agency to prepare and make available to the public a regulatory flexibility analysis that describes the effect of a proposed rule on small entities (*i.e.,* small businesses, small organizations, and small governmental jurisdictions) when the agency is required to publish a general notice of proposed rulemaking for a rule. Because this document is not subject to the notice and public procedure requirements of 5 U.S.C. 553, it is not subject to the provisions of the Regulatory Flexibility Act.

D. Paperwork Reduction Act

As there is no new collection of information required in this document, the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507) are inapplicable.

FINAL%20SAA%20USMCA.pdf (last visited Apr. 19, 2022).

List of Subjects

8 CFR Part 103

Administrative practice and procedure, Authority delegations (Government agencies), Fees, Freedom of information, Immigration, Privacy, Reporting and recordkeeping requirements, Surety bonds.

8 CFR Part 212

Administrative practice and procedure, Aliens, Immigration, Passports and visas, Reporting and recordkeeping requirements.

8 CFR Part 214

Administrative practice and procedure, Aliens, Cultural exchange program, Employment, Foreign officials, Health professions, Reporting and recordkeeping requirements, Students.

8 CFR Part 274a

Administrative practice and procedure, Aliens, Cultural exchange program, Employment, Penalties, Reporting and recordkeeping requirements, Students.

Amendments to the DHS Regulations

For the reasons stated above in the preamble, DHS amends parts 103, 212, 214, and 274a of title 8 of the Code of Federal Regulations (8 CFR parts 103, 212, 214, and 274a) as set forth below:

PART 103—IMMIGRATION BENEFIT REQUESTS; USCIS FILING REQUIREMENTS; BIOMETRIC REQUIREMENTS; AVAILABILITY OF RECORDS

■ 1. The authority citation for part 103 continues to read as follows:

Authority: 5 U.S.C. 301, 552, 552a; 8 U.S.C. 1101, 1103, 1304, 1356, 1365b; 31 U.S.C. 9701; Pub. L. 107–296, 116 Stat. 2135 (6 U.S.C. 1 *et seq.*); E.O. 12356, 47 FR 14874, 15557; 3 CFR, 1982 Comp., p. 166; 8 CFR part 2; Pub. L. 112–54; 125 Stat. 550; 31 CFR part 223.

§ 103.7 [Amended]

■ 2. Amend § 103.7, in paragraph (d)(11), by removing the words ''North American Free Trade Agreement'' and adding in their place the words ''Agreement Between the United States of America, the United Mexican States, and Canada (USMCA)''.

PART 212—DOCUMENTARY REQUIREMENTS: NONIMMIGRANTS; WAIVERS; ADMISSION OF CERTAIN INADMISSIBLE ALIENS; PAROLE

■ 3. The general authority citation for part 212 continues to read as follows:

Authority: 6 U.S.C. 111, 202(4) and 271; 8 U.S.C. 1101 and note, 1102, 1103, 1182 and note, 1184, 1187, 1223, 1225, 1226, 1227, 1255, 1359; section 7209 of Pub. L. 108–458 (8 U.S.C. 1185 note); Title VII of Pub. L. 110–229 (8 U.S.C. 1185 note); 8 CFR part 2; Pub. L. 115–218.

* * * * *

§ 212.1 [Amended]

■ 4. Amend § 212.1, in paragraph (l), by removing the words ''North American Free Trade Agreement (NAFTA)'' and adding, in their place, the words ''Agreement Between the United States of America, the United Mexican States, and Canada (USMCA)''.

PART 214—NONIMMIGRANT CLASSES

■ 5. The authority citation for part 214 continues to read as follows:

Authority: 6 U.S.C. 202, 236; 8 U.S.C. 1101, 1102, 1103, 1182, 1184, 1186a, 1187, 1221, 1281, 1282, 1301–1305, 1357, and 1372; sec. 643, Pub. L. 104–208, 110 Stat. 3009–708; Pub. L. 106–386, 114 Stat. 1477–1480; section 141 of the Compacts of Free Association with the Federated States of Micronesia and the Republic of the Marshall Islands, and with the Government of Palau, 48 U.S.C. 1901 note and 1931 note, respectively; 48 U.S.C. 1806; 8 CFR part 2; Pub. L. 115–218, 132 Stat. 1547 (48 U.S.C. 1806).

■ 6. Amend § 214.1, in the table in paragraph (a)(2), by removing the entries for ''NAFTA, Principal'' and ''NAFTA, Dependent'' and adding entries for ''USMCA, Principal'' and ''USMCA, Dependent'' in their places to read as follows:

§ 214.1 Requirements for admission, extension, and maintenance of status.

(a) * * *

(2) * * *

Section	Designation
* * *	* *
USMCA, Principal	TN.
USMCA, Dependent	TD.
* * *	* *

* * * * *

■ 7. Amend § 214.2 as follows:

■ a. Revise paragraph (b)(4);

■ b. In paragraph (e)(22)(i) introductory text, remove the words ''section B of Annex 1603 of the NAFTA'' and add in their place the words ''Section B of Annex 16–A of Chapter 16 of the USMCA''; and

■ c. In the heading to paragraph (l)(17), remove the words ''North American Free Trade Agreement (NAFTA)'' and add in their place the words ''Agreement Between the United States of America, the United Mexican States, and Canada (USMCA)''.

The revision reads as follows:

§ 214.2 Special requirements for admission, extension, and maintenance of status.

* * * * *

(b) * * *

(4) *Admission of aliens pursuant to the Agreement Between the United States of America, the United Mexican States, and Canada (USMCA).* A citizen of Canada or Mexico seeking temporary entry for purposes set forth in paragraph (b)(4)(i) of this section, who otherwise meets the requirements under section 101(a)(15)(B) of the Act, including but not limited to requirements regarding the source of remuneration, shall be admitted upon presentation of proof of such citizenship in the case of Canadian applicants, and valid, unexpired entry documents such as a passport and visa, or a passport and BCC in the case of Mexican applicants, a description of the purpose for which the alien is seeking admission, and evidence demonstrating that he or she is engaged in one of the occupations or professions set forth in paragraph (b)(4)(i) of this section.

(i) *Occupations and professions set forth in Section B of Appendix 1 of Chapter 16 of the USMCA*—(A) *Research and design.* Technical, scientific and statistical researchers conducting independent research or research for an enterprise located in the territory of another Party.

(B) *Growth, manufacture, and production.* (*1*) Harvester owner supervising a harvesting crew admitted under applicable law. (Applies only to harvesting of agricultural crops: Grain, fiber, fruit and vegetables.)

(*2*) Purchasing and production management personnel conducting commercial transactions for an enterprise located in the territory of another Party.

(C) *Marketing.* (*1*) Market researchers and analysts conducting independent research or analysis, or research or analysis for an enterprise located in the territory of another Party.

(*2*) Trade fair and promotional personnel attending a trade convention.

(D) *Sales.* (*1*) Sales representatives and agents taking orders or negotiating contracts for goods or services for an enterprise located in the territory of another Party but not delivering goods or supplying services.

(*2*) Buyers purchasing for an enterprise located in the territory of another Party.

(E) *Distribution.* (*1*) Transportation operators transporting goods or passengers to the United States from the

territory of another Party or loading and transporting goods or passengers from the United States, with no unloading in the United States, to the territory of another Party. (These operators may make deliveries in the United States if all goods or passengers to be delivered were loaded in the territory of another Party. Furthermore, they may load from locations in the United States if all goods or passengers to be loaded will be delivered in the territory of another Party. Purely domestic service or solicitation, in competition with the United States operators, is not permitted.)

(*2*) Customs brokers performing brokerage duties associated with the export of goods from the United States to or through Canada.

(F) *After-sales services.* Installers, repair and maintenance personnel, and supervisors, possessing specialized knowledge essential to the seller's contractual obligation, performing services or training workers to perform services, pursuant to a warranty or other service contract incidental to the sale of commercial or industrial equipment or machinery, including computer software, purchased from an enterprise located outside the United States, during the life of the warranty or service agreement. (For the purposes of this provision, the commercial or industrial equipment or machinery, including computer software, must have been manufactured outside the United States.)

(G) *General service.* Professionals engaging in a business activity at a professional level in a profession set out in Appendix 2 to Annex 16–A of Chapter 16 of the USMCA, but receiving no salary or other remuneration from a United States source (other than an expense allowance or other reimbursement for expenses incidental to the temporary stay) and otherwise satisfying the requirements of Section A to Annex 16–A of the USMCA.

(H) *Commercial transactions.* (*1*) Management and supervisory personnel engaging in commercial transactions for an enterprise located in the territory of another Party.

(*2*) Financial services personnel (insurers, bankers or investment brokers) engaging in commercial transactions for an enterprise located in the territory of another Party.

(I) *Public relations and advertising.* Public relations and advertising personnel consulting with business associates, or attending or participating in conventions.

(J) *Tourism.* Tourism personnel (tour and travel agents, tour guides or tour operators) attending or participating in conventions or conducting a tour that has begun in the territory of another Party. (The tour may begin in the United States; but must terminate in foreign territory, and a significant portion of the tour must be conducted in foreign territory. In such a case, an operator may enter the United States with an empty conveyance and a tour guide may enter on his or her own and join the conveyance.)

(K) *Tour bus operation.* Tour bus operators entering the United States:

(*1*) With a group of passengers on a bus tour that has begun in, and will return to, the territory of another Party.

(*2*) To meet a group of passengers on a bus tour that will end, and the predominant portion of which will take place, in the territory of another Party.

(*3*) With a group of passengers on a bus tour to be unloaded in the United States and returning with no passengers or reloading with the group for transportation to the territory of another Party.

(L) *Translation.* Translators or interpreters performing services as employees of an enterprise located in the territory of another Party.

(ii) *Occupations and professions not listed in Section B of Appendix 1 of Chapter 16 of the USMCA.* Nothing in paragraph (b)(4) of this section shall preclude a business person engaged in an occupation or profession other than those listed in Section B of Appendix 1 of Chapter 16 of the USMCA from temporary entry under section 101(a)(15)(B) of the Act, if such person otherwise meets the requirements for admission as prescribed by the Attorney General.

* * * * *

■ 8. Amend § 214.6 as follows:

■ a. Revise the section heading;

■ b. In paragraph (a), remove the words ''North American Free Trade Agreement (NAFTA)'' and add in their place the words ''Agreement Between the United States of America, the United Mexican States, and Canada (USMCA)'';

■ c. In paragraph (b):

■ i. In the definition for *Business activities at a professional level,* remove the words ''Appendix 1603.D.1 of the NAFTA'' and add, in their place, the words ''Appendix 2 to Annex 16–A of Chapter 16 of the USMCA'';

■ ii. In the definition for *Business person,* remove ''NAFTA'' and add in its place ''USMCA'';

■ iii. In the definition for *Business person,* remove the word ''provision'' and add in its place the word ''supply'';

■ iv. In the definition for *Temporary entry,* remove ''NAFTA'' and add in its place ''USMCA'';

■ d. Revise paragraph (c);

■ e. In the heading of paragraph (d), remove the word ''NAFTA'' and add in its place the word ''USMCA'';

■ f. In paragraph (d)(1), remove ''NAFTA'' and add in its place ''USMCA'';

■ g. In paragraph (d)(3)(ii)(A), remove the words ''Appendix 1603.D.1'' and add the words ''under Appendix 2 to Annex 16–A of Chapter 16 of the USMCA'' after the word ''applicant'';

■ h. In paragraph (d)(3)(ii)(D), add a closing parenthesis after ''(D'';

■ i. In paragraph (e), remove ''NAFTA'' and add in its place, ''USMCA''; and

■ j. In paragraph (i)(2), remove ''NAFTA'' and add in its place ''USMCA''.

The revision reads as follows:

§ 214.6 Citizens of Canada or Mexico seeking temporary entry under USMCA to engage in business activities at a professional level.

* * * * *

(c) *Appendix 2 to Annex 16–A of Chapter 16 of the USMCA.* Pursuant to the USMCA, an applicant seeking admission under this section shall demonstrate business activity at a professional level in one of the professions set forth in Appendix 2 to Annex 16–A of Chapter 16. The professions in Appendix 2 to Annex 16–A and the minimum requirements for qualification for each are as follows: [1]

Appendix 2 to Annex 16–A of Chapter 16 (Annotated)

General

—Accountant—Baccalaureate or Licenciatura Degree; or C.P.A., C.A., C.G.A., or C.M.A.

—Architect—Baccalaureate or Licenciatura Degree; or state/provincial license.[2]

—Computer Systems Analyst—Baccalaureate or Licenciatura Degree; or Post-Secondary Diploma [3] or Post-Secondary Certificate,[4] and three years experience.

—Disaster Relief Insurance Claims Adjuster (claims adjuster employed by an insurance

[1] A business person seeking temporary employment under this Appendix may also perform training functions relating to the profession, including conducting seminars.

[2] The terms ''state/provincial license'' and ''state/provincial/federal license'' mean any document issued by a state, provincial, or federal government, as the case may be, or under its authority, but not by a local government, that permits a person to engage in a regulated activity or profession.

[3] ''Post-Secondary Diploma'' means a credential issued, on completion of two or more years of postsecondary education, by an accredited academic institution in Canada or the United States.

[4] ''Post-Secondary Certificate'' means a certificate issued, on completion of two or more years of postsecondary education at an academic institution, by the federal government of Mexico or a state government in Mexico, an academic institution recognized by the federal government or a state government, or an academic institution created by federal or state law.

company located in the territory of a Party, or an independent claims adjuster)—Baccalaureate or Licenciatura Degree, and successful completion of training in the appropriate areas of insurance adjustment pertaining to disaster relief claims; or three years experience in claims adjustment and successful completion of training in the appropriate areas of insurance adjustment pertaining to disaster relief claims.

—Economist—Baccalaureate or Licenciatura Degree.

—Engineer—Baccalaureate or Licenciatura Degree; or state/provincial license.

—Forester—Baccalaureate or Licenciatura Degree; or state/provincial license.

—Graphic Designer—Baccalaureate or Licenciatura Degree; or Post-Secondary Diploma or Post-Secondary Certificate, and three years experience.

—Hotel Manager—Baccalaureate or Licenciatura Degree in hotel/restaurant management; or Post-Secondary Diploma or Post-Secondary Certificate in hotel/restaurant management, and three years experience in hotel/restaurant management.

—Industrial Designer—Baccalaureate or Licenciatura Degree; or Post-Secondary Diploma or Post-Secondary Certificate, and three years experience.

—Interior Designer—Baccalaureate or Licenciatura Degree; or Post-Secondary Diploma or Post-Secondary Certificate, and three years experience.

—Land Surveyor—Baccalaureate or Licenciatura Degree; or state/provincial/federal license.

—Landscape Architect—Baccalaureate or Licenciatura Degree.

—Lawyer (including Notary in the province of Quebec)—L.L.B., J.D., L.L.L., B.C.L., or Licenciatura Degree (five years); or membership in a state/provincial bar.

—Librarian—M.L.S. or B.L.S. (for which another Baccalaureate or Licenciatura Degree was a prerequisite).

—Management Consultant—Baccalaureate or Licenciatura Degree; or equivalent professional experience as established by statement or professional credential attesting to five years experience as a management consultant, or five years experience in a field of specialty related to the consulting agreement.

—Mathematician (including Statistician)—Baccalaureate or Licenciatura Degree.[5]

—Range Manager/Range Conservationist—Baccalaureate or Licenciatura Degree.

—Research Assistant (working in a post-secondary educational institution)—Baccalaureate or Licenciatura Degree.

—Scientific Technician/Technologist[6]—Possession of (a) theoretical knowledge of any of the following disciplines: agricultural sciences, astronomy, biology, chemistry, engineering, forestry, geology, geophysics, meteorology, or physics; and (b) the ability to solve practical problems in any of those disciplines, or the ability to apply principles of any of those disciplines to basic or applied research.

—Social Worker—Baccalaureate or Licenciatura Degree.

—Sylviculturist (including Forestry Specialist)—Baccalaureate or Licenciatura Degree.

—Technical Publications Writer—Baccalaureate or Licenciatura Degree; or Post-Secondary Diploma or Post-Secondary Certificate, and three years experience.

—Urban Planner (including Geographer)—Baccalaureate or Licenciatura Degree.

—Vocational Counselor—Baccalaureate or Licenciatura Degree.

Medical/Allied Professionals

—Dentist—D.D.S., D.M.D., Doctor en Odontologia or Doctor en Cirugia Dental; or state/provincial license.

—Dietitian—Baccalaureate or Licenciatura Degree; or state/provincial license.

—Medical Laboratory Technologist (Canada)/Medical Technologist (Mexico and the United States)[7]—Baccalaureate or Licenciatura Degree; or Post-Secondary Diploma or Post-Secondary Certificate, and three years experience.

—Nutritionist—Baccalaureate or Licenciatura Degree.

—Occupational Therapist—Baccalaureate or Licenciatura Degree; or state/provincial license.

—Pharmacist—Baccalaureate or Licenciatura Degree; or state/provincial license.

—Physician (teaching or research only)—M.D. or Doctor en Medicina; or state/provincial license.

—Physiotherapist/Physical Therapist—Baccalaureate or Licenciatura Degree; or state/provincial license.

—Psychologist—State/provincial license; or Licenciatura Degree.

—Recreational Therapist—Baccalaureate or Licenciatura Degree.

—Registered Nurse—State/provincial license; or Licenciatura Degree.

—Veterinarian—D.V.M., D.M.V., or Doctor en Veterinaria; or state/provincial license.

Scientist

—Agriculturist (including Agronomist)—Baccalaureate or Licenciatura Degree.

—Animal Breeder—Baccalaureate or Licenciatura Degree.

—Animal Scientist—Baccalaureate or Licenciatura Degree.

—Apiculturist—Baccalaureate or Licenciatura Degree.

—Astronomer—Baccalaureate or Licenciatura Degree.

—Biochemist—Baccalaureate or Licenciatura Degree.

—Biologist—Baccalaureate or Licenciatura Degree.[8]

—Chemist—Baccalaureate or Licenciatura Degree.

—Dairy Scientist—Baccalaureate or Licenciatura Degree.

—Entomologist—Baccalaureate or Licenciatura Degree.

—Epidemiologist—Baccalaureate or Licenciatura Degree.

—Geneticist—Baccalaureate or Licenciatura Degree.

—Geochemist—Baccalaureate or Licenciatura Degree.

—Geologist—Baccalaureate or Licenciatura Degree.

—Geophysicist (including Oceanographer in Mexico and the United States)—Baccalaureate or Licenciatura Degree.

—Horticulturist—Baccalaureate or Licenciatura Degree.

—Meteorologist—Baccalaureate or Licenciatura Degree.

—Pharmacologist—Baccalaureate or Licenciatura Degree.

—Physicist (including Oceanographer in Canada)—Baccalaureate or Licenciatura Degree.

—Plant Breeder—Baccalaureate or Licenciatura Degree.

—Poultry Scientist—Baccalaureate or Licenciatura Degree.

—Soil Scientist—Baccalaureate or Licenciatura Degree.

—Zoologist—Baccalaureate or Licenciatura Degree.

Teacher

—College—Baccalaureate or Licenciatura Degree.

—Seminary—Baccalaureate or Licenciatura Degree.

—University—Baccalaureate or Licenciatura Degree.

* * * * *

PART 274a—CONTROL OF EMPLOYMENT OF ALIENS

■ 9. The authority citation for part 274a continues to read as follows:

Authority: 8 U.S.C. 1101, 1103, 1105a, 1324a; 48 U.S.C. 1806; 8 CFR part 2; Pub. L. 101–410, 104 Stat. 890, as amended by Pub. L. 114–74, 129 Stat. 599.

§ 274a.12 [Amended]

■ 10. Amend § 274a.12, in paragraph (b)(19), by removing the words ''North American Free Trade Agreement (NAFTA)'' and adding in their place the words ''Agreement Between the United States of America, the United Mexican States, and Canada (USMCA)''.

Alejandro N. Mayorkas,

Secretary, U.S. Department of Homeland Security.

[FR Doc. 2022–14728 Filed 7–8–22; 8:45 am]

BILLING CODE 9111–14–P

[5] The term ''Mathematician'' includes the profession of Actuary. An Actuary must satisfy the necessary requirements to be recognized as an actuary by a professional actuarial association or society. A professional actuarial association or society means a professional actuarial association or society operating in the territory of at least one of the Parties.

[6] A business person in this category must be seeking temporary entry for work in direct support of professionals in agricultural sciences, astronomy, biology, chemistry, engineering, forestry, geology, geophysics, meteorology or physics.

[7] A business person in this category must be seeking temporary entry to perform in a laboratory, chemical, biological, hematological, immunologic, microscopic or bacteriological tests and analyses for diagnosis, treatment, or prevention of diseases.

[8] The term ''Biologist'' includes the profession of Plant Pathologist.

EXPORT-IMPORT BANK

12 CFR Part 404

[Docket No. EIB–2022–0004]

Freedom of Information Act Requirements

AGENCY: Export-Import Bank of the United States.

ACTION: Final rule.

SUMMARY: The Export-Import Bank of the United States (EXIM) is publishing revised regulations under the Freedom of Information Act (FOIA). The revisions incorporate amendments to the FOIA under the FOIA Improvement Act of 2016, developments in case law, and changes in Federal and EXIM policies. The revisions also clarify procedural requirements.

DATES: This rule is effective August 10, 2022.

FOR FURTHER INFORMATION CONTACT: Chief Freedom Information Act Officer Lisa Terry at *lisa.terry@exim.gov;* (202) 565–3290.

SUPPLEMENTARY INFORMATION:

I. Background

EXIM has revised its regulations under the FOIA, 5 U.S.C. 552. The revisions incorporate changes in law under the FOIA Improvement Act of 2016, developments in case law, and changes in Federal and EXIM policies. While incorporating these changes, EXIM has also sought to simplify and clarify its regulations. The final rule replaces EXIM's current FOIA regulations in their entirety (12 CFR 404.1 through 404.11).

II. Discussion

The numbered paragraphs immediately below provide an overview of the changes to the regulations. At the conclusion of this preamble, the new regulations are set forth in their entirety.

1. *Amended:* Authority.

The authority citation for part 404 is amended to include additional cites to EXIM's statutory charter (12 U.S.C. 635(a)(1)) and the rulemaking provisions of the Administrative Procedures Act (5 U.S.C. 553). Citations to executive orders imposing administrative requirements on EXIM are removed. The amended general authority is 12 U.S.C. 635(a)(1); 5 U.S.C. 552, 5 U.S.C. 552(a), 5 U.S.C. 553.

2. Redesignation of §§ 404.12 through 404.23.

Old section	New section
404.12	404.14
404.13	404.15
404.14	404.16
404.15	404.17
404.16	404.18
404.17	404.19
404.18	404.20
404.19	404.21
404.20	404.22
404.21	404.23
404.22	404.24
404.23	404.25

3. Redesignation of §§ 404.24 through 404.36.

Old section	New section
404.24	404.26
404.25	404.27
404.26	404.28
404.27	404.29
404.28	404.30
404.29	404.31
404.30	404.32
404.31	404.33
404.32	404.34
404.33	404.35
404.34	404.36
404.35	404.37

4. *Amended:* § 404.1, General provisions.

This section is amended to clarify the purpose and scope of the FOIA regulations and to remove the current paragraph (b) setting forth EXIM policy. EXIM policy complies with the FOIA and related guidance, as set forth in the remainder of the regulations, and the current (un-amended) paragraph (b) is either duplicative or could cause confusion.

Current paragraphs (d) and (e) describe EXIM's proactive disclosures and provide EXIM's internet address and mailing address. This information is amended and moved to §§ 404.2, Proactive disclosures, and 404.3, Request requirements.

5. *Removed:* Current § 404.2, Definitions.

This section is eliminated, with most of the definitions relocated to the sections in which the defined terms are used. The majority of the relocated definitions pertain to current § 404.16, Schedule of fees. The definitions of ''Confidential business information'' and ''Submitter'' are relocated to the section currently labelled ''Confidential business information.'' The regulations change the phrase ''confidential business information'' to ''confidential commercial information'' for greater consistency with the statutory language, related case law, and applicable guidance. ''Working days'' was relocated to the section addressing time for processing, previously at § 404.5.

Several other definitions are eliminated as unnecessary due to their being common usage, duplicative of information contained elsewhere, or otherwise sufficiently clear in meaning from the context in which they were used. These terms are eliminated for purposes of brevity and clarity. This includes the definitions of ''appeal,'' ''final determination,'' ''initial determination,'' ''person,'' ''redaction,'' ''request,'' and ''requester.''

The current definition of ''trade secrets'' is eliminated as legally incorrect.

6. *Amended:* § 404.2, Proactive disclosures.

This section is renumbered from current § 404.3 to § 404.2 and renamed ''Proactive disclosures.'' The current wording describes procedures for accessing a physical reading room at EXIM's headquarters, while the revision includes the online reading room now required by the FOIA. The amended section also states that EXIM's FOIA Liaison is available to help requesters locate information online. In addition, the amended section newly describes the data that EXIM posts at *data.exim.gov* on EXIM's transactions.

7. *Amended:* § 404.3, Request requirements.

This section is renumbered from current § 404.4 to § 404.3. This section encourages potential requesters to review the information publicly available on the EXIM website before submitting a request. EXIM believes it is in requesters' best interest to review the significant amount of information available online before submitting a request.

This section also states the electronic means for submitting a request, including by email to *foia@exim.gov,* through the online portal at *www.exim.gov/about/foia* or in the alternative, to the national request portal at *https://www/foia.gov.* The current requirement that requesters sign their request was eliminated as inconsistent with the FOIA and EXIM's past practice of accepting unsigned electronic submissions. Requesters would instead need to provide contact information.

The current statement that a general request to pay applicable fees is deemed a request to pay up to $50.00 was eliminated. This statement is viewed as potentially inconsistent with the Office of Management and Budget's (OMB's) FOIA Fee Guidelines, which requires agencies to notify requesters of fees exceeding $25.00.

This section also clarifies and updates the language that sets forth the process for obtaining records by the requester (or a third party), and the need for a request to provide an adequate

description of the records. The section also provides for FOIA Public Liaison assistance in reformulating a request.

8. *Added:* § 404.5, Responsibility for responding to requests.

This newly added section provides the Freedom of Information and Privacy Office the authority to respond to requests, establish a ''cut off'' date for searches at the time the search is conducted, address classified information, and describe EXIM's procedures for working with other agencies in the processing of requests—including through consultations, referrals, and other types of coordination.

9. *Amended:* § 404.6, Time for processing.

This section is renumbered from current § 404.5 to § 404.6. It newly incorporates the statutory definition of ''unusual circumstances'' and ''working days.'' This section also provides for multitrack processing, with the following tracks: expedited, simple, and complex. This section also seeks to clarify the current language and add additional detail to the expedited processing provisions.

10. *Amended:* § 404.7, Release of records.

This section is renumbered from current § 404.6 to § 404.7 and renamed. It includes the foreseeable harm requirement for discretionary exemptions, added by the FOIA Improvement Act of 2016.

The current paragraph (a), addressing the ''creation of records,'' was eliminated as both inconsistent with the FOIA and unnecessary. Even though this subsection is eliminated, EXIM would retain the authority to create appropriate records.

As indicated in this section, the current paragraph (d) addressing the ''cut off'' date for searches is amended and relocated to § 404.5.

11. *Amended:* § 404.8, Responses to requests.

Section 404.8, Initial determination, is renamed for purposes of clarity and greater consistency with other agency FOIA regulations. The section also newly provides for communication with requesters by email and EXIM's online portal, newly provides for the acknowledgement of requests, and more fully describe EXIM obligations when there is either a full grant of the requested records or an adverse determination of some kind. This section also newly addresses FOIA exclusions under 5 U.S.C. 552(c).

As required by the FOIA Improvement Act of 2016, this section requires EXIM to notify requesters of the services provided by the Office of Government Information Services (OGIS).

12. *Amended:* § 404.9, Confidential commercial information.

This section is renumbered from current § 404.7, Confidential business information, to § 404.9 and renamed. The title ''confidential business information'' is changed to ''confidential commercial information'' to better match the wording of the requirements in Exemption 4, case law, related guidance, and other agency FOIA regulations. The protections and procedures remain the same and are in accordance with Executive Order 12600, but the amendments here seek to provide additional detail and clarity for requesters based on the legal standards applicable under Exemption 4.

13. *Amended:* § 404.10, Schedule of fees.

This section is renumbered from current § 404.9 to § 404.10. As referenced above, this section newly incorporates amended versions of the definitions that are currently located in a general definitions section at § 404.2. The amended language also updates and provides additional detail on EXIM's fee practices, consistent with OMB's Fee Guidelines.

The rate for clerical search and review time are increased from $16.00/hour to $33.00/hour. The rate for professional search and review time are increased from $32.00/hour to $57.00/hour. This reflects increased labor rates since the regulations were last updated in 1999.

Notice of anticipated fees are generally provided when the estimated fees exceed $25.00, unless a requester has already agreed to pay more or has received a waiver. This is lowered from the current $50.00 to match OMB's Fee Guidelines.

14. *Amended:* § 404.11, Fee waivers or reductions.

This section is renumbered from current § 404.10 to § 404.11. As with the prior two sections addressed above, this section is expanded to provide additional guidance and clarity for requesters. The substantive standards for seeking fee waivers are governed by the FOIA and related case law, however, and would remain unchanged. Current paragraph (e), Employee Requests, are removed because the FOIA is generally not needed for employees or applicants to obtain information related to a complaint of discrimination. Discrimination complaints are governed by procedures established by the Equal Employment Opportunity Commission and, regardless, EXIM would retain the authority to grant discretionary fee waivers and reductions.

15. *Amended:* § 404.12, Administrative appeals.

This section is renumbered from current § 404.11 to § 404.12. The changes are provided for the electronic submission of appeals and to notify appellants of the ability to seek assistance from OGIS.

16. *Amended:* § 404.13, Preservation of records.

This newly added section provides for the preservation of all correspondence associated with a request, as well as all requested records, under appropriate records schedules. It also prohibits the destruction or modification of records while they are subject to a pending request, administrative appeal, or lawsuit.

17. *Amended:* Subparts B and C.

Cross references in subparts B and C are updated to reflect section redesignations in the subparts.

Regulatory Flexibility Act Certification

When an agency issues a rulemaking proposal, the Regulatory Flexibility Act (RFA) requires the agency to ''prepare and make available for public comment an initial regulatory flexibility analysis'' which will ''describe the impact of the proposed rule on small entities.'' (5 U.S.C. 603(a)). Section 605 of the RFA allows an agency to certify a rule, in lieu of preparing an analysis, if the proposed rulemaking is not expected to have a significant economic impact on a substantial number of small entities.

The changes to EXIM's FOIA regulations are predominantly procedural in nature and many incorporate already binding law and policy. While the changes also increase the rates that EXIM uses to charge certain FOIA requesters the direct costs of responding to a request, this updated fee schedule reflects current EXIM costs and EXIM remains only able to charge its direct costs of searching for, reviewing, and duplicating the records processed for requesters. There are a number of possible exceptions and waivers that reduce the number of requesters and small entities that may be affected by the fee changes and, even when charged, these fees are typically small. When needed, EXIM is able to work with requesters to modify their request to reduce the chargeable fees while still obtaining the core information they seek.

As a result, the changes are unlikely to have an economic impact on requesters regardless of their size and resources. Accordingly, EXIM hereby certifies that these amendments to the FOIA regulations would not have a significant economic impact on a substantial number of small entities.

Executive Order 12866

This final rule is not a ''significant regulatory action'' for purposes of Executive Order 12866.

Executive Order 13771

This final rule is not a regulatory action under Section 2 of Executive Order 13771 because it is not significant under Executive Order 12866 and does not constitute a significant guidance document.

Paperwork Reduction Act

This regulation does not contain a ''collection of information'' as defined by the Paperwork Reduction Act, 44 U.S.C. 3501, *et seq.*

List of Subjects in 12 CFR Part 404

Administrative procedures, Freedom of information.

Text of Amendments

For the reasons stated in the preamble, EXIM amends 12 CFR part 404 as follows:

PART 404—INFORMATION DISCLOSURE

■ 1. The authority citation for part 404 is revised to read as follows:

Authority: 12 U.S.C. 635(a)(1); 5 U.S.C. 552, 5 U.S.C. 552(a), 5 U.S.C. 553.

Section 404.7 also issued under E.O. 12600, 52 FR 23781, 3 CFR, 1987 Comp., p. 235.

Section 404.21 also issued under 5 U.S.C. 552a note.

Subpart C also issued under 5 U.S.C. 301, 12 U.S.C. 635.

§§ 404.24 through 404.36 [Redesignated as §§ 404.26 through 404.38]

■ 2. Redesignate §§ 404.24 through 404.36 as §§ 404.26 through 404.38.

§§ 404.12 through 404.23 [Redesignated as §§ 404.14 through 404.25]

■ 3. Redesignate §§ 404.12 through 404.23 as §§ 404.14 through 404.25.

■ 4. Revise subpart A to read as follows:

Subpart A—Procedures for Disclosure of Records Under the Freedom of Information Act

Sec.

404.1 General provisions.
404.2 Proactive disclosures.
404.3 Request requirements.
404.5 Responsibility for responding to requests.
404.6 Time for processing response to requests.
404.7 Release of records.
404.8 Responses to requests.
404.9 Confidential commercial information.
404.10 Schedule of fees.
404.11 Fee waivers or reductions.
404.12 Administrative appeals.
404.13 Preservation of records.

§ 404.1 General provisions.

(a) *Purpose.* This subpart contains the rules that the Export-Import Bank of the United States (EXIM) follows in processing requests for records under the Freedom of Information Act (FOIA), 5 U.S.C. 552. This subpart should be read in conjunction with the text of the FOIA and the Uniform Freedom of Information Fee Schedule and Guidelines published by the Office of Management and Budget (OMB Guidelines).

(b) *Scope.* Requests made by individuals for records about themselves under the Privacy Act of 1974, 5 U.S.C. 552a, are processed in accordance with EXIM's Privacy Act regulations in subpart B of this part as well as under this subpart.

(c) *Delegation.* Any action or determination in this subpart which is the responsibility of a specific EXIM employee may be delegated.

§ 404.2 Proactive disclosures.

(a) Records that the FOIA requires agencies to make available for public inspection in an electronic format may be accessed through the EXIM internet site at *https://www.exim.gov/about/foia/frequently-requested-records-and-proactive-disclosures* and *https://data.exim.gov/.* EXIM is responsible for determining which records must be made publicly available, for identifying additional records of interest to the public that are appropriate for public disclosure, and for posting and indexing such records. EXIM must ensure that its website of posted records and indices is reviewed and updated on an ongoing basis. EXIM's FOIA Public Liaison can assist individuals in locating records particular to the agency. The contact information for the Public Liaison is available at *https://www.exim.gov/about/foia,* along with other FOIA resources.

(b) EXIM proactively discloses information at *data.exim.gov* on applications and transactions, whether denied or authorized, including: unique identifiers EXIM assigns; approval and declination decisions; the expiration date for a guarantee or insurance policy; whether an insurance policy was brokered or not; whether an approved transaction was cancelled after approval; the country where the credit risk is; the financing program or product that was applied for, including the type of any insurance; the primary export product; a product description; the length of financing on a deal; the principal applicant; the principal lender; the principal exporter; the city and state of the primary exporter; the company name of the principal borrower; the primary source of repayment; the amount of financing approved or declined; the amount of the loan or guarantee that has been disbursed or the amount that has been shipped on an insurance policy; the undisbursed exposure amount; the portion of the disbursed/shipped amount that has not been repaid; the portion of an approved amount that assisted a small business; the portion of an approved company that assisted a woman owned company; the portion of an approved amount that assisted a minority owned company; the interest rate being applied to a direct loan; and whether a working capital amount is pursuant to an extension of a previously approved working capital facility.

§ 404.3 Request requirements.

(a) Before submitting a FOIA request, potential requesters are encouraged to review the information publicly available at *https://www.exim.gov/about/foia/frequently-requested-records-and-proactive-disclosures* and *https://data.exim.gov/.* The material you seek may be immediately available at no cost.

(b)(1)(i) A request for records must be made directly to EXIM in writing. Requests may be submitted to the EXIM FOIA Office:

(A) By email to *foia@exim.gov*;

(B) Using the online form available at *https://www.exim.gov/about/foia*;

(C) Using the online FOIAXpress PAL Portal available at *https://palprod.eximefoia.com/*; and

(D) By mail addressed to the Freedom of Information and Privacy Office, 811 Vermont Ave. NW, Washington, DC 20571.

(E) In the alternative, requests may be submitted to the national request portal at *https://www.foia.gov.*

(ii) Additional resources and contact information are available at *https://www.exim.gov/about/foia.*

(2) A requester who is making a request for records about himself or herself must comply with the verification of identity requirements as set forth at § 404.16(d). This requires the request and signature to be notarized. Requester may instead submit a statement under 28 U.S.C. 1746, a law that permits statements to be made under penalty of perjury as a substitute for notarization.

(3) Where a request for records pertains to another individual, a requester may receive greater access by submitting either a notarized authorization signed by that individual or a declaration made in compliance

with the requirements set forth in 28 U.S.C. 1746 by that individual authorizing disclosure of the records to the requester, or by submitting proof that the individual is deceased (*e.g.,* a copy of a death certificate or an obituary). As an exercise of administrative discretion, EXIM can require a requester to supply additional information if necessary, in order to verify that a particular individual has consented to disclosure.

(c)(1) Each request must describe the records sought in sufficient detail to enable EXIM personnel to locate the records with a reasonable amount of effort. To the extent possible, requesters should include specific information that may help EXIM identify the requested records, such as relevant dates, format, subject matter, title, transaction or reference number, and the name of any person to whom the record is known to relate. For assistance in drafting a records request, requesters can contact EXIM's FOIA Public Liaison.

(2) If after receiving a request EXIM determines that it does not reasonably describe the records sought, EXIM must inform the requester what additional information is needed or why the request is otherwise insufficient. Requesters who are attempting to reformulate or modify such a request may discuss their request with EXIM's FOIA contact or FOIA Public Liaison. If, after contacting the requestor, EXIM is unable to clarify the timeframe for which a particular request seeks records, EXIM may deem the request to be a request for records created within the preceding twelve months.

(d) Requests may specify the preferred form or format (including electronic formats) for the records sought. EXIM will accommodate your request if the records are readily reproducible in that form or format.

(e) Requesters must provide contact information, such as their phone number, email, and mailing address, to assist EXIM in communicating with them and providing released records.

(f) A request must state the requester's willingness to pay any applicable fees or contain a request for a fee waiver. A requester may set a maximum amount the requester is willing to pay. The fee schedule and related provisions are provided in § 404.10. The ability to request fee waivers is set forth at § 404.11. EXIM will not process your request while clarifying fee issues.

§ 404.5 Responsibility for responding to requests.

(a) *In general.* In determining which records are responsive to a request, EXIM ordinarily will only include records that qualify as agency records under the FOIA on the date EXIM begins its search. If any other date is used, EXIM must inform the requester of that date. A record that is excluded from the requirements of the FOIA pursuant to 5 U.S.C. 552(c), is not considered responsive to a request.

(b) *Authority to grant or deny requests.* The Freedom of Information and Privacy Office is authorized to grant or deny any requests for records. This is the initial determination that can be appealed. The Freedom of Information and Privacy Office is also responsible for coordinating the search for responsive records and other matters concerning the processing of the request.

(c) *Consultation, referral, and coordination.* When reviewing records located by EXIM in response to a request, EXIM will determine whether another agency of the Federal Government is better able to determine whether the record is exempt from disclosure under the FOIA. With any such record, EXIM must proceed in one of the following ways:

(1) *Consultation.* When records originated with EXIM, but contain within them information of interest to another agency or Federal Government office, EXIM will typically consult with that other entity prior to making a release determination.

(2) *Referral.* (i) When EXIM determines that a different agency is best able to determine whether to disclose the record, EXIM will typically refer the responsibility for responding to the request regarding that record to that agency. Ordinarily, the agency that originated the record is presumed to be the best agency to make the disclosure determination. However, if the agency processing the request and the originating agency jointly agree that the agency processing the request is in the best position to respond regarding the record, then the record may be handled as a consultation.

(ii) Whenever EXIM refers any part of the responsibility for responding to a request to another agency, it must document the referral, maintain a copy of the record that it refers, and notify the requester of the referral, informing the requester of the name(s) of the agency to which the record was referred, including that agency's FOIA contact information.

(3) *Coordination.* The standard referral procedure in paragraph (c)(2) of this section is not appropriate where disclosure of the identity of the agency to which the referral would be made could harm an interest protected by an applicable exemption under FOIA, such as the exemptions that protect personal privacy or national security interests. For example, if a non-law enforcement agency responding to a request for records on a living third party locates within its files records originating with a law enforcement agency, and if the existence of that law enforcement interest in the third party was not publicly known, then to disclose that law enforcement interest could cause an unwarranted invasion of the personal privacy of the third party. Similarly, if an agency locates within its files material originating with an Intelligence Community agency, and the involvement of that agency in the matter is classified and not publicly acknowledged, then to disclose or give attribution to the involvement of that Intelligence Community agency could cause national security harms. In such instances, in order to avoid harm to an interest protected by an applicable exemption, EXIM will typically coordinate with the originating agency to seek its views on the releasability of the record. Subsequently, EXIM will convey the release determination for the record that is the subject of the coordination to the requester.

(d) *Classified information.* On receipt of any request involving classified information, EXIM must determine whether the information is currently and properly classified in accordance with applicable laws. When a request involves a record containing information that has been classified or may be appropriate for classification by another agency under an applicable Executive order, EXIM must refer the request for response to the agency that classified the information, or should consider the information for classification. Whenever an agency's record contains information that has been derivatively classified (for example, when it contains information classified by another agency), EXIM must refer the responsibility for responding to that portion of the request to the agency that classified the underlying information.

(e) *Timing of responses to consultations and referrals.* All consultations and referrals received by EXIM will be handled according to the date that the first agency received the FOIA request.

(f) *Agreements regarding consultations and referrals.* EXIM may establish agreements with other agencies to eliminate the need for consultations or referrals with respect to particular types of records.

§ 404.6 Time for processing response to requests.

(a) *In general.* EXIM is obligated to respond to requests within 20 working days of the date of receipt of the request unless unusual circumstances exist. EXIM ordinarily processes requests according to their order of receipt.

(b) *Definitions.* As used in this section:

(1) *Unusual circumstances* means, only to the extent reasonably necessary to the proper process of requests:

(i) The need to search for and collect requested records from facilities that are separate from the office processing the request;

(ii) The need to search for, collect, and appropriately examine a voluminous amount of separate and distinct records which are demanded in a single request; or

(iii) The need for consultation with another agency that has a substantial interest in the determination of the request or among two or more components of the agency having substantial subject matter interest therein. EXIM shall conduct any such consultations with all practicable speed.

(2) *Working days* means all calendar days excluding Saturdays, Sundays, and Federal Government holidays.

(c) *Date of receipt.* A request will be deemed to have been received on the date that the request is received in the Freedom of Information and Privacy Office, provided that the requester has met all the mandatory requirements of § 404.4. EXIM will notify the requester of the date on which a request was officially received in the acknowledgment correspondence.

(d) *Order of processing.* EXIM will ordinarily process requests in order of receipt within their processing track.

(e) *Multitrack processing.* EXIM has designated processing tracks that distinguish between expedited, simple, and complex requests based on the estimated amount of work or time needed to process the request. Among the factors EXIM considers are the number of offices involved, the number of pages involved in processing the request and the need for consultation or referrals. EXIM will advise requesters of the track into which their request falls and, when appropriate, EXIM may offer the requester an opportunity to narrow or modify their request so that it can be placed in a different processing track.

(f) *Unusual circumstances.* When EXIM cannot meet the statutory time limit for processing a request because of ''unusual circumstances,'' as defined in the FOIA, and extends the time limit on that basis, EXIM must, before expiration of the 20-day period to respond, notify the requester in writing of the unusual circumstances involved and of the date by which EXIM estimates processing of the request will be completed. Where the extension exceeds 10 working days, EXIM must provide the requester with an opportunity to modify the request or arrange an alternative time period for processing the original or modified request. EXIM's FOIA contact or Public Liaison is available for this purpose. EXIM will also alert requesters to the availability of the Office of Government Information Services (OGIS) to provide dispute resolution services.

(g) *Aggregating requests.* To satisfy unusual circumstances under the FOIA, EXIM may aggregate requests in cases where it reasonably appears that multiple requests, submitted either by a requester or by a group of requesters acting in concert, constitute a single request that would otherwise involve unusual circumstances. EXIM cannot aggregate multiple requests that involve unrelated matters.

(h) *Expedited processing.* (1) EXIM must process requests and appeals on an expedited basis when EXIM determines that the requester or appellant has demonstrated:

(i) Circumstances in which the lack of expedited processing could reasonably be expected to pose an imminent threat to the life or physical safety of an individual; or

(ii) In the case of a requester who is primarily engaged in disseminating information, an urgency to inform the public concerning actual or alleged Federal Government activity. A requester who is not a full-time member of the news media must establish that the requester is a person whose primary professional activity or occupation is information dissemination, though it need not be the requester's sole occupation. Such a requester also must establish a particular urgency to inform the public about the Government activity involved in the request—one that extends beyond the public's right to know about Government activity generally. The existence of numerous articles published on a given subject can be helpful in establishing the requirement that there be an ''urgency to inform'' the public on the topic.

(2) A request for expedited processing may be made at any time. When making a request for expedited processing of an administrative appeal, the request should be submitted to the EXIM's Assistant General Counsel for Administrative Law and Board Support.

(3) A request for expedited processing and other submissions in support of the request must be accompanied by a statement certified by the requester to be true and correct to the best of his or her knowledge and belief. EXIM may waive this formal certification requirement as a matter of discretion. The statement must be in the form prescribed by 28 U.S.C. 1746:

(i) If executed within the United States: ''I declare (or certify, verify, or state) under penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief. Executed on [date]. (signature).''

(ii) If executed outside the United States: ''I declare (or certify, verify, or state) under penalty of perjury that the foregoing is true and correct. Executed on (date). (Signature).''

(i) *Determination.* Upon receipt of a request for expedited processing, EXIM will consider the request and notify the requester of its determination within 10 calendar days of receipt of the request. If a request for expedited treatment is granted, the request will be given priority and will be placed in a processing track for expedited requests and processed as soon as practicable.

(j) *Appeal.* A requester may file an administrative appeal, as set forth at § 404.12, based on a denial of a request for expedited processing. EXIM will grant expeditious consideration to any such appeal. The appeal should be clearly marked ''Appeal for Expedited Processing.''

§ 404.7 Release of records.

(a) *Foreseeable harm standard.* As required by the FOIA, EXIM will disclose material unless it reasonably foresees that disclosure would harm an interest protected by an exemption or disclosure is prohibited by law.

(b) *Segregable records.* Whenever it is determined that a portion of a record is exempt from disclosure, any reasonably segregable portion of the record will be provided to the requester after redaction of the exempt material.

§ 404.8 Responses to requests.

(a) *General.* To the extent practicable, EXIM will communicate with requesters having access to the internet electronically through email or web portal available at *https://www.exim.gov/about/foia.*

(b) *Acknowledgment of request.* EXIM must acknowledge all FOIA requests in writing and assign a request number for reference and tracking the status of the request online. EXIM must also include in the acknowledgment a brief description of the records sought to allow requesters to more easily keep track of their request.

(c) *Estimated dates of completion and interim responses.* Upon request, EXIM will provide an estimated date by which

EXIM expects to provide a response to the requester. If a request involves a voluminous amount of material or searches in multiple locations, EXIM may provide interim responses, releasing the records on a rolling basis.

(d) *Grant of request.* Once EXIM has made a determination to grant a request in whole or in part, it will notify the requester in writing. EXIM also will inform the requester of any fees charged under § 404.10 and will disclose the requested records to the requester promptly upon payment of any applicable fees. EXIM shall inform the requester that EXIM's FOIA Public Liaison is available to offer assistance.

(e) *Adverse determination.* EXIM will notify the requester in writing if it makes an adverse determination denying a request in any respect. Adverse determination or denials of request may include decisions that: the requested records are exempt in whole or in part; the request does not reasonably describe the records sought; the information requested is not a record subject to the FOIA; the requested records do not exist, cannot be located or have been destroyed; or the requested record is not readily reproducible in the form or format sought by the requester. Adverse determinations also include denials involving fees or fee waiver matters or denials of requests for expedited processing. Whenever EXIM makes an adverse determination, the denial notice will be signed by the Chief FOIA Officer or other appropriate executive or designee and include:

(1) The name and title or position of the person responsible for the denial;

(2) A brief statement of the reasons for the denial, including any FOIA exemption applied in denying the request;

(3) An estimate of the volume of any records or information withheld, such as the number of pages or some other reasonable form of estimation, although such an estimate is not required if the volume is otherwise indicated by deletions marked on records that are disclosed in part, or if providing an estimate would harm an interest protected by an applicable exemption;

(4) A statement that the denial may be appealed under § 404.12(a) and a description of the requirements of § 404.12(a); and

(5) A statement notifying the requester of the assistance available from FOIA Public Liaison and the dispute resolution services offered by the Office of Government Information Services (OGIS).

(f) *Markings on released documents.* Markings on released documents must be clearly visible to the requester. Records disclosed in part will be marked to show the amount of information deleted and the exemption under which the deletion was made unless doing so would harm an interest protected by an applicable exemption.

(g) *Use of record exclusions.* (1) In the event that EXIM identifies records that may be subject to exclusion from the requirements of the FOIA pursuant to 5 U.S.C. 552(c), EXIM must confer with the Department of Justice (DOJ) Office of Information Policy (OIP) to obtain approval to apply the exclusion.

(2) When invoking an exclusion EXIM will maintain an administrative record of the process of invocation and approval of the exclusion by OIP.

§ 404.9 Confidential commercial information.

(a) *Definitions.* As used in this section:

(1) *Confidential commercial information.* Trade secrets and commercial or financial information obtained by EXIM from a submitter that may be protected from disclosure under Exemption 4 of the FOIA, 5 U.S.C. 552(b)(4).

(2) *Submitter.* Any person or entity, including a corporation, State, or foreign government, but not including another Federal Government entity, that provides confidential commercial information, either directly or indirectly to the Federal Government.

(b) *Submitter designation.* All submitters of confidential commercial information must use good faith efforts to designate, by appropriate markings, at the time of submission, any portion of their submissions that they consider to be exempt from disclosure under Exemption 4. This obligation continues after submission, such that a submitter should inform EXIM if it later identifies submitted information that was not marked or newly considers submitted information to be protected by Exemption 4.

(c) *Pre-disclosure notice to the submitter.* EXIM must provide prompt written notice to the submitter of information that is potentially confidential commercial information whenever records containing such information are requested under the FOIA if EXIM determines that it may be required to disclose the records and:

(1) The requested information has been designated by the submitter as information considered protected from disclosure under Exemption 4; or

(2) EXIM has a reason to believe that the requested information may be protected from disclosure under Exemption 4, but has not yet determined whether the information is protected from disclosure.

(d) *Notice requirements.* The notice must either describe the commercial information requested or include a copy of the requested records or portions of records containing the information. In cases involving a voluminous number of submitters, EXIM may post or publish a notice in a place or manner reasonably likely to inform the submitters of the proposed disclosure, instead of sending individual notifications.

(e) *When notice is not required.* EXIM does not need to send the notice called for by paragraph (c) of this section if:

(1) EXIM determines that the information is exempt under the FOIA, and therefore will not be disclosed;

(2) The information has been lawfully published or has been officially made available to the public;

(3) Disclosure of the information is required by a statute other than the FOIA or by a regulation issued in accordance with the requirements of Executive Order 12600 of June 23, 1987; or

(4) The designation made by the submitter under paragraph (b) of this section appears obviously frivolous. In such case, EXIM must give the submitter written notice of any final decision to disclose the information within a reasonable number of days prior to a specified disclosure date, as specified in paragraph (g) of this section for disclosures made over a submitter's objection.

(f) *Opportunity to object to disclosure*—(1) *Timeline for a response.* (i) A submitter located within the United States will have 10 working days from and including the date of the notification letter to respond to an EXIM notice sent under paragraph (c) of this section, unless another reasonable time period is specified in EXIM's notice.

(ii) A submitter located outside the United States will have 20 working days from and including the date of the notification letter to respond to an EXIM notice sent under paragraph (c) of this section, unless another reasonable time period is specified in EXIM's notice.

(iii) EXIM may extend the time for objection upon timely request from the submitter and for good cause shown.

(2) *Content of submitter's response.* (i) If a submitter has any objections to EXIM's disclosure of the information identified in the notice, the submitter should specify all grounds for EXIM to withhold the particular information under the FOIA.

(ii) In order to rely on Exemption 4 as a basis for EXIM withholding any of the information as confidential commercial information, the submitter must provide

a specific and detailed written explanation of why the information constitutes a trade secret or commercial or financial information that is privileged or confidential. A submitter invoking Exemption 4 in its response should consider including or addressing the following:

(A) Why the information qualifies as a trade secret or is privileged; or

(B) Why the information is confidential commercial or financial information.

(iii) A submitter who fails to respond within the time period specified will be considered to have no objection to disclosure of the information. EXIM will not consider any information received after this time period.

(iv) Any information provided by a submitter under this subpart may itself be subject to disclosure under the FOIA and should be appropriately marked if confidential.

(g) *Notices to the requester.* EXIM will notify the requester in writing whenever EXIM provides a submitter the opportunity to object to disclosure of records pursuant to paragraph (b) of this section; whenever EXIM notifies the submitter of EXIM's intent to disclose information; and whenever a submitter files a lawsuit to prevent the disclosure of the information.

(h) *Consideration of a submitter's response.* EXIM must consider a submitter's timely response prior to making its disclosure decision, including all objections and specific grounds for nondisclosure under the FOIA.

(i) *Notice of intent to disclose.* Whenever EXIM decides to disclose information over the objection of a submitter, EXIM must notify the submitter, in writing, of EXIM's determination. EXIM must include in this notice:

(1) The reasons for the disclosure decision, including a response to each of the submitter's disclosure objections; and

(2) A description of the information to be disclosed or copies of the records as EXIM intends to release them; and

(3) A specified disclosure date, which must provide the submitter a reasonable time after the notice to file suit to prevent the disclosure. This time period will be at least 10 working days from EXIM's transmission of the notice of intent to disclose.

(j) *Appeals by requesters.* In response to a requester's administrative appeal of a withholding under Exemption 4, EXIM will comply with the provisions of this section before disclosing any such information.

(k) *Notice of requester's FOIA lawsuit.* EXIM must promptly notify the submitter whenever a requester brings suit against EXIM seeking to compel the disclosure of confidential commercial information.

(l) *Publicly available information.* EXIM may, upon request or on its own initiative, publicly disclose the information contained at *exim.data.gov,* listed at § 404.2, including the parties to transactions for which EXIM approves support, the amount of such support, the identity of any primary participants involved, a general description of the related U.S. exports, and the country to which such exports are destined.

§ 404.10 Schedule of fees.

(a) *In general.* EXIM will charge fees to recover the full allowable direct costs it incurs in processing requests under the FOIA in accordance with the provisions of this section and OMB Guidelines. OMB Guidelines are accessible at *https://www.justice.gov/oip/foia-resources.* Requesters may seek a fee waiver. EXIM will consider requests for fee waiver in accordance with the requirements in § 404.11. To resolve any fee issues that arise under this section, EXIM may contact a requester for additional information. EXIM will attempt to conduct searches in the most efficient manner to minimize costs. EXIM ordinarily will collect all applicable fees before sending copies of records to a requester. Requesters must pay fees by check or money order made payable to the Treasury of the United States, or another method EXIM determines.

(b) *Definitions.* For purposes of this section:

(1) *Commercial use request.* A request for a use or purpose that furthers the commercial, trade or profit interest of the requester, which can include furthering those interests through litigation.

(2) *Direct costs.* Expenditures EXIM incurs in searching for and duplicating (and, in the case of commercial use requests, reviewing) records in response to a FOIA request. For example, direct costs include the salary of the employee performing the work (*i.e.,* the basic rate of pay for the employee, including locality pay adjustment, plus 16 percent of that rate to cover benefits), fees associated with the return of records stored offsite, the cost of operating computers and other electronic equipment, such as photocopiers and scanners. Direct costs do not include overhead expenses such as the costs of space, and of heating or lighting a facility.

(3) *Duplication.* Is reproducing a copy of a record, or of the information contained in it, necessary to respond to a FOIA request. Copies can take the form of paper, audiovisual materials, or electronic records, among others.

(4) *Educational institution.* Any school that operates a program of scholarly research. A requester in the fee category in this paragraph (b)(4) must show that the request is made in connection with his or her role at the education institution. EXIM may seek verification from the requester that the request is in furtherance of scholarly research and will advise requesters of their placement in this category.

(i) *Example 1.* A request from a professor of geology at a university for records relating to soil erosion, written on letterhead of the Department of Geology, would be presumed to be from an educational institution.

(ii) *Example 2.* A request from the same professor of geology seeking drug information from the Food and Drug Administration in furtherance of a murder mystery he is writing would not be presumed to be an institutional request, regardless of whether it was written on institutional stationery.

(iii) *Example 3.* A student who makes a request in furtherance of their coursework or other school-sponsored activities and provides a copy of a course syllabus or other reasonable documentation to indicate the research purpose for the request, would qualify as part of this fee category.

(5) *Non-commercial scientific institution.* An institution that is not operated on a ''commercial'' basis, as defined in paragraph (b)(1) of this section for purposes of a ''commercial use request,'' and is operated solely for the purpose of conducting scientific research the results of which are not intended to promote any particular product or industry. A requester in the fee category in this paragraph (b)(5) must show that the request is authorized by and is made under the auspices of a qualifying institution and that the records are sought to further scientific research and are not for commercial use. EXIM will advise requesters of their placement in this category.

(6) *Representative of the news media.* Any person or entity that gathers information of potential interest to a segment of the public, uses its editorial skills to turn the raw material into a distinct work, and distributes that work to an audience. The term ''news'' means information that is about current events or that would be of current interest to the public. Examples of news media entities include television or radio stations that broadcast ''news'' to the

public at large and publishers of periodicals that disseminate ''news'' and make their products available through a variety of means to the general public, including news organizations that disseminate solely on the internet. A request for records supporting the news-dissemination function of the requester will not be considered to be for a commercial use. ''Freelance'' journalists who demonstrate a solid basis for expecting publication through a news media entity will be considered as a representative of the news media. A publishing contract would provide the clearest evidence that publication is expected; however EXIM can also consider a requester's past publication record in making this determination. EXIM will advise requesters of their placement in the fee category in this paragraph (b)(6).

(7) *Review.* The process of examining a record in response to a request to determine whether any portion is exempt from disclosure. Review time includes processing any record for disclosure, such as doing all that is necessary to prepare the record for disclosure, including the process of redacting the record and marking the appropriate exemptions. Review costs are properly charged even if a record ultimately is not disclosed. Review time also includes time spent both obtaining and considering any formal objection to disclosure made by confidential commercial information submitter under § 404.9, but it does not include time spent resolving general legal or policy issues regarding the application of exemptions.

(8) *Search.* The process of looking for, identifying, and collecting records responsive to a request. For fee purposes, this refers to all time spent looking for materials that is responsive to a request. Searches may be conducted manually or by electronic means. Search time includes page-by-page or line-by-line identification of information within records and the reasonable efforts expended to locate and retrieve information from electronic records.

(c) *Categories of requesters.* Fees will be assessed depending on the category of the requester. The specific schedule of fees for each requester category is prescribed as follows:

(1) *Commercial use requesters.* EXIM will charge the full costs for search, review, and duplication.

(2) *Educational, non-commercial scientific institution, and representatives of the news media requesters.* When the records are not sought for commercial use, EXIM will charge only for the cost of duplication in excess of 100 pages and no fee will be charged for search or review.

(3) *All other requesters.* For requesters who are not covered by paragraphs (c)(1) and (2) of this section, EXIM will charge for the cost of search and duplication, except that the first 100 pages of duplication (or the cost equivalent of other media) and two hours of search time will be furnished without charge.

(d) *Search and review fees.* Subject to the restrictions in paragraph (i) of this section and in accordance with the applicable requester categories in paragraph (c) of this section, EXIM will charge the following fees for search and review, based on:

(1) *Clerical.* Hourly rate—$33.00.

(2) *Professional.* Hourly rate—$57.00

(3) *Direct cost.* Hourly rate—based upon the salary of the employee performing (base salary, including locality pay adjustment, and 16 percent for benefits). May also include fees for the return of records stored offsite, the cost of operating computers and other electronic equipment.

(4) *Quarter-hour period.* No search or review fees will be charged for a quarter-hour period unless more than half of that period is required for search or review.

(5) *No fee.* No fee will be charged when the total fee, after deducting the 100 free pages (or its cost equivalent) and the first two hours of search, is equal to or less than $25.

(e) *Search.* (1) Subject to the restrictions in paragraph (i) of this section EXIM will charge search fees.

(2) EXIM may properly charge for time spent searching even if EXIM does not locate any responsive records or if EXIM determines that the records are entirely exempt from disclosure.

(3) EXIM will charge the direct cost associated with conducting any search that requires the creation of a new computer program to locate the requested records. EXIM must notify the requester of the cost associated with creating such a program, and the requester must agree to pay the associated cost before the costs may be incurred.

(4) For requests that require the retrieval of records stored by EXIM at a records storage facility, including a Federal records center operated by the National Archives and Records Administration (NARA), EXIM will charge additional costs in accordance with the Transactional Billing Rate Schedule established by NARA.

(f) *Duplication.* EXIM will charge duplication fees to all requesters, subject to the restrictions of paragraph (b) of this section. EXIM must honor a requester's preference for receiving a record in a particular form or format where EXIM can readily produce it in the form or format requested. Where photocopies are supplied, EXIM will provide one copy per request at the cost of $.10 per page. For copies of records produced on disk or other media, EXIM will charge the direct cost of producing the copy, including operator time. Where paper documents must be scanned in order to comply with a requester's preference to receive the records in an electronic format, the requester must also pay the direct costs associated with scanning those materials. For other forms of duplication, EXIM will charge the direct costs. EXIM may also offer the requester the opportunity to alter the request in order to reduce duplication costs.

(g) *Review.* EXIM will charge review fees to requesters who make commercial use requests. Review fees will be assessed in connection with the initial review of the record, *i.e.,* the review conducted by EXIM to determine whether an exemption applies to a particular record or portion of a record. No charge will be made for review at the administrative appeal stage of exemptions applied at the initial review stage. However, if a particular exemption is deemed to no longer apply, any costs associated with EXIM's re-review of the records in order to consider the use of other exemptions may be assessed as review fees. Review fees will be charged at the same rates as those charged for a search under paragraph (e) of this section.

(h) *Special services charges.* Complying with requests for special services such as those listed in this paragraph (h) is entirely at the discretion of EXIM. EXIM will recover the full costs of providing such services to the extent that it elects to provide them.

(1) *Certifications.* EXIM will charge $25.00 to certify the authenticity of any EXIM record or any copy of such record.

(2) *Special shipping.* EXIM may ship by special means (*e.g.,* express mail) if the requester so desires, provided that the requester has paid or has expressly undertaken to pay all costs of such special services. EXIM will not charge for ordinary packaging and mailing.

(i) *Restrictions on charging fees.* (1) When EXIM determines that a requester is an educational institution, non-commercial scientific institution, or representative of the news media, and the records are not sought for commercial use, it will not charge search fees.

(2) If EXIM fails to comply with the FOIA's time limits in which to respond to a request:

(i) It will not charge search fees, or, in the instance of request from requesters described in paragraph (d)(1) of this section, may not charge duplication fees, except as follows in paragraphs (d)(2)(ii) through (iv) of this section.

(ii) If EXIM has determined that unusual circumstances, as defined by the FOIA, apply and EXIM provided timely written notice to the requester in accordance with the FOIA, a failure to comply with the time limit shall be excused for an additional 10 working days.

(iii) If EXIM has determined that unusual circumstances, as defined by the FOIA, apply and more than 5,000 pages are necessary to respond to the request, EXIM may charge search fees, or in the case of requesters described in paragraph (d)(1) of this section, may charge duplication fees, if the following steps are taken. EXIM must have provided timely written notice of unusual circumstances to the requester in accordance with the FOIA and EXIM must have discussed with the requester via written mail, email, or telephone (or made not less than three good-faith attempts to do so) how the requester could effectively limit the scope of the request in accordance 5 U.S.C. 552(a)(6)(B)(ii). If the exception in this paragraph (d)(2)(iii) is satisfied, EXIM may charge all applicable fees incurred in the processing of the request.

(iv) If a court has determined that exceptional circumstances exist, as defined by the FOIA, a failure to comply with the time limits shall be excused for the length of time provided by the court order.

(j) *Notice of anticipated fees in excess of $25.00.* (1) When EXIM determines or estimates that the fees to be assessed in accordance with this section will exceed $25.00, EXIM must notify the requester of the actual or estimated amount of the fees, including a breakdown of the fees for search, review, or duplication, unless the requester has indicated a willingness to pay fees as high as those anticipated. If only a portion of the fees can be estimated readily, EXIM will advise the requester accordingly. If the request is not for noncommercial use, the notice will specify that the requester is entitled to the statutory entitlements of 100 pages of duplication at no charge and, if the requester is charged search fees, two hours of search time at no charge, and will advise the requester whether those entitlements have been provided.

(2) If EXIM notifies the requester that the actual or estimated fees are in excess of $25.00, the request will not be considered received and further work will not be completed until the requester commits in writing to pay actual or estimated total fees, or designates some amount of fees the requester is willing to pay, or in the case of a non-commercial use requester who has not yet been provided with the requester's statutory entitlements, designates that the requester seeks only that which can be provided by statutory entitlements. The requester must provide the commitment or designation in writing, and must, when applicable, designate an exact dollar amount the requester is willing to pay. EXIM will not accept payments in installments.

(3) If the requester has indicated a willingness to pay some designated amount of fees, but EXIM estimates that the total fee will exceed that amount, EXIM will toll the processing of the request when it notifies the requester of the estimated fees in excess of the amount the requester has indicated a willingness to pay. EXIM will inquire whether the requester wishes to revise the amount of fees the requester is willing to pay or modify the request. Once the requester responds, the time to respond will resume from where it was at the date of notifications.

(4) EXIM's FOIA Public Liaison or another FOIA professional is available to assist any requester in reformulating a request to meet the requester's needs at a lower cost.

(k) *Charging interest.* EXIM may charge interest on any unpaid bill starting on the 31st day following the date of billing the requester. Interest charges will be assessed at the rate provided by 31 U.S.C. 3717 and will accrue from the billing date until payment is received by EXIM. EXIM follow the provisions of the Debt Collection Act of 1982 (Pub. L. 97–365, 96 Stat.1749), as amended, and its administrative procedures, including the use of consumer reporting agencies, collection agencies, and offset.

(l) *Aggregating requests for fee purposes.* When EXIM reasonably believes that a requester or a group of requesters acting in concert is attempting to divide a single request into a series of requests for the purpose of avoiding fees, EXIM may aggregate those requests and charge accordingly. EXIM may presume that multiple requests of this type made within a 30-day period have been made in order to avoid fees. For requests separated by a longer period, EXIM will aggregate them only where there is a reasonable basis for determining that aggregation is warranted in view of all the circumstances involved. Multiple requests involving unrelated matters cannot be aggregated.

(m) *Advance payments.* (1) For requests other than those described in paragraph (n)(2) or (3) of this section, EXIM cannot require the requester to make an advance payment before work is commenced or continues on a request. Payment owed for work already completed (*i.e.,* payment before copies are sent to the request) is not an advance payment.

(2) When EXIM determines or estimates that a total fee to be charged under this section will exceed $250.00, it may require that the requester make an advance payment up to the amount of the entire anticipated fee before beginning to process the request. EXIM may elect to process the request prior to collecting fees when it receives a satisfactory assurance of full payment from a requester with a history of prompt payment.

(3) Where a requester has previously failed to pay a properly charged FOIA fee to any agency within 30 calendar days of the billing date, EXIM may require that the requester pay the full amount due, plus any applicable interest on that prior request, and EXIM may require that the requester make an advance payment of the full amount of any anticipated fee before EXIM begins to process a new request or continues to process a pending request or any pending appeal. Where EXIM has a reasonable basis to believe that a requester has misrepresented the requester's identity in order to avoid paying outstanding fees, it may require that the requester provide proof of identity.

(4) In cases in which EXIM requires advance payment, the request will not be considered received and further work will not be completed until the required payment is received. If the requester does not pay the advance payment within 30 calendar days after the date of EXIM's fee determination, the request will be closed.

(n) *Other statutes specifically providing for fees.* The fee schedule of this section does not apply to fees charged under any statute that specifically requires an agency to set and collect fees for particular types of records. In instances where records responsive to a request are subject to a statutorily-based fee schedule program, EXIM must inform the requester of the contact information for that program.

§ 404.11 Fee waivers or reductions.

(a) *General.* Requesters may seek a waiver of fees by submitting a written request demonstrating how disclosure of the requested information is in the

public interest because it is likely to contribute significantly to public understanding of the operations or activities of the Government and is not primarily in the commercial interest of the requester.

(b) *Form of request for fee waiver.* EXIM must furnish records responsive to a request without charge or at a reduced rate when it determines, based on all available information, that the factors described in paragraphs (b)(1) through (3) of this section are satisfied:

(1) Disclosure of the requester information would shed light on the operations or activities of the Government. The subject of the request must concern identifiable operations or activities of the Federal Government with a connection that is direct and clear, not remote or attenuated.

(2) Disclosure of the requested information is likely to contribute to the public understanding of those operations or activities. This factor is satisfied when the following criteria are met:

(i) Disclosure of the requested records must be meaningfully informative about Government operations or activities. The disclosure of information that already is in the public domain, in either the same or substantially identical for, would not be meaningfully informative if nothing new would be added to the public understanding.

(ii) The disclosure must contribute to the understanding of a reasonably broad audience of persons interested in the subject, as opposed to the individual understanding of the requester. A requester's expertise in the subject area as well as the requester's ability and intention to effectively convey information to the public must be considered.

(3) The disclosure must not be primarily in the commercial interest of the requester. To determine whether disclosure of the requested information is primarily in the commercial interest of the requester, EXIM will consider the following criteria:

(i) EXIM must identify whether the requester has any commercial interest that would be furthered by the requested disclosure. A commercial interest includes any commercial, trade, or profit interest. Requesters must be given an opportunity to provide explanatory information regarding this consideration.

(ii) If there is an identified commercial interest EXIM must determine whether that is the primary interest furthered by the request.

(4) A waiver or reduction of fees is justified when the requirements of paragraphs (b)(1) and (2) of this section are satisfied and any commercial interest is not the primary interest furthered by the request. EXIM ordinarily will presume that when a news media requester has satisfied paragraphs (b)(1) and (2), the request is not primarily in the commercial interest of the requester. Disclosure to data brokers or others who merely compile and market government information for direct economic return will not be presumed to primarily serve the public interest.

(5) Where only some of the records to be released satisfy the requirements for a waiver of fees under this section, a waiver must be granted for those records.

(6) Requests for a waiver or reduction of fees should be made when the request is first submitted to EXIM and should address the criteria referenced in paragraphs (b)(1) through (5) of this section. A requester may submit a fee waiver request at a later time so long as the underlying record request is pending or on administrative appeal. When a requester who has committed to pay fees subsequently asks for a waiver of those fees and that waiver is denied, the requester must pay any costs incurred up to the date the fee waiver request was received.

(7) In all cases, the requester has the burden of presenting sufficient evidence or information to justify the fee waiver or reduction. The requester may use the procedures set forth in § 404.12 to appeal a denial of a fee waiver request.

§ 404.12 Administrative appeals.

(a) *General requirements for making an appeal.* A requester may appeal any adverse determination to the EXIM's Assistant General Counsel for Administrative Law and Board Support. Requesters can submit appeals by mail or via email at *FOIA.Appeals@exim.gov* in accordance with the following requirements: Appeals must be made in writing and contain the appellant's contact information, such as return address, email, or telephone number. To be timely it must be postmarked, or in the case of electronic submissions, transmitted within 90 calendar days after the date of the final response. The appeal should clearly identify the EXIM determination that is being appealed and the assigned request number. To facilitate handling, the requester should mark both appeal letter and envelope, or subject line of the electronic transmission, ''Freedom of Information Act Appeal.''

(b) *Adjudication of appeals.* (1) The Assistant General Counsel for Administrative Law and Board Support or designee will act on behalf of EXIM's Chief FOIA officer on all appeals under this section.

(2) An appeal ordinarily will not be adjudicated if the request becomes a matter of litigation.

(3) On receipt of any appeal involving classified information, EXIM must take appropriate action to ensure compliance with applicable classification laws.

(c) *Decisions on appeals.* A decision that upholds an agency's determination, in whole or in part, must contain a statement that identifies the reasons for the affirmance, including any FOIA exemptions applied. The decision must provide the requester with notification of the statutory right to file a lawsuit and will inform the requester of the mediation services offered by the Office of Government Information Services (OGIS) of National Archives and Records Administration as a non-exclusive alternative to litigation. If EXIM's initial determination is remanded or modified on appeal, EXIM will notify the requester of that determination in writing. EXIM will then further process the request in accordance with that appeal determination and will respond directly to the requester.

(d) *Engaging in dispute resolution services provided by OGIS.* Mediation is a voluntary process. If EXIM agrees to participate in the mediation services provided by OGIS, it will actively engage as a partner to the process in an attempt to resolve the dispute.

(e) *When appeal is required.* Before seeking review by a court of an adverse determination, a requester generally must submit a timely administrative appeal.

§ 404.13 Preservation of records.

EXIM will preserve all correspondence pertaining to the request that it receives under this subpart, as well as copies of all requested records, until disposition or destruction is authorized pursuant to title 44 of the United States Code or the General Records Schedule 4.2 of the National Archives and Records Administration. EXIM will not dispose or destroy records while they are the subject of a pending request, appeal, or lawsuit under the FOIA.

§ 404.14 [Amended]

■ 5. Amend newly redesignated § 404.14 in paragraph (b) by removing ''§ 404.13'' and adding ''§ 404.15'' in its place.

§ 404.16 [Amended]

■ 6. Amend newly redesignated § 404.16 as follows:

■ a. In paragraph (a), removing ''§ 404.12(e)'' and adding ''§ 404.14(e)'' in its place; and
■ b. In paragraph (c) introductory text, removing ''§ 404.16(d)'' and adding ''§ 404.18(d)'' in its place.

§ 404.17 [Amended]

■ 7. Amend newly redesignated § 404.17 in paragraph (b)(2)(iii) by removing ''§ 404.17'' and adding ''§ 404.19'' in its place.

§ 404.19 [Ameded]

■ 8. Amend newly redesignated § 404.19 in paragraph (a) introductory text by removing ''§ 404.12(e)'' and adding ''§ 404.14(e)'' in its place.

§ 404.20 [Amended]

■ 9. Amend newly redesignated § 404.20 as follows:
■ a. In paragraph (a), removing ''§ 404.12(e)'' and ''§ 404.14(d) and (e)'' and adding ''§ 404.14(e)'' and ''§ 404.16(d) and (e)'' in their places, respectively.
■ b. In paragraphs (c) introductory text and (e), removing ''§ 404.12(e)'' and adding ''§ 404.14(e)'' in its place.

§ 404.21 [Amended]

■ 10. Amend newly redesignated § 404.21 in paragraph (b) by removing ''§ 404.14(d) and (e)'' and ''§ 404.12(e)'' and adding ''§ 404.16(d) and (e)'' and ''§ 404.14(e)'' in their places, respectively.

§ 404.35 [Amended]

■ 11. Amend newly redesignated § 404.35 by removing ''§ 404.32'' and adding ''§ 404.34'' in its place.

Joyce B. Stone,

Assistant Corporate Secretary.

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BUREAU OF CONSUMER FINANCIAL PROTECTION

12 CFR Part 1022

The Fair Credit Reporting Act's Limited Preemption of State Laws

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Interpretive rule.

SUMMARY: States play an important role in the regulation of consumer reporting. State laws that are not ''inconsistent'' with the Fair Credit Reporting Act (FCRA) are generally not preempted by that statute. The FCRA also expressly preempts certain categories of State laws. This interpretive rule clarifies that FCRA's express preemption provisions have a narrow and targeted scope. States therefore retain substantial flexibility to pass laws involving consumer reporting to reflect emerging problems affecting their local economies and citizens. For example, if a State law were to forbid consumer reporting agencies from including information about medical debt, evictions, arrest records, or rental arrears in a consumer report (or from including such information for a certain period of time), such a law would generally not be preempted. Likewise, if a State law were to prohibit furnishers from furnishing such information to consumer reporting agencies, such a law would also not generally be preempted. Similarly, if a State law required that a consumer reporting agency provide information required by the FCRA at the consumer's requests in languages other than English, such a law would generally not be preempted.

DATES: This interpretive rule is effective on July 11, 2022.

FOR FURTHER INFORMATION CONTACT: Shiva Nagaraj, Senior Counsel, Legal Division, and Bradley Lipton, Senior Counsel, Legal Division, (202) 435–7700. If you require this document in an alternative electronic format, please contact *CFPB_Accessibility@cfpb.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Fair Credit Reporting Act (FCRA)—which was enacted in 1970 and has since been amended several times—was intended by Congress to ''ensure fair and accurate credit reporting, promote efficiency in the banking system, and protect consumer privacy.'' *Safeco Ins. Co. of Am.* v. *Burr,* 551 U.S. 47, 52 (2007). The FCRA ''imposes a host of requirements concerning the creation and use of consumer reports.'' *Spokeo, Inc.* v. *Robins,* 578 U.S. 330, 335 (2016). Among other things, the statute sets forth the permissible uses of consumer reports, establishes limits for information included in consumer reports, and creates a process for consumers to dispute information in their credit files.

In the Consumer Financial Protection Act of 2010, Congress granted the Consumer Financial Protection Bureau general rulemaking authority over the FCRA (except for certain provisions that are administered by other Federal agencies).[1] The Bureau also has authority to enforce the FCRA, along with other Federal regulators.[2]

States also play an important role in the regulation of consumer reporting. The FCRA itself grants States the authority to enforce the statute.[3] Additionally, in the wake of Congress's enactment of the FCRA, many States passed their own versions of the statute. States have continued to enact legislation regulating the conduct of consumer reporting agencies, furnishers, and users of consumer reports. In some cases, State legislation provides protections to consumers that go above and beyond the requirements of the FCRA.

These State statutes exist alongside the FCRA, which says that—subject to certain exceptions—it ''does not annul, alter, affect, or exempt any person subject to [the FCRA] from complying with the laws of any State with respect to the collection, distribution, or use of any information on consumers, or for the prevention or mitigation of identity theft, except to the extent that those laws are inconsistent with any provision of this subchapter, and then only to the extent of the inconsistency.''[4] In other words, State laws that are not ''inconsistent'' with the FCRA—including State laws that are more protective of consumers than the FCRA—are generally not preempted.

The FCRA also expressly preempts certain categories of State laws. As relevant here, 15 U.S.C. 1681t(b) says that ''[n]o requirement or prohibition may be imposed under the laws of any State with respect to any subject matter regulated under'' certain sections or subsections of the FCRA:

- subsection (c) or (e) of section 1681b, relating to the prescreening of consumer reports;
- section 1681i, relating to the time by which a consumer reporting agency must take any action, including the provision of notification to a consumer or other person, in any procedure related to the disputed accuracy of information in a consumer's file, [with an exception for laws in effect on September 30, 1996];
- subsections (a) and (b) of section 1681m, relating to the duties of a person

[1] The Bureau is generally authorized to issue regulations as ''necessary or appropriate to administer and carry out the purposes and objectives of [the FCRA], and to prevent evasions thereof or to facilitate compliance therewith.'' 15 U.S.C. 1681s(e)(1). The CFPA did not, however, transfer to the Bureau rulemaking authority for 15 U.S.C. 1681m(e) (''Red Flag Guidelines and Regulations Required''') and 15 U.S.C. 1681w (''Disposal of Records'').

[2] 15 U.S.C. 1681s(b).

[3] 15 U.S.C. 1681(c).

[4] 15 U.S.C. 1681t(a); *see also Davenport* v. *Farmers Ins. Group,* 378 F.3d 839, 842 (8th Cir. 2004) (''The FCRA makes clear that it is not intended to occupy the entire regulatory field with regard to consumer reports.'').

who takes any adverse action with respect to a consumer;

- section 1681m(d), relating to the duties of persons who use a consumer report of a consumer in connection with any credit or insurance transaction that is not initiated by the consumer and that consists of a firm offer of credit or insurance;
- section 1681c, relating to information contained in consumer reports, [with an exception for laws in effect on September 30, 1996];
- section 1681s–2, relating to the responsibilities of persons who furnish information to consumer reporting agencies [with exceptions for certain enumerated State laws]
- section 1681g(e), relating to information available to victims under section 1681g(e);
- section 1681s–3, relating to the exchange and use of information to make a solicitation for marketing purposes;
- section 1681m(h), relating to the duties of users of consumer reports to provide notice with respect to terms in certain credit transactions;
- subsections (i) and (j) of section 1681c–1 relating to security freezes; or
- subsection (k) of section 1681c–1, relating to credit monitoring for active duty military consumers.

Similarly, 15 U.S.C. 1681t(b)(5) says that ''[n]o requirement or prohibition may be imposed under the laws of any State with respect to the conduct required by the specific provisions of'' certain sections or subsections of the FCRA:

- section 1681c(g);
- section 1681c–1;
- section 1681c–2;
- section 1681g(a)(1)(A);
- section 1681j(a);
- subsections (e), (f), and (g) of section 1681m;
- section 1681s(f);
- section 1681s–2(a)(6); or
- section 1681w.

This interpretive rule clarifies the preemptive scope of 15 U.S.C. 1681t(b), with a particular focus on 15 U.S.C. 1681t(b)(1) and (5), which have been the subject of recent legal challenges to State laws.[5] As 15 U.S.C. 1681t(b)(1) says, that provision preempts only those State laws ''with respect to any subject matter regulated under'' certain sections or subsections of the FCRA. Similarly, 15 U.S.C. 1681t(b)(5) preempts only those States law ''with respect to the conduct required by the specific provisions of'' certain sections or subsections of the FCRA. The term ''with respect to'' indicates that Congress intended these provisions to have a narrow sweep. As the Supreme Court has held in a similar context, ''with respect to'' means to ''concern.'' In other words, section 1681t(b)(1) does not preempt State laws unless they concern a subject matter regulated under the enumerated portions of the FCRA. Similarly, section 1681t(b)(5) does not preempt State laws unless they concern conduct required by the enumerated portions of the FCRA.

II. Analysis

The Supremacy Clause of the United States Constitution says that ''the Laws of the United States'' shall be ''the supreme Law of the Land . . . any Thing in the Constitution or Laws of any state to the Contrary notwithstanding.'' Art. VI, cl. 2. When a Federal statute includes a preemption clause—as the FCRA does—''[t]he purpose of Congress is the ultimate touchstone'' in interpreting such a clause. *Altria Grp., Inc.* v. *Good,* 555 U.S. 70, 76 (2008). ''Congressional intent, of course, primarily is discerned from the language of the pre-emption statute and the 'statutory framework' surrounding it.'' *Medtronic, Inc.* v. *Lohr,* 518 U.S. 470, 486 (1996). Thus, any preemption analysis must ''focus on the plain wording of the clause.'' *Puerto Rico* v. *Franklin California Tax-Free Tr.,* 579 U.S. 115, 125 (2016).

Focusing on the plain text of sections 1681t(b)(1) and 1681t(b)(5), it is apparent that both provisions have a narrow and targeted scope.

A. Under 15 U.S.C. 1681t(b)(1), State Laws Are Not Preempted Unless They Are ''With Respect to Any Subject Matter Regulated Under'' Certain Sections or Subsections of the FCRA

Section 1681t(b)(1) has eleven subsections, each of which follows the same syntax. Each subsection preempts State laws ''with respect to any subject matter regulated under'' an enumerated part of the FCRA (*e.g.,* section 1681c). Following the enumerated section of the FCRA comes a parenthetical phrase beginning with ''relating to'' that describes or further narrows the section that has just been enumerated. For instance, section 1681(b)(1)(E) generally preempts State laws ''with respect to any subject matter regulated under section 1681c of this title, relating to information contained in consumer reports.'' Preemption under section 1681t(b)(1) thus depends on the meaning of both the ''with respect to'' and ''relating to'' clauses.

Foremost, State laws are not preempted unless they are ''with respect to any subject matter regulated under'' the enumerated sections of the FCRA. In the case of section 1681t(b)(1)(E), State laws would not be preempted unless they are ''with respect to any subject matter regulated under section 1681c.''

In addition, a State law is preempted under section 1681t(b)(1) only if it *also* falls within the description in the ''relating to'' parenthetical. In some cases, the ''relating to'' parenthetical merely reiterates the enumerated section. For instance, 15 U.S.C. 1681t(b)(1)(C) preempts State laws ''with respect to any subject matter regulated under subsections (a) and (b) of section 1681m of this title, relating to the duties of a person who takes any adverse action with respect to a consumer.'' Both subsections (a) and (b) of section 1681m lay out certain duties of a person who takes an adverse action with respect to a consumer. Thus, both the ''with respect to'' clause and the ''relating to'' clause of section 1681t(b)(1)(C) have the same scope.

But in other cases, the ''relating to'' clause serves as a further limitation on the ''with respect to'' clause. For example (and as noted above), section 1681t(b)(1)(E) preempts State laws ''with respect to any subject matter regulated under section 1681c of this title, relating to information contained in consumer reports.'' Although section 1681c primarily contains limitations on information that can be included in consumer reports, it also includes other miscellaneous provisions. See, *e.g.,* 15 U.S.C. 1681c(g) (requirement for truncating credit card and debit card numbers in receipts provided to cardholder). Thus, the plain text of section 1681t(b)(1)(E) indicates that only those State laws ''with respect to'' section 1681c that also ''relate to'' information contained in consumer reports are preempted.

It has been argued by some that the preemptive scope of section 1681t(b)(1) is defined only by the ''relating to'' clause. For example, in *Consumer Data Indus. Ass'n* v. *Frey,* 26 F.4th 1 (1st Cir. 2022), the plaintiffs argued that section 1681t(b)(1)(E) preempts any State laws ''relating to information contained in consumer reports,'' regardless of whether the law is ''with respect to any subject matter regulated under'' section 1681c. As courts have correctly held,

[5] The CFPB ''encourages State Officials to consult with the Bureau whenever interpretation of Federal consumer financial law, as defined in section 1002(14) of the Dodd-Frank Act, . . . is relevant to a State regulatory or law enforcement matter, even if it is not the type of action for which notification is required'' pursuant to the State Official Notification Rule. 77 FR 39112, 39113 (June 29, 2012). The Office of the New Jersey Attorney General recently notified the CFPB about pending litigation in which the plaintiff alleges that a New Jersey consumer protection statute is preempted by the FCRA.

that ''is not the most natural reading of the statute's syntax and structure.'' *Frey,* 26 F.4th at 6. That interpretation would render the ''with respect to'' clause surplusage. A statute, however, ''ought to be construed in a way that 'no clause, sentence, or word shall be superfluous, void, or insignificant.'' *Duncan* v. *Walker,* 533 U.S. 167, 174 (2001). Moreover, Congress knows how to broadly preempt State laws that are ''related to'' fields or topics. For instance, the Employee Retirement Income Security Act ''supersede[s] any and all State laws insofar as they may now or hereafter relate to any employee benefit plan.'' 29 U.S.C. 1144(a). Congress could have used similar syntax in the FCRA—but it did not. Instead, Congress made clear that a State law is not preempted by section 1681t(b)(1) unless it falls within the ''with respect to'' clause.

Whether a particular State law is ''with respect to any subject matter regulated under'' the enumerated sections of the FCRA will depend on the facts and circumstances. But it bears noting that the phrase ''with respect to any subject matter regulated under'' is an important limiting factor. As the Supreme Court has noted in a case involving a statute that—like the FCRA—included a preemption provision with both ''related to'' and ''with respect to'' phrases, the ''with respect to'' phrase served to ''massively limit[ ] the scope of preemption.'' *Dan's City Used Cars, Inc.* v. *Pelkey,* 569 U.S. 251, 261 (2013). The ''with respect to'' phrase ''necessarily reaches a subset of laws narrower than those that merely relate to information contained in consumer reports.'' *Frey,* 26 F.4th at 8. It narrows the universe of preemption only to those laws that ''concern'' the subject matter regulated under the enumerated FCRA sections. *Dan's City Used Cars,* 569 U.S. at 261; see also, *e.g., Frey,* 26 F.4th at 7 (section 1681t(b)(1)(E) ''preempt[s] those claims that concern subject matter regulated under section 1681c''); *Galper* v. *JP Morgan Chase Bank, N.A.,* 802 F.3d 437, 446 (2d Cir. 2015) (section 1681t(b)(1)(F) ''preempts only those claims that concern a furnisher's responsibilities). Thus, if a State law does not ''concern'' the subject matters regulated under the FCRA sections specified in section 1681t(b)(1), it is not preempted by that clause.

It bears emphasis that section 1681t(b)(1) does *not* preempt all State laws relating to the content or information contained in consumer reports. Indeed, the legislative history of this provision confirms that it was intended to provide only ''limited'' preemption on ''procedural'' issues.[6]

For example, section 1681t(b)(1)(E) preempts State laws ''with respect to any subject matter regulated under'' section 1681c ''relating to information contained in consumer reports.'' In turn, section 1681c states requirements relating to four topics relating to information contained in consumer reports: (1) obsolescence, *i.e.,* how long certain specific types of information may continue to appear on a consumer report;[7] (2) certain information about medical information furnishers;[8] (3) certain information relating to veterans' medical debt;[9] and (4) certain information that must be included in a consumer report (*e.g.,* the fact that the consumer has disputed information provided by a furnisher to the consumer reporting agency issuing the report).[10]

The legislative history of the FCRA preemption provision confirms that only subject matter at this level of specificity is subject to preemption. The legislative history expressly references ''obsolescence periods'' as an example of a subject matter governed by preemption—not the broader subject matter of the content of a consumer report more generally.[11] Hence, FCRA 1681t(b)(1)(E) does *not* preempt State laws about subject matter regarding the content of or information on consumer reports beyond these topics.[12]

For instance, although *how long* the specific types of information listed in section 1681c may continue to appear on a consumer report is a subject matter regulated under section 1681c, what or when items generally may be *initially* included on a consumer report is not a subject matter regulated under section 1681c. Indeed, section 1681c(a)(7) provides requirements about when veterans' medical debt, specifically, may be included on a consumer report by a nationwide consumer reporting agency, but nothing in section 15 U.S.C. 1681c addresses what or when information of other types may initially be included on reports.[13] (For example, section 1681c(a)(5) regulates how long ''adverse item[s] of information, other than records of convictions of crimes'' may appear on consumer reports, but not whether or when adverse items may initially appear on a consumer report.) Similarly, only 1681c(a)(6) and (8), relating specifically to information about medical information furnishers and veterans' medical debt, contain restrictions on the content of a consumer report; the other provisions restrictions relate only to how long information may appear. section 1681c therefore does not provide any general restrictions on the content of a consumer report. Accordingly, State laws relating to what or when items generally may be initially included on a consumer report—or what or when certain types of information may initially be included on a consumer report—would generally not be preempted by section 1681t(b)(1)(E).

States therefore retain substantial flexibility to pass laws involving consumer reporting to reflect emerging problems affecting their local economies and citizens. For instance, medical debt that shows up in a consumer report can be factored into a consumer's credit score, though whether and how these debts affect their scores varies

[6] *See* 141 Cong. Rec. S5450 (daily ed. Apr. 5, 1995) (statement of Sen. Bond) (''This bill also contains limited Federal preemption to ensure that there are uniform Federal standards to govern a number of procedural issues which are part of credit reporting and which will reduce the burdens on the credit industry from having to comply with a variety of different State requirements. For example, the bill preempts requirements regarding prescreening, information shared among affiliates, reinvestigation timetables, obsolescence time periods and certain disclosure forms.'').

[7] 15 U.S.C. 1681c(a)(1)–(5).

[8] 15 U.S.C. 1681c(a)(6).

[9] 15 U.S.C. 1681c(a)(7)–(8).

[10] 15 U.S.C. 1681c(d), (e), (f).

[11] *See* 141 Cong. Rec. S5450 (daily ed. Apr. 5, 1995) (statement of Sen. Bond) (referring to ''obsolescence time periods'' as an example of a subject matter on which there would be preemption).

[12] To be sure, the title of Section 1681c is stated more broadly as ''Requirements relating to information contained in consumer reports.'' But the title of a statutory provision is of only limited significance. *See, e.g., Bhd. of R.R. Trainmen* v. *Balt. & Ohio R.R. Co.,* 331 U.S. 519, 529 (explaining that titles and headings ''are but tools available for the resolution of a doubt,'' ''[b]ut they cannot undo or limit that which the text makes plain''). And the actual subject matter regulated by the text of Section 1681c is limited to the narrow topics actually addressed. Further, the legislative history confirms that the subject matter intended to be preempted is only the specific topics regulated in Section 1681c.

[13] Section 1681c(a)(1)–(5) regulates when certain types of information that ''antedate the report'' by ''more than'' certain periods of time may appear. But only 1681c(a)(7), relating specifically to veterans' medical debt, regulates when a type of information that antedates the report by ''less than'' a period of time may appear. Hence, only 1681c(a)(7), which is limited to veterans' medical debt, regulates when a type of information that antedates a report by *less than* a certain period of time may appear. Moreover, restrictions on what or when types of information may initially appear on a consumer report do not alter the period of time that information may remain on a report under Section 1681c. The restrictions in Section 1681c(a)(1)–(5) each provide that information may remain on a report for a certain period of time following the date that particular events occurred. A restriction on what or when information may initially appear on a report would not alter the date of those events. Such a restriction therefore does not change the date on which Section 1681c(a)(1)–(5) prohibits the information from continuing to appear on the report.

depending on the score model.[14] Research by the CFPB has found that medical collections are less predictive of future consumer credit performance than nonmedical collections.[15] Additionally, paid medical collections are less predictive of future performance than unpaid medical collections. Individuals with more medical than non-medical collections and individuals with more paid than unpaid medical collections had delinquency rates that were comparable to those of individuals with credit scores of 10 points higher and 20 points higher, respectively. In other words, these individuals were less likely to be delinquent than other individuals with the same credit score. Nonetheless, some widely used models still weight medical and nonmedical collections equally.[16] This means that consumers with medical debt may be negatively affected if creditors use older scoring models that may overweight medical debt. To address these concerns and others, States may pass laws addressing the furnishing and reporting of medical debt.

If a State law were to forbid a consumer reporting agency from including medical debt in a consumer report for a certain period of time after the debt was incurred, such a law would generally not be preempted. Section 1681c does not regulate the subject matter of when medical debt (or debt generally) may be first included in a consumer report. As noted above, section 1681t(b)(1) does not preempt all State laws relating to the content or information contained in consumer reports; rather, 1681t(b)(1) preempts only State laws concerning the subject matter regulated under the specified FCRA sections. Hence, as described above, 1681t(b)(1)(E) preempts State laws only with respect to the four specific topics regulated under section 1681c. Section 1681c(a)(7) provides requirements regarding veterans' medical debt, but section 1681c does not regulate the subject matter of medical debt information more generally. Further, although medical debt information may be ''adverse information'' regulated under 1681c((a)(5), as explained above, that provision regulates only the subject of *how long* such information may appear on a consumer report, not the content of the information or when such information may initially appear.

Likewise, if a State law prohibited a furnisher from furnishing information about medical debt for a certain period of time after the debt was incurred, such a law would not be preempted by section 1681t(b)(1)(F), which voids only State laws ''with respect to any subject matter regulated under section 1681s–2 of this title, relating to the responsibilities of persons who furnish information to consumer reporting agencies.'' Section 1681s–2 sets forth several requirements for furnishers in order to assure the accuracy of information provided to consumer reporting agencies. For instance, ''[a] person shall not furnish any information relating to a consumer to any consumer reporting agency if the person knows or has reasonable cause to believe that the information is inaccurate.''[17] However, section 1681s–2 says nothing about when a furnisher may or must begin furnishing information about a consumer's account. Consistent with the discussion above about section 1681, the subject matter of section 1681s–2 that is subject to preemption is limited to these topics that are actually addressed in the section. Accordingly, when a furnisher may or must begin furnishing information about a consumer's account is not a ''subject matter regulated under section 1681s–2.'' Thus, a State law governing when a furnisher may begin furnishing on a consumer's account (including medical debt) would not be preempted by section 1681t(b)(1)(F).

Additionally, for example, the CFPB has noted that rental information in consumer reports plays a critical role in consumers' access to rental housing, credit, and other opportunities.[18] The CFPB has received consumer complaints about receiving collection notices from landlords or debt collectors for rent-related charges and fees they viewed as questionable.[19] These charges may then appear on their consumer reports. Complaints to the CFPB also indicate that tenant screening companies may report inaccurate or misleading criminal and civil information, which led to consumers being denied for housing applications,[20] and the Federal Trade Commission has found that certain tenant screening companies have failed to follow reasonable procedures to ensure the accuracy of their reports about potential tenants.[21] CFPB examiners have also found that the oversight of public records providers by one or more consumer reporting agencies was weak and required corrective action.[22] Further, research suggests that a significant number of eviction records ''contain ambiguous information on how the case was resolved or falsely represent a tenant's eviction history.''[23] There is little or no empirical research showing that tenant screening report content is reliably predictive of future tenant behavior. For example, the CFPB has expressed concern regarding how reliably predictive pandemic era rental data is on a consumer's future performance.[24] To address these concerns and others, States may pass laws addressing the furnishing and reporting of rental information.

A State law prohibiting a consumer reporting agency from including information (or certain types of information) about a consumer's eviction, rental arrears, or arrests on a consumer report would generally not be preempted under section 1681t(b)(1). As noted above, section 1681t(b)(1)(E) preempts State laws only ''with respect to any subject matter regulated under'' section 1681c ''relating to information contained in consumer reports.'' Again, nothing in section 1681c regulates the content of eviction information, rental arrears, or arrest records or when such information may initially appear on a consumer report. Although such information may be information about ''[c]ivil suits, civil judgments, and records of arrest'' regulated under section 1681c((a)(2) or ''adverse information'' regulated under section

[14] CFPB, *Medical Debt Burden in the United States,* at 27 (Feb. 2022), *https://files.consumerfinance.gov/f/documents/cfpb_medical-debt-burden-in-the-united-states_report_2022-03.pdf.*

[15] CFPB, *Data point: Medical debt and credit scores* (May 2014), *https://files.consumerfinance.gov/f/201405_cfpb_report_data-point_medical-debtcredit-scores.pdf.*

[16] *Medical Debt Burden in the United States,* at 27–28.

[17] 15 U.S.C. 1681s–2(a)(1)(A).

[18] CFPB, *Bulletin 2021–03: Consumer Reporting of Rental Information,* at 2 (July 2021), *https://files.consumerfinance.gov/f/documents/cfpb_consumer-reporting-rental-information_bulletin-2021-03_2021-07.pdf.*

[19] CFPB, *Complaint Bulletin: COVID–19 issues described in consumer complaints,* at 14 (July 2021), *https://files.consumerfinance.gov/f/documents/cfpb_covid-19-issues-described-consumer-complaints_complaint-bulletin_2021-07.pdf.*

[20] CFPB, *Complaint Bulletin: COVID–19 issues described in consumer complaints,* at 15, *https://files.consumerfinance.gov/f/documents/cfpb_covid-19-issues-described-consumer-complaints_complaint-bulletin_2021-07.pdf.*

[21] *See FTC* v. *RealPage, Inc.* (Oct. 2018), *https://www.ftc.gov/system/files/documents/cases/152_3059_realpage_inc_stipulated_order_10-16-18.pdf; USA* v. *AppFolio, Inc.* (Dec. 2020), *https://www.ftc.gov/system/files/documents/cases/ecf_1_-_us_v_appfolio_complaint.pdf.*

[22] CFPB, *Supervisory Highlights,* at 6 (Summer 2015), *https://files.consumerfinance.gov/f/201506_cfpb_supervisory-highlights.pdf.*

[23] Adam Porton, Ashley Gromis, and Matthew Desmond, *Inaccuracies in Eviction Records: Implications for Renters and Researchers,* Housing Policy Debate 31:3–5 (Sept. 2021).

[24] CFPB, *Bulletin 2021–03: Consumer Reporting of Rental Information,* at 10 (July 2021), *https://files.consumerfinance.gov/f/documents/cfpb_consumer-reporting-rental-information_bulletin-2021-03_2021-07.pdf.*

1681c((a)(5), as explained above, those provisions regulate only the subject of *how long* such information may appear on a consumer report, not the content of the information. Section 1681t(b)(1) preempts only State laws concerning the subject matter regulated under the specified FCRA sections, and whether or when information such as eviction information, rental arrears, or arrest records appears on a consumer report is not such a subject matter.

B. Under 15 U.S.C. 1681t(b)(5), Only Those State Laws ''With Respect to the Conduct Required by'' Certain Sections or Subsections of the FCRA Are Preempted

Similarly, Congressional purpose in 15 U.S.C. 1681t(b)(5) is evident from its plain text. It has nine subsections, and each follows the same syntax: State laws are preempted to the extent they are ''with respect to the conduct required by the specific provisions of [an enumerated FCRA provision].'' For example, 15 U.S.C. 1681t(b)(5)(E) preempts State laws ''with respect to the conduct required by the specific provisions of section 1681j(a),'' which sets forth requirements for nationwide consumer reporting agencies and nationwide specialty consumer reporting agencies to provide free annual credit reports to consumers. A State law on this topic—for example, a State law requiring consumer reporting agencies to provide semi-annual credit reports to consumers—would likely be ''with respect to the conduct required'' by this provision. On the other hand, if a State law does not concern ''the conduct required by'' the enumerated section—the annual disclosure requirement, in the case of section 1681j(a)—then it is not preempted. For example, section 1681j(a) provides no requirements regarding the language in which disclosures of information are provided. Accordingly, if a State law required that a consumer reporting agency provide information required by the FCRA at the consumer's requests in languages other than English, such a law would generally not be preempted by section 1681t(b)(5)(E).

III. Regulatory Matters

This is an interpretive rule issued under the Bureau's authority to interpret the Dodd-Frank Wall Street Reform and Consumer Protection Act (CFPA), including under section 1022(b)(1) of the CFPA, which authorizes guidance as may be necessary or appropriate to enable the Bureau to administer and carry out the purposes and objectives of Federal consumer financial laws, such as the CFPA.[25]

As an interpretive rule, this rule is exempt from the notice-and-comment rulemaking requirements of the Administrative Procedure Act.[26] Because no notice of proposed rulemaking is required, the Regulatory Flexibility Act does not require an initial or final regulatory flexibility analysis.[27] The Bureau has also determined that this interpretive rule does not impose any new or revise any existing recordkeeping, reporting, or disclosure requirements on covered entities or members of the public that would be collections of information requiring approval by the Office of Management and Budget under the Paperwork Reduction Act.[28]

Pursuant to the Congressional Review Act,[29] the Bureau will submit a report containing this interpretive rule and other required information to the United States Senate, the United States House of Representatives, and the Comptroller General of the United States prior to the rule's published effective date. The Office of Information and Regulatory Affairs has designated this interpretive rule as not a ''major rule'' as defined by 5 U.S.C. 804(2).

Rohit Chopra,

Director, Consumer Financial Protection Bureau.

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–0295; Project Identifier MCAI–2021–00840–R; Amendment 39–22100; AD 2022–13–14]

RIN 2120–AA64

Airworthiness Directives; Airbus Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all Airbus Helicopters Model AS–365N2, AS 365 N3, EC 155B, EC155B1, and SA–365N1 helicopters. This AD was prompted by a large amount of critical scale particles found on the tail rotor gearbox (TGB) chip detector magnetic plug during an unscheduled check of the TGB. The particles belonged to the double bearing (pitch control rod bearing) installed inside the TGB. This AD requires repetitive inspections of the TGB chip detector for particles, analyzing any particles collected, performing a double bearing washing, repetitive replacements of certain part-numbered double bearings, and corrective actions if necessary, as specified in a European Union Aviation Safety Agency (EASA) AD, which is incorporated by reference. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective August 15, 2022.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of August 15, 2022.

ADDRESSES: For EASA material incorporated by reference (IBR) in this final rule, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu*. You may find the EASA material on the EASA website at *https://ad.easa.europa.eu*. For Airbus Helicopters service information identified in this final rule, contact Airbus Helicopters, 2701 N Forum Drive, Grand Prairie, TX 75052; telephone (972) 641–0000 or (800) 232–0323; fax (972) 641–3775; or at *https://www.airbus.com/helicopters/services/technical-support.html*. You may view this material at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110. Service information that is IBRed is also available in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0295.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0295; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the EASA AD, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200

[25] 12 U.S.C. 5512(b)(1).

[26] 5 U.S.C. 553(b).

[27] 5 U.S.C. 603(a), 604(a).

[28] 44 U.S.C. 3501–3521.

[29] 5 U.S.C. 801 *et seq.*

New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Andrea Jimenez, Aerospace Engineer, COS Program Management Section, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 1600 Stewart Ave., Suite 410, Westbury, NY 11590; telephone (516) 228–7330; email *andrea.jimenez@faa.gov*.

SUPPLEMENTARY INFORMATION:

Background

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2021–0170, dated July 19, 2021 (EASA AD 2021–0170), to correct an unsafe condition for all Airbus Helicopters (AH), formerly Eurocopter, Eurocopter France, Aerospatiale, Sud Aviation, Model AS 365 N2, AS 365 N3, EC 155 B, EC 155 B1 and SA 365 N1 helicopters.

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all Airbus Helicopters Model AS–365N2, AS 365 N3, EC 155B, EC155B1, and SA–365N1 helicopters. The NPRM published in the **Federal Register** on April 11, 2022 (87 FR 21052). The NPRM was prompted by a large amount of critical scale particles found on the TGB chip detector magnetic plug during an unscheduled check of a Model AS 365 N2 helicopter. The NPRM proposed to require repetitive inspections of the TGB chip detector for particles, analyzing any particles collected, performing a double bearing washing, repetitive replacements of certain part-numbered double bearings, and corrective actions if necessary, as specified in EASA AD 2021–0170.

The FAA is issuing this AD to prevent bearing degradation and subsequent failure. The unsafe condition, if not addressed, could result in loss of yaw control of the helicopter. See EASA AD 2021–0170 for additional background information.

Discussion of Final Airworthiness Directive

Comments

The FAA received a comment from an anonymous commenter. The commenter did not request any changes to the NPRM or to the determination of costs.

Conclusion

These helicopters have been approved by EASA and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the European Union, EASA has notified the FAA about the unsafe condition described in its AD. The FAA reviewed the relevant data, considered the comments received, and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on these helicopters. This AD is adopted as proposed in the NPRM.

Related Service Information Under 1 CFR Part 51

EASA AD 2021–0170 requires analyzing any particles collected during close monitoring or during any required inspections, repetitive inspections of the TGB chip detector for particles, performing a double bearing washing, and corrective actions. Corrective actions include removing an affected TGB and repairing or replacing that TGB, sending affected parts and certain information to the manufacturer, replacing a TGB chip detector or TGB electrical magnetic plug, and replacing an affected O-ring and double bearing. EASA AD 2021–0170 also requires performing a double bearing washing or performing a metallurgical analysis based on inspection results.

EASA AD 2021–0170 also requires for any double bearing part number (P/N) 704A33–651–245 or 704A33–651–246, installed on any TGB P/N 365A33–6005–09, before exceeding 610 flight hours (FH) since first installation, or within 110 FH after October 28, 2019 (the effective date of EASA AD 2019–0267–E, dated October 25, 2019), whichever occurs later, and thereafter at intervals not to exceed 500 FH, replacing the affected double bearing with a serviceable one. EASA AD 2021–0170 allows double bearing part number P/N 704A33–651–245 or 704A33–651–246 to be installed, provided it has never been installed on a helicopter and it is inspected as required by EASA AD 2021–0170. Finally, EASA AD 2021–0170 allows TGB P/N 365A33–6005–09 to be installed, provided it has a serviceable double bearing installed that is inspected as required by EASA AD 2021–0170.

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

Other Related Service Information

The FAA reviewed Airbus Helicopters Emergency Alert Service Bulletin (EASB) No. 01.00.24 for non FAA-type certificated military Model AS565MA, MB, MBe, SA, SB, and UB helicopters; EASB No. 01.00.71 for Model AS365N1, N2, and N3 helicopters, and non FAA-type certificated military Model AS365F, Fi, K, and K2 helicopters; EASB No. 01.31 for non FAA-type certificated military Model SA366GA helicopters; and EASB No. 04A016 for Model EC155B and B1 helicopters, each Revision 3 and dated June 14, 2021 (co-published as one document).

This service information specifies procedures to inspect the TGB chip detector for particles, analyze and define the particles by performing a metallurgical analysis, perform a washing of the double bearing, replace the double bearing, and send certain information and affected parts to the manufacturer.

Interim Action

The FAA considers this AD to be an interim action. If final action is later identified, the FAA might consider further rulemaking.

Differences Between This AD and EASA AD 2021–0170

Service information referenced in EASA AD 2021–0170 specifies sending compliance forms, and certain parts to the manufacturer; this AD does not. Service information referenced in EASA AD 2021–0170 specifies contacting Airbus Helicopters for approved repairs or corrective actions if certain discrepancies are found, whereas this AD requires accomplishing repairs or corrective actions using a method approved by the Manager, General Aviation and Rotorcraft Section, International Validation Branch, FAA; or EASA; or Airbus Helicopters' EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

Costs of Compliance

The FAA estimates that this AD affects 53 helicopters of U.S. Registry. Labor rates are estimated at $85 per work-hour. Based on these numbers, the FAA estimates the following costs to comply with this AD.

Analyzing any particles collected during close monitoring takes about 1 work-hour for an estimated cost of $85 per inspection and up to $4,505 for the U.S. fleet.

Replacing a double bearing takes about 16 work-hours and parts cost about $1,620 for an estimated cost of $2,980 per replacement and $157,940 for the U.S. fleet.

Inspecting the TGB chip detector for particles takes about 1 work-hour for an estimated cost of $85 per inspection and $4,505 for the U.S. fleet.

Performing a double bearing washing takes about 8 work-hours for an estimated cost of $680 per helicopter.

The FAA estimates the following costs to do any necessary on-condition replacements that are required based on the results of the inspection. The agency has no way of determining the number of aircraft that might need these on-condition replacements:

Analyzing collected particles takes about 1 work-hour for an estimated cost of $85 per helicopter.

Replacing a double bearing takes about 16 work-hours and parts cost about $1,620 for an estimated cost of $2,980 per bearing.

Replacing a TGB chip detector or TGB electrical magnetic plug takes about 1 work-hour and parts cost about $900 for an estimated cost of $985 per part replacement.

Replacing an O-ring takes about 1 work-hour and parts cost about $100 for an estimated cost of $185 per O-ring.

Replacing a TGB takes about 8 work-hours and parts cost about $155,302 for an estimated cost of $155,982 per replacement.

The FAA has received no definitive data for the repair cost of a TGB.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Will not affect intrastate aviation in Alaska, and

(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

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

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:

2022–13–14 Airbus Helicopters: Amendment 39–22100; Docket No. FAA–2022–0295; Project Identifier MCAI–2021–00840–R.

(a) Effective Date

This airworthiness directive (AD) is effective August 15, 2022.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all Airbus Helicopters Model AS–365N2, AS 365 N3, EC 155B, EC155B1, and SA–365N1 helicopters, certificated in any category.

(d) Subject

Joint Aircraft Service Component (JASC) Code 6500, Tail Rotor Drive System.

(e) Unsafe Condition

This AD was prompted by a large amount of critical scale particles found on the tail rotor gearbox (TGB) chip detector magnetic plug during an unscheduled check of the TGB. The particles belonged to the double bearing (pitch control rod bearing) installed inside the TGB. The FAA is issuing this AD to prevent bearing degradation and subsequent failure. The unsafe condition, if not addressed, could result in loss of yaw control of the helicopter.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2021–0170, dated July 19, 2021 (EASA AD 2021–0170).

(h) Exceptions to EASA AD 2021–0170

(1) Where EASA AD 2021–0170 requires compliance in terms of flight hours (FH), this AD requires using hours time-in-service (TIS).

(2) Where EASA AD 2021–0170 refers to the effective dates specified in paragraphs (h)(2)(i) through (iii) of this AD, this AD requires using the effective date of this AD.

(i) October 28, 2019 (the effective date of EASA AD 2019–0267–E, dated October 25, 2019).

(ii) November 19, 2019 (the effective date of EASA AD 2019–0267R1, dated November 12, 2019, and corrected November 13, 2019).

(iii) The effective date of EASA AD 2021–0170.

(3) Where EASA AD 2021–0170 requires actions during each ''after last flight (ALF) of the day inspection'' or ''ALF,'' this AD requires those actions before the first flight of each day.

(4) Where paragraph (7) of EASA AD 2021–0170 specifies ''any discrepancy,'' for this AD discrepancies include the presence of particles and other conditions such as abrasions, particles that consist of any scale, chip, flake, splinter, M50 particles, magnetic abrasion dust, or other particles other than cotter pin fragments, pieces of lock wire, swarf, or miscellaneous non-metallic waste.

(5) Where paragraph (8) of EASA AD 2021–0170 specifies for Group 2 helicopters, the first replacement of the affected part must be accomplished not later than December 31, 2021, this AD requires, for Group 2 helicopters, the first replacement of the affected part as defined in EASA AD 2021–0170 must be accomplished within 5 months after the effective date of this AD.

(6) Where any work card referenced in the service information referenced in EASA AD 2021–0170 specifies ''if there is an anomaly, replace the chip detector,'' or ''if there is an anomaly, replace the TGB electrical magnetic plug,'' for this AD an anomaly may be indicated by the magnetic component of the TGB chip detector or the TGB electrical magnetic plug not being magnetized. If there is an anomaly, this AD requires before further flight, removing from service the TGB chip detector or the TGB electrical magnetic plug as applicable to your model helicopter.

(7) Where any work card referenced in the service information referenced in EASA AD 2021–0170 specifies ''make sure that the chip detector is in good condition,'' or ''make sure that the TGB electrical magnetic plug is in good condition,'' as applicable to your model helicopter, for this AD ''good condition'' is indicated when there are no signs of wear on the locking systems (including wear on the bayonets, and slotted tubes). If there are any signs of wear on the locking systems, this AD requires before further flight, removing from service the TGB chip detector or the TGB magnetic electrical magnetic plug as applicable to your model helicopter.

(8) Where any work card referenced in the service information referenced in EASA AD 2021–0170 specifies ''if necessary, replace the O-rings,'' this AD requires before further

flight, removing any affected O-ring from service.

(9) Where the service information referenced in EASA AD 2021–0170 specifies to return certain parts to the manufacturer, including for repair, this AD does not require returning parts to the manufacturer, however, this AD does require before further flight, repair done in accordance with a method approved by the Manager, General Aviation and Rotorcraft Section, International Validation Branch, FAA; or EASA; or Airbus Helicopters' EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(10) Where the service information referenced in EASA AD 2021–0170 specifies to remove the TGB as per technical documentation, or remove the concerned module(s), this AD requires before further flight, removing the TGB and replacing it with an airworthy part, or repairing the TGB in accordance with a method approved by the Manager, General Aviation & Rotorcraft Section, International Validation Branch, FAA; or EASA; or Airbus Helicopters' EASA DOA. If approved by the DOA, the approval must include the DOA-authorized signature.

(11) Where the service information referenced in EASA AD 2021–0170 specifies if the collected particles cannot be clearly defined, perform a metallurgical analysis and contact Airbus Helicopters, before continuing flights, this AD does require before further flight, characterization of the particles collected, and performing a metallurgical analysis for any particles collected using a method in accordance with FAA-approved procedures. However, this AD does not require contacting the manufacturer to determine the characterization of the particles collected.

(12) Where the service information or any work card referenced in EASA AD 2021–0170 specifies to do the actions identified in paragraphs (h)(12)(i) through (v) of this AD, this AD does not include those requirements.

(i) Complete Appendix 4.A and 4.B.

(ii) Comply with paragraph 2.D.

(iii) Send all collected particles and metallurgical analysis report to depot level maintenance facility with the concerned module.

(iv) Inform EST using chip detection tracking sheet.

(v) Complete the ''Particle Detection'' follow up sheet.

(13) Where a work card referenced in the service information referenced in EASA AD 2021–0170 specifies ''send all oversized particles for analysis and wait for results before continuing flight,'' this AD does not require sending particles for analysis, however this AD does require before further flight, analyzing the particles using a method in accordance with FAA-approved procedures.

(14) This AD does not mandate compliance with the ''Remarks'' section of EASA AD 2021–0170.

(15) Where paragraph (7) of EASA AD 2021–0170 specifies to accomplish the applicable corrective actions ''within the compliance time as identified in the applicable ASB,'' this AD requires accomplishing corrective actions before further flight.

(16) Where paragraph (1) of EASA AD 2021–0170 specifies ''within the applicable compliance time as identified in the close monitoring and until completion of the close monitoring,'' this AD requires a close monitoring compliance time of a total of 25 hours TIS.

(i) No Reporting Requirement

Although the service information referenced in EASA AD 2021–0170 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(j) Special Flight Permit

Special flight permits may be issued in accordance with 14 CFR 21.197 and 21.199, provided no passengers are onboard.

(k) Alternative Methods of Compliance (AMOCs)

(1) The Manager, International Validation 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 International Validation Branch, send it to the attention of the person identified in paragraph (l) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.*

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

(l) Related Information

For more information about this AD, contact Andrea Jimenez, Aerospace Engineer, COS Program Management Section, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 1600 Stewart Ave., Suite 410, Westbury, NY 11590; telephone (516) 228–7330; email *andrea.jimenez@faa.gov.*

(m) 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 this AD specifies otherwise.

(i) European Union Aviation Safety Agency (EASA) AD 2021–0170, dated July 19, 2021.

(ii) [Reserved]

(3) For EASA AD 2021–0170, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find the EASA material on the EASA website at *https://ad.easa.europa.eu.*

(4) You may view this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110. This material may be found in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0295.

(5) You may view this material 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 June 16, 2022.

Christina Underwood,

Acting Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022–14589 Filed 7–8–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–0809; Project Identifier MCAI–2022–00711–G; Amendment 39–22116; AD 2022–14–11]

RIN 2120–AA64

Airworthiness Directives; Stemme AG (Type Certificate Previously Held by Stemme GmbH & Co. KG) Gliders

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Stemme AG (type certificate previously held by Stemme GmbH & Co. KG) Model Stemme S 12 gliders. This AD was prompted by mandatory continuing airworthiness information (MCAI) issued by the aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI identifies the unsafe condition as a deviation in the construction of the connection of the inner wing to the outer wing, resulting in a wrong positioning of the glass-fiber reinforced plastic (GFRP) blocks. This AD requires inspecting the left-hand (LH) and right-hand (RH) outer wing spars for correct positioning of the GFRP blocks and, if incorrect positioning is found, repairing of the reinforcement blocks. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective July 26, 2022.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of July 26, 2022.

The FAA must receive comments on this AD by August 25, 2022.

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 Stemme AG, Flugplatzstrasse F2 Nr. 6–7, Strausberg, Germany; phone: +49 3341 3612 0; email: *airworthiness@stemme.de;* website: *https://stemme.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 (817) 222–5110. It is also available at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0809.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0809; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the MCAI, any comments received, and other information. The street address for the Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Jim Rutherford, Aviation Safety Engineer, General Aviation & Rotorcraft Section, International Validation Branch, FAA, 901 Locust, Room 301, Kansas City, MO 64106; phone: (816) 329–4165; email: *jim.rutherford@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The European Union Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA Emergency AD 2022–0101–E, dated June 2, 2022 (referred to after this as ''the MCAI''), to address an unsafe condition on certain serial-numbered Stemme AG Model Stemme S12 powered sailplanes (gliders). The MCAI states:

An occurrence was reported by the production line of the Stemme S12 of finding a deviation in the construction of the connection of the inner wing to the outer wing, resulting in a wrong positioning of the glass-fibre reinforced plastic (GFRP) blocks in the outer wing spar.

This condition, if not corrected, could lead to loss of structural integrity at the joint (connection) between the outer wing and inner wing, possibly resulting in rupture of the affected wing, with consequent loss of control of the sailplane.

To address this potential unsafe condition, Stemme identified the sailplanes possibly affected by this unintended production deviation and issued the SB [service bulletin], as defined in this [EASA] AD, to provide instructions to determine the (correct) positioning of the GFRP blocks in the outer wing spars.

For the reasons described above, this [EASA] AD requires a one-time inspection of each affected part and, depending on findings, accomplishment of applicable corrective action(s).

This [EASA] AD is considered to be an interim action and further AD action may follow.

You may examine the MCAI in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0809.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Stemme Procedural Instruction P320–912060, Revision 00, dated May 20, 2022. This service information specifies procedures for inspecting the LH and RH outer wing spars for correct positioning of the GFRP reinforcement blocks, including sealing the inspection holes. 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**.

Other Related Service Information

The FAA also reviewed Stemme Service Bulletin P062–980060, Revision 00, dated May 20, 2022. This service information specifies inspecting the LH and RH outer wing spars for correct positioning of the GFRP reinforcement blocks by following Stemme Procedural Instruction P320–912060, Revision 00, dated May 20, 2022. This service information also prohibits operation and informing Stemme AG if incorrect positioning is found.

FAA's Determination

This product has been approved by the aviation authority of another country and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI and service information referenced above. The FAA is issuing this AD because it has determined the unsafe condition described previously is likely to exist or develop on other products of the same type design.

AD Requirements

This AD requires accomplishing the actions specified in the service information already described, except as discussed under ''Differences Between this AD and the MCAI.''

Differences Between This AD and the MCAI

The MCAI specifies contacting Stemme for approved corrective action instructions, and this AD requires using a repair method approved by the FAA, EASA, or Stemme AG's Design Organization Approval.

Interim Action

The FAA considers this AD to be an interim action. The design approval holder is currently developing a modification that will address the unsafe condition identified in this AD. Once this modification is developed, approved, and available, the FAA might 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 waiving notice and comment prior to adoption of this rule because loss of structural integrity between the inner and outer wing sections could cause a sudden rupture of the affected wing and consequent loss of glider control. Therefore, the inspection and any necessary repair must be accomplished before further flight. 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–2022–0809 and Project Identifier MCAI–2022–00711–G'' 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 Jim Rutherford, Aviation Safety Engineer, General Aviation & Rotorcraft Section, International Validation Branch, FAA, 901 Locust, Room 301, Kansas City, MO 64106. 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 21 gliders of U.S. registry.

The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per glider	Cost on U.S. operators
Inspect reinforcement blocks	2 work-hours × $85 per hour = $170	$100	$270	$5,670

The FAA estimates the following costs to replace reinforcement blocks on both sides, if required based on the results of the inspection. The FAA has no way of determining the number of gliders that might need this action:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per glider
Replace both reinforcement blocks	16 work-hours × $85 per hour = $1,360	$1,000	$2,360

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:

2022–14–11 Stemme AG (Type Certificate Previously Held by Stemme GmbH & Co. KG): Amendment 39–22116; Docket No. FAA–2022–0809; Project Identifier MCAI–2022–00711–G.

(a) Effective Date

This airworthiness directive (AD) is effective July 26, 2022.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Stemme AG (type certificate previously held by Stemme GmbH & Co. KG) Model Stemme S 12 gliders, serial numbers 12–002 through 12–042 inclusive and serial number 12–044, certificated in any category.

(d) Subject

Joint Aircraft System Component (JASC) Code 5700, Wing Structure.

(e) Unsafe Condition

This AD was prompted by mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI identifies the unsafe condition as a deviation in the construction of the connection of the inner wing to the outer wing, resulting in a wrong positioning of the left-hand (LH) and right-hand (RH) outer wing spar glass-fiber reinforced plastic (GFRP) blocks. The FAA is issuing this AD to detect wrong positioning of the GFRP blocks, which, if not corrected, could cause a rupture of the affected wing and consequent loss of control of the glider.

(f) Compliance

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

(g) Inspection and Replacement

Before further flight after the effective date of this AD, inspect the LH and RH outer wing spars for positioning of the GFRP blocks by following Working Steps 1.1 through 3.2 in Stemme Procedural Instruction P320–912060, Revision 00, dated May 20, 2022.

(1) If a GFRP block is correctly positioned, seal the inspection holes by following Working Steps 4.1 through 4.3 in Stemme Procedural Instruction P320–912060, Revision 00, dated May 20, 2022.

(2) If a GFRP block is incorrectly positioned, before further flight, repair using a method approved by the FAA; the European Union Aviation Safety Agency (EASA); or Stemme AG's Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(h) Alternative Methods of Compliance (AMOCs)

(1) The Manager, International Validation 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 International Validation Branch, send it to the attention of the person identified in paragraph (i)(1) of this AD and email to: *9-AVS-AIR-730-AMOC@faa.gov.*

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

(i) Related Information

(1) For more information about this AD, contact Jim Rutherford, Aviation Safety Engineer, General Aviation & Rotorcraft Section, International Validation Branch, FAA, 901 Locust, Room 301, Kansas City, MO 64106; phone: (816) 329–4165; email: *jim.rutherford@faa.gov.*

(2) Refer to EASA Emergency AD 2022–0101–E, dated June 2, 2022, for more information. You may examine the EASA AD at *https://www.regulations.gov* in Docket No. FAA–2022–0809.

(j) Material Incorporated by Reference

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

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

(i) Stemme Procedural Instruction P320–912060, Revision 00, dated May 20, 2022.

Note 1 to paragraph (j)(2)(i): This service information contains German to English translation. EASA used the English translation in referencing the document from Stemme. For enforceability purposes, the FAA will cite the service information in English as it appears on the document.

Note 2 to paragraph (j)(2)(i): Only the first page of the document contains the document date.

(ii) [Reserved]

(3) For service information identified in this AD, contact Stemme AG, Flugplatzstrasse F2 Nr. 6–7, Strausberg, Germany; phone: +49 3341 3612 0; email: *airworthiness@stemme.de;* website: *https://stemme.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 (817) 222–5110.

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

Issued on June 29, 2022.

Christina Underwood,

Acting Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022–14810 Filed 7–7–22; 4:15 pm]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–0859; Airspace Docket No. 19–AAL–57]

RIN 2120–AA66

Establishment of United States Area Navigation (RNAV) Route T–390; St. Paul Island, AK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes United States Area Navigation (RNAV) route T–390 in the vicinity of St. Paul Island, AK in support of a large and comprehensive T-route modernization project for the state of Alaska.

DATES: Effective date 0901 UTC, September 8, 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 Rules and Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Jesse Acevedo, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

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 the 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 expands the availability of RNAV in Alaska and improve the efficient flow of air traffic

within the National Airspace System by lessening the dependency on ground based navigation.

History

The FAA published a notice of proposed rulemaking for Docket No. FAA–2021–0859 in the **Federal Register** (86 FR 58814; October 25, 2021), establishing United States Area Navigation (RNAV) route T–390 in the vicinity of St. Paul Island, AK in support of a large and comprehensive T-route modernization project for the state of Alaska. Interested parties were invited to participate in this rulemaking effort by submitting comments on the proposal. There were no comments received.

United States Area Navigation Routes are published in paragraph 6011 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 RNAV route listed in this document would be published subsequently in FAA Order JO 7400.11F.

Differences From the NPRM

Subsequent to the publication of the NPRM for Docket No. FAA–2021–0859 in the **Federal Register** (86 FR 58814; October 25, 2021), establishing United States Area Navigation (RNAV) route T–390 in the vicinity of St. Paul Island, AK, the FAA determined it was necessary to and rename the ZEKTI waypoint (WP) to the DUMZU WP to comply with FAA administrative guidance for FIX-name reservations. Additionally, the FAA determined it was necessary to relocate the WANKI and ZEKTI (now DUMZU) waypoints to address instrument flight procedure concerns related to two points (*i.e.* FIX, navigational aid, waypoints) being located too close to one another. As a result, the latitude/long geographic coordinates for the WANKI and DUMZU waypoints are changed from what was proposed in the NPRM. This change moves the waypoints by approximately 600-feet from the location as proposed in the NPRM. This rule incorporates these changes.

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 Rule

This action amends 14 CFR part 71 by establishing RNAV route T–390 in the vicinity of St. Paul Island, AK in support of a large and comprehensive T-route modernization project for the state of Alaska.

The route is described below.

T–390: This action establishes T–390 from the WANKI, AK, WP to the DUMZU, AK, WP located adjacent to the Iliamna, AK, (ILI) Non-Directional Beacon (NDB).

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

Regulatory Notices and Analyses

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

Environmental Review

The FAA determined that this airspace action of establishing RNAV route T–390 in the vicinity of St. Paul Island, AK qualifies for categorical exclusion under the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) and its implementing regulations at 40 CFR part 1500, and in accordance with FAA Order 1050.1F, Environmental Impacts: Policies and Procedures, paragraph 5–6.5a, which categorically excludes from further environmental impact review rulemaking actions that designate or modify classes of airspace areas, airways, routes, and reporting points (see 14 CFR part 71, Designation of Class A, B, C, D, and E Airspace Areas; Air Traffic Service Routes; and Reporting Points), and paragraph 5–6.5i, which categorically excludes from further environmental review the establishment of new or revised air traffic control procedures conducted at 3,000 feet or more above ground level (AGL); procedures conducted below 3,000 feet AGL that do not cause traffic to be routinely routed over noise sensitive areas; modifications to currently approved procedures conducted below 3,000 feet AGL that do not significantly increase noise over noise sensitive areas; and increases in minimum altitudes and landing minima. As such, this action is not expected to result in any potentially significant environmental impacts. In accordance with FAA Order 1050.1F, paragraph 5–2 regarding Extraordinary Circumstances, the FAA has reviewed this action for factors and circumstances in which a normally categorically excluded action may have a significant environmental impact requiring further analysis. Accordingly, the FAA has determined that no extraordinary circumstances exist that warrant preparation of an environmental assessment or environmental impact study.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Amendment

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

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

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

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

§ 71.1 [Amended]

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

Paragraph 6011 United States Area Navigation Routes.

* * * * *

T–390 WANKI, AK to ZEKTI, AK [New]

WANKI, AK WP (Lat. 57°09′20.20″ N, long. 170°13′52.46″ W)

DIBWO, AK	WP	(Lat. 56°19′43.49″ N, long. 169°13′13.14″ W)
ALEUT, AK	WP	(Lat. 54°14′16.58″ N, long. 166°32′51.82″ W)
ZEBUV, AK	WP	(Lat. 54°18′15.84″ N, long. 165°56′54.35″ W)
TESPE, AK	WP	(Lat. 54°55′58.89″ N, long. 164°46′55.85″ W)
King Salmon, AK (AKN)	VORTAC	(Lat. 58°43′28.97″ N, long. 156°45′08.45″ W)
DUMZU, AK	WP	(Lat. 59°44′53.05″ N, long. 154°54′46.79″ W)

* * * * *

Issued in Washington, DC, on July 1, 2022.

Scott M. Rosenbloom,

Manager, Airspace Rules and Regulations.

[FR Doc. 2022–14494 Filed 7–8–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–0865; Airspace Docket No. 21–AAL–24]

RIN 2120–AA66

Establishment of United States Area Navigation (RNAV) Route T–417; Tok Junction, AK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes United States Area Navigation (RNAV) route T–417 in the vicinity of Tok Junction, AK in support of a large and comprehensive T-route modernization project for the state of Alaska.

DATES: Effective date 0901 UTC, September 8, 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 Rules and Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Jesse Acevedo, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

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 the 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 expands the availability of RNAV in Alaska and improve the efficient flow of air traffic within the National Airspace System by lessening the dependency on ground based navigation.

History

The FAA published a notice of proposed rulemaking for Docket No. FAA–2021–0865 in the **Federal Register** (86 FR 59670; October 28, 2021), establishing United States Area Navigation (RNAV) route T–417 in the vicinity of Tok Junction, AK in support of a large and comprehensive T-route modernization project for the state of Alaska. Interested parties were invited to participate in this rulemaking effort by submitting comments on the proposal. There were no comments received.

United States Area Navigation Routes are published in paragraph 6011 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 RNAV route listed in this document will be published subsequently in FAA Order JO 7400.11F.

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 action amends 14 CFR part 71 by establishing RNAV route T–417 in the vicinity of Tok Junction, AK in support of a large and comprehensive T-route modernization project for the state of Alaska.

The route is described below.

T–417: This action establishes T–417 extending between the CEBUN, AK, waypoint (WP) located to the southwest of Northway, AK and the EGAXE, AK, FIX located to the west of Tok Junction Airport (PFTO).

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

Regulatory Notices and Analyses

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

Environmental Review

The FAA determined that this airspace action of establishing RNAV route T–417 in the vicinity of Tok Junction, AK qualifies for categorical exclusion under the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) and its implementing regulations at 40 CFR part 1500, and in accordance with FAA Order 1050.1F, Environmental Impacts: Policies and Procedures, paragraph 5–6.5a, which categorically excludes from further environmental impact review rulemaking actions that designate or modify classes of airspace areas, airways, routes, and reporting points (see 14 CFR part 71, Designation of Class A, B, C, D, and E Airspace Areas; Air Traffic Service Routes; and Reporting Points), and paragraph 5–6.5i, which categorically excludes from

further environmental review the establishment of new or revised air traffic control procedures conducted at 3,000 feet or more above ground level (AGL); procedures conducted below 3,000 feet AGL that do not cause traffic to be routinely routed over noise sensitive areas; modifications to currently approved procedures conducted below 3,000 feet AGL that do not significantly increase noise over noise sensitive areas; and increases in minimum altitudes and landing minima. As such, this action is not expected to result in any potentially significant environmental impacts. In accordance with FAA Order 1050.1F, paragraph 5–2 regarding Extraordinary Circumstances, the FAA has reviewed this action for factors and circumstances in which a normally categorically excluded action may have a significant environmental impact requiring further analysis. Accordingly, the FAA has determined that no extraordinary circumstances exist that warrant preparation of an environmental assessment or environmental impact study.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Amendment

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

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

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

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

§ 71.1 [Amended]

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

Paragraph 6011 United States Area Navigation Routes.

* * * * *

T–417 CEBUN, AK to EGAXE, AK [New]

CEBUN, AK	WP	(Lat. 62°38′09.30″ N, long. 144°16′27.61″ W)
HATIX, AK	WP	(Lat. 63°04′36.80″ N, long. 143°28′48.02″ W)
EGAXE, AK	FIX	(Lat. 63°26′31.64″ N, long. 143°36′50.29″ W)

* * * * *

Issued in Washington, DC, on July 1, 2022.

Scott M. Rosenbloom,

Manager, Airspace Rules and Regulations.

[FR Doc. 2022–14495 Filed 7–8–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–0848; Airspace Docket No. 19–AAL–41]

RIN 2120–AA66

Establishment of United States Area Navigation (RNAV) Route T–372; Gulkana, AK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes United States Area Navigation (RNAV) route T–372 in the vicinity of Gulkana, AK in support of a large and comprehensive T-route modernization project for the state of Alaska.

DATES: Effective date 0901 UTC, September 8, 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 Rules and Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Jesse Acevedo, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

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 the 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 expand the availability of RNAV in Alaska and improve the efficient flow of air traffic within the National Airspace System by lessening the dependency on ground based navigation.

History

The FAA published a notice of proposed rulemaking for Docket No. FAA–2021–0848 in the **Federal Register** (86 FR 58609; October 22, 2021), establishing United States Area Navigation (RNAV) route T–372 in the vicinity of Gulkana, AK in support of a large and comprehensive T-route modernization project for the state of Alaska. Interested parties were invited to participate in this rulemaking effort by submitting comments on the proposal. There were no comments received.

United States Area Navigation Routes are published in paragraph 6011 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 RNAV route listed in this document will be published subsequently in FAA Order JO 7400.11F.

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 action amends 14 CFR part 71 by establishing RNAV route T–372 in the vicinity of Gulkana, AK in support of a large and comprehensive T-route modernization project for the state of Alaska.

The route is described below.

T–372: This action establishes T–372 from the Big Lake, AK, (BGQ) VHF Omnidirectional Range and Tactical Air Navigational System (VORTAC) to the OLARU, AK, FIX, on the Canadian border south east of the Northway, AK, (ORT) VORTAC.

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

Regulatory Notices and Analyses

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

Environmental Review

The FAA determined that this airspace action of establishing RNAV route T–372 in the vicinity of Gulkana, AK qualifies for categorical exclusion under the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) and its implementing regulations at 40 CFR part 1500, and in accordance with FAA Order 1050.1F, Environmental Impacts: Policies and Procedures, paragraph 5–6.5a, which categorically excludes from further environmental impact review rulemaking actions that designate or modify classes of airspace areas, airways, routes, and reporting points (see 14 CFR part 71, Designation of Class A, B, C, D, and E Airspace Areas; Air Traffic Service Routes; and Reporting Points), and paragraph 5–6.5i, which categorically excludes from further environmental review the establishment of new or revised air traffic control procedures conducted at 3,000 feet or more above ground level (AGL); procedures conducted below 3,000 feet AGL that do not cause traffic to be routinely routed over noise sensitive areas; modifications to currently approved procedures conducted below 3,000 feet AGL that do not significantly increase noise over noise sensitive areas; and increases in minimum altitudes and landing minima. As such, this action is not expected to result in any potentially significant environmental impacts. In accordance with FAA Order 1050.1F, paragraph 5–2 regarding Extraordinary Circumstances, the FAA has reviewed this action for factors and circumstances in which a normally categorically excluded action may have a significant environmental impact requiring further analysis. Accordingly, the FAA has determined that no extraordinary circumstances exist that warrant preparation of an environmental assessment or environmental impact study.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Amendment

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

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

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

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

§ 71.1 [Amended]

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

Paragraph 6011 United States Area Navigation Routes.

* * * * *

T–372 Big Lake (BGQ), AK to OLARU, AK [New]

Big Lake, AK (BGQ)	VORTAC	(Lat. 61°34′09.96″ N, long. 149°58′01.77″ W)
WUNTU, AK	WP	(Lat. 61°39′45.05″ N, long. 149°01′19.62″ W)
CAGOP, AK	WP	(Lat. 61°45′11.32″ N, long. 148°41′36.03″ W)
FITAT, AK	WP	(Lat. 61°48′13.09″ N, long. 148°25′58.83″ W)
TOYOC, AK	WP	(Lat. 61°50′01.83″ N, long. 148°09′21.18″ W)
ZAMUP, AK	WP	(Lat. 61°50′11.52″ N, long. 148°00′30.00″ W)
CANGI, AK	WP	(Lat. 61°49′36.38″ N, long. 147°49′10.69″ W)
WAPRU, AK	WP	(Lat. 61°53′10.56″ N, long. 147°24′11.32″ W)
HOSON, AK	WP	(Lat. 61°55′03.32″ N, long. 147°12′53.20″ W)
SMOKY, AK	WP	(Lat. 62°03′19.52″ N, long. 146°18′31.81″ W)
Gulkana, AK(GKN)	VOR/DME	(Lat. 62°09′13.51″ N, long. 145°26′50.51″ W)
BEFTI, AK	WP	(Lat. 62°33′28.06″ N, long. 144°27′09.48″ W)
CEBUN, AK	WP	(Lat. 62°38′09.30″ N, long. 144°16′27.61″ W)
Northway, AK (ORT)	VORTAC	(Lat. 62°56′49.92″ N, long. 141°54′45.39″ W)
OLARU, AK	FIX	(Lat. 62°28′52.33″ N, long. 141°00′00.00″ W)

* * * * *

Issued in Washington, DC, on July 1, 2022.

Scott M. Rosenbloom,

Manager, Airspace Rules and Regulations.

[FR Doc. 2022–14496 Filed 7–8–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–0108; Airspace Docket No. 22–AAL–5]

RIN 2120–AA66

Revocation of Colored Federal Airway Blue 5 (B–5); Point Hope, AK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action revokes Colored Federal airway Blue 5 (B–5) in the vicinity of Point Hope, AK due to the pending decommissioning of the Point Hope, AK, (PHO) Non-directional Beacon (NDB).

DATES: Effective date 0901 UTC, September 8, 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 Rules and Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Jesse Acevedo, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

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 the 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 modifies the route to preserve the safe and efficient flow of air traffic within the National Airspace System.

History

The FAA published a notice of proposed rulemaking for Docket No. FAA–2022–0108 in the **Federal Register** (87 FR 10995; February 28, 2022), revoking Colored Federal airway B–5 in the vicinity of Point Hope, AK due to the pending decommissioning of the Point Hope, AK, (PHO) NDB. Interested parties were invited to participate in this rulemaking effort by submitting comments on the proposal. There were no comments received.

The Area Navigation (RNAV) T–route, T–366, will overlay the existing B–5 airway and have the same lower minimum enroute altitude. T–366 will be established and charted with a publication date coinciding with the B–5 revocation of September 8, 2022.

Colored Federal airways are published in paragraph 6009(d) 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 Colored Federal airway listed in this document will be removed subsequently from FAA Order JO 7400.11.

Differences From the NPRM

Subsequent to the notice of proposed rulemaking for Docket No. FAA–2022–0108 in the **Federal Register** (87 FR 10995; February 28, 2022), revoking Colored Federal airway B–5 in the vicinity of Point Hope, AK, an FAA study revealed that aircraft have not been able to fly B–5 because the Point Hope, AK, (PHO) NDB has not been operational for several years. Further, a radar traffic study of the Colored Federal airway B–5 annual usage verified that no non-Global Positioning System (GPS) equipped aircraft have used B–5. The airway is essentially abandoned. Additionally, the operator of the Point Hope NDB, has no intention of restoring the NDB site since it is already approved for decommissioning. Based on this information, this action revokes the Colored Federal airway B–5 in its entirety.

Availability and Summary of Documents for Incorporation by Reference

This 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 action amends 14 CFR part 71 by revoking Colored Federal airway B–5. B–5 currently navigates between the Cape Lisburne, AK, (LUR) NDB and the Point Hope, AK, (PHO) Non-directional Beacon (NDB). This action revokes the Colored Federal airway B–5 in its entirety.

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

Regulatory Notices and Analyses

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

Environmental Review

The FAA determined that this airspace action of revoking Colored Federal airway Blue–5 (B–5) in the vicinity of Point Hope, AK qualifies for categorical exclusion under the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) and its implementing regulations at 40 CFR part 1500, and in accordance with FAA Order 1050.1F, Environmental Impacts: Policies and Procedures, paragraph 5–6.5a, which categorically excludes from further environmental impact review rulemaking actions that designate or modify classes of airspace areas, airways, routes, and reporting points (see 14 CFR part 71, Designation of Class A, B, C, D, and E Airspace Areas; Air Traffic Service Routes; and Reporting Points), and paragraph 5–6.5k, which categorically excludes from

further environmental review the publication of existing air traffic control procedures that do not essentially change existing tracks, create new tracks, change altitudes, or change concentration of aircraft on these tracks. As such, this action is not expected to result in any potentially significant environmental impacts. In accordance with FAA Order 1050.1F, paragraph 5–2 regarding Extraordinary Circumstances, the FAA has reviewed this action for factors and circumstances in which a normally categorically excluded action may have a significant environmental impact requiring further analysis. Accordingly, the FAA has determined that no extraordinary circumstances exist that warrant preparation of an environmental assessment or environmental impact study.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

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 6009(d) Colored Federal Airway.

* * * * *

B–5 [Removed]

* * * * *

Issued in Washington, DC, on July 5, 2022.

Scott M. Rosenbloom,

Manager, Airspace Rules and Regulations.

[FR Doc. 2022–14667 Filed 7–8–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–0813; Airspace Docket No. 19–AAL–74]

RIN 2120–AA66

Amendment of United States Area Navigation (RNAV) Route T–275; Bethel, AK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends United States Area Navigation (RNAV) route T–275 in the vicinity of Bethel, AK in support of a large and comprehensive T-route modernization project for the state of Alaska.

DATES: Effective date 0901 UTC, September 8, 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 Rules and Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Jesse Acevedo, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

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 the 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 expands the availability of RNAV in Alaska and improve the efficient flow of air traffic within the National Airspace System by lessening the dependency on ground based navigation.

History

The FAA published a notice of proposed rulemaking for Docket No. FAA–2021–0813 in the **Federal Register** (86 FR 55754; October 7, 2021), amending United States Area Navigation (RNAV) route T–275 in the vicinity of Bethel, AK in support of a large and comprehensive T-route modernization project for the state of Alaska. Interested parties were invited to participate in this rulemaking effort by submitting comments on the proposal. There were no comments received.

United States Area Navigation Routes are published in paragraph 6011 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 RNAV route listed in this document would be published subsequently in FAA Order JO 7400.11.

Differences From the NPRM

Subsequent to the publication of the NPRM for Docket No. FAA–2021–0813 in the **Federal Register** (86 FR 55754; October 7, 2021), amending United States Area Navigation (RNAV) route T–275 in the vicinity of Bethel, AK, the FAA determined it was necessary to relocate the ZIKNI waypoint (WP) to address instrument flight procedure concerns related to two points (*i.e.,* fix, navigational aid, WPs) being located too close to one another. As a result, the latitude/longitude geographic coordinates for the WP are changed from what was proposed in the NPRM. This change moves the WP by approximately 600-feet from the location as proposed in the NPRM. The regulatory text in this action incorporates this change.

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 action amends 14 CFR part 71 by amending RNAV route T–275 in the vicinity of Bethel, AK in support of a large and comprehensive T-route

modernization project for the state of Alaska.

The route changes are described below.

T–275: T–275 extends from the Bethel, AK, (BET) VHF Omnidirectional Range Tactical Air Navigation (VORTAC) and the Unalakleet, AK, (UNK) VOR Distance Measuring Equipment (VOR/DME). This action extends the route south from the Bethel, AK, (BET) VORTAC to provide alternate navigation for Colored Federal airway B–7. An additional turn point is added between the Bethel, AK, (BET) VORTAC and the Unalakleet, AK, (UNK) VOR/DME taking the airway slightly to the west to allow for better route connectivity with other proposed and current T-routes. The resulting T-route extends between the ZIKNI, AK, WP and the Unalakleet, AK, (UNK) VOR/DME.

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

Regulatory Notices and Analyses

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

Environmental Review

The FAA determined that this airspace action of amending RNAV route T–275 in the vicinity of Bethel, AK qualifies for categorical exclusion under the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) and its implementing regulations at 40 CFR part 1500, and in accordance with FAA Order 1050.1F, Environmental Impacts: Policies and Procedures, paragraph 5–6.5a, which categorically excludes from further environmental impact review rulemaking actions that designate or modify classes of airspace areas, airways, routes, and reporting points (see 14 CFR part 71, Designation of Class A, B, C, D, and E Airspace Areas; Air Traffic Service Routes; and Reporting Points), and paragraph 5–6.5i, which categorically excludes from further environmental review the establishment of new or revised air traffic control procedures conducted at 3,000 feet or more above ground level (AGL); procedures conducted below 3,000 feet AGL that do not cause traffic to be routinely routed over noise sensitive areas; modifications to currently approved procedures conducted below 3,000 feet AGL that do not significantly increase noise over noise sensitive areas; and increases in minimum altitudes and landing minima. As such, this action is not expected to result in any potentially significant environmental impacts. In accordance with FAA Order 1050.1F, paragraph 5–2 regarding Extraordinary Circumstances, the FAA has reviewed this action for factors and circumstances in which a normally categorically excluded action may have a significant environmental impact requiring further analysis. Accordingly, the FAA has determined that no extraordinary circumstances exist that warrant preparation of an environmental assessment or environmental impact study.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Amendment

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

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

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

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

§ 71.1 [Amended]

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

Paragraph 6011 United States Area Navigation Routes.

* * * * *

T–275 ZIKNI, AK to Unalakleet, AK (UNK) [Amended]

ZIKNI, AK	WP	(Lat. 58°39′21.68″ N, long. 162°04′13.87″ W)
Bethel, AK (BET)	VORTAC	(Lat. 60°47′05.41″ N, long. 161°49′27.59″ W)
DAVBE, AK	WP	(Lat. 61°50′52.64″ N, long. 161°30′41.89″ W)
Unalakleet, AK (UNK)	VOR/DME	(Lat. 63°53′30.99″ N, long. 160°41′03.39″ W)

* * * * *

Issued in Washington, DC, on July 5, 2022.

Scott M. Rosenbloom,

Manager, Airspace Rules and Regulations.

[FR Doc. 2022–14666 Filed 7–8–22; 8:45 am]

BILLING CODE 4910–13–P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1241

[CPSC Docket No. 2020–0023]

Safety Standard for Crib Mattresses; Correction

AGENCY: Consumer Product Safety Commission.

ACTION: Final rule; correction.

SUMMARY: On February 15, 2022, the U.S. Consumer Product Safety Commission (CPSC) promulgated a final rule establishing a safety standard for crib mattresses. The crib mattress rule incorporated by reference a voluntary standard for crib mattresses that had been published by ASTM International (ASTM) and provided a uniform resource locator (URL) allowing the public to link to ASTM's website to retrieve a read-only, free copy of ASTM's voluntary standard for crib mattresses. In this document, CPSC is correcting the URL for ASTM's website stated in the final rule.

DATES: This correction is effective on August 15, 2022.

FOR FURTHER INFORMATION CONTACT: Alberta E. Mills, Division of the

Secretariat, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, Maryland 20814, telephone: 301–504–7479; email: *cpsc-os@cpsc.gov.*

SUPPLEMENTARY INFORMATION: The Commission's regulation at 16 CFR part 1241, titled ''Safety Standard for Crib Mattresses,'' provides a URL to access the voluntary standard incorporated by reference into CPSC's mandatory standard. That voluntary standard, ASTM F2933–21, Standard Consumer Safety Specification for Crib Mattresses (approved on June 15, 2021) (ASTM F2933–21), will be available for viewing free of charge on the ASTM website once the rule becomes effective on August 15, 2022. 87 FR 8640 (Feb. 15, 2022). Section 1241.2(a) of the Safety Standard for Crib Mattresses states: ''Once incorporated by reference, you may review a read-only copy of ASTM F2933–21 at *http://www.astm.org/READINGROOM/.*'' 87 FR 8674. This URL is incorrect, and the public should be directed instead to: *https://www.astm.org/READINGLIBRARY/.* Accordingly, the Commission issues this final rule to update 16 CFR 1241.2(a) with the correct URL citation for the ASTM reading library containing voluntary standards incorporated by reference into regulations. This document does not make any substantive changes to the final rule.

Correction

In FR Doc. 2022–02414 appearing on page 8640 in the **Federal Register** of Tuesday, February 15, 2022, the following correction is made:

§ 1241.2 [Corrected]

■ 1. On page 8674, in the first column, in § 1241.2, in paragraph (a), remove the term ''*http://www.astm.org/READINGROOM/*'' and add ''*https://www.astm.org/READINGLIBRARY/*'' in its place.

List of Subjects in 16 CFR Part 1241

Consumer protection, Imports, Incorporation by reference, Infants and children, Labeling, Law enforcement, Mattresses.

Alberta E. Mills, Secretary,

United States Consumer Product Safety Commission.

[FR Doc. 2022–14649 Filed 7–8–22; 8:45 am]

BILLING CODE 6355–01–P

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 270

[Release Nos. 34–95148A; IA–6056A; IC–34635A; File No. S7–15–21]

RIN 3235–AM97

Electronic Submission of Applications for Orders Under the Advisers Act and the Investment Company Act, Confidential Treatment Requests for Filings on Form 13F, and Form ADV–NR; Amendments to Form 13F

AGENCY: Securities and Exchange Commission.

ACTION: Final rule; correction.

SUMMARY: This document makes a technical correction to an amendment concerning the electronic submission of applications for orders under the Investment Company Act, as adopted in Release No. 34–95148 (June 23, 2022) (''Adopting Release''), which was published in the **Federal Register** on June 30, 2022.

DATES: Effective August 29, 2022.

FOR FURTHER INFORMATION CONTACT: Zeena Abdul-Rahman, Branch Chief; Sara Cortes, Senior Special Counsel; or Brian McLaughlin Johnson, Assistant Director, at (202) 551–6792, Investment Company Regulation Office, Division of Investment Management; or Alexis Palascak, Senior Counsel at (202) 551–6787 or *IArules@sec.gov,* Investment Adviser Regulation Office, Division of Investment Management, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–8549.

SUPPLEMENTARY INFORMATION: We are making a technical amendment to correct § 270.0–2. Specifically, this document amends Instruction 12.b. published in the Adopting Release to correct a sentence reference.

In document FR doc. 2022–13936, which was published in the **Federal Register** on June 30, 2022, at 87 FR 38943, the following correction is made:

§ 270.0–2 [Corrected]

■ 1. On page 38976, in the second column, Instruction 12.b. for § 270.0–2 is corrected to read as follows: ''Removing the sixth sentence in paragraph (b).''

Dated: July 6, 2022.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–14683 Filed 7–8–22; 8:45 am]

BILLING CODE 8011–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2022–0506]

Safety Zone; Four Seasons Hotel Fireworks Display Event, New Orleans, LA

AGENCY: Coast Guard, DHS.

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce a temporary safety zone for a fireworks display located on the navigable waters of the Lower Mississippi River (LMR) between Mile Marker (MM) 94.5 and MM 95.5 Above Head of Passes (AHP). This action is needed to provide for the safety of life on these navigable waterways during the event. During the enforcement periods, the operator of any vessel in the regulated area must comply with directions from the Captain of the Port or designated representative.

DATES: The regulations in 33 CFR 165.845 will be enforced from 8:30 p.m. to 10 p.m. on July 21, 2022.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, call or email Lieutenant Commander William Stewart, Sector New Orleans, U.S. Coast Guard; telephone 504–365–2246, email *William.A.Stewart@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce safety zone located in 33 CFR 165.845 for the Four Seasons Hotel Fireworks Display event. The regulations will be enforced from 8:30 p.m. through 10 p.m. on July 21, 2022. This action is being taken to provide for the safety of life on navigable waterways during this event, which will be located between MM 94.5 and MM 95.5 AHP, LMR, LA. During the enforcement periods, the operator of any vessel in the regulated area must comply with directions from the Captain of the Port or designated representative.

In addition to this notification of enforcement in the **Federal Register**, the Coast Guard plans to provide notification of this enforcement period via Marine Safety Information Bulletins (MSIBs), Local Notice to Mariners (LNMs), and/or Broadcast Notice to Mariners (BNMs).

Dated: July 5, 2022.

K.K. Denning,

Captain, U.S. Coast Guard, Captain of the Port Sector New Orleans.

[FR Doc. 2022–14695 Filed 7–8–22; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2022–0145; FRL–9844–02–R4]

Air Plan Approval; Alabama; NO_X SIP Call

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve a State Implementation Plan (SIP) revision submitted by the State of Alabama, through the Alabama Department of Environmental Management (ADEM), in a letter dated October 18, 2021. The revision includes corrections to deficiencies to Alabama's regulation titled ''NO_X Budget Program Monitoring and Reporting'' (AL NO_X SIP Call Monitoring Rule), which EPA previously conditionally approved into the SIP. Specifically, the AL NO_X SIP Call Monitoring Rule establishes monitoring and reporting requirements for units subject to the nitrogen oxides (NO_X) SIP Call, including alternative monitoring options for certain sources of NO_X. EPA is also taking final action to convert the conditional approval to a full approval. In addition, EPA is approving other minor changes into the SIP.

DATES: This rule is effective August 10, 2022.

ADDRESSES: All documents in the docket are listed on the *www.regulations.gov* website. Although listed in the index, some information may not be publicly available, *i.e.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. EPA requests that if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Steven Scofield, Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. The telephone number is (404) 562–9034. Mr. Scofield can also be reached via electronic mail at *scofield.steve@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Under Clean Air Act (CAA or Act) section 110(a)(2)(D)(i)(I), also called the good neighbor provision, states are required to address the interstate transport of air pollution. Specifically, the good neighbor provision requires that each state's implementation plan contain adequate provisions to prohibit air pollutant emissions from within the state that will significantly contribute to nonattainment of the national ambient air quality standards (NAAQS), or that will interfere with maintenance of the NAAQS, in any other state.

On October 27, 1998 (63 FR 57356), EPA finalized the ''Finding of Significant Contribution and Rulemaking for Certain States in the Ozone Transport Assessment Group Region for Purposes of Reducing Regional Transport of Ozone'' (NO_X SIP Call). The NO_X SIP Call required eastern states, including Alabama, to submit SIPs that prohibit excessive emissions of ozone season NO_X by implementing statewide emissions budgets.[1] The NO_X SIP Call addressed the good neighbor provision for the 1979 ozone NAAQS and was designed to mitigate the impact of transported NO_X emissions, one of the precursors of ozone.[2] EPA developed the NO_X Budget Trading Program, an allowance trading program that states could adopt to meet their obligations under the NO_X SIP Call. This trading program allowed the following sources to participate in a regional cap and trade program: generally, electricity generating units (EGUs) with capacity greater than 25 megawatts (MW); and large industrial non-EGUs, such as boilers and combustion turbines, with a rated heat input greater than 250 million British thermal units per hour (MMBtu/hr). The NO_X SIP Call also identified potential reductions from cement kilns and stationary internal combustion engines.

To comply with the NO_X SIP Call requirements, in 2001, ADEM submitted a revision to add new rule sections to the SIP-approved version of Alabama Administrative Code Chapter 335–3–1, General Provisions, and Chapter 335–3–8, Control of Nitrogen Oxides Emissions. EPA approved the revision as compliant with Phase I of the NO_X SIP Call in 2001. *See* 66 FR 36919 (July 16, 2001). The approved revision required EGUs and large non-EGUs in the State to participate in the NO_X Budget Trading Program beginning in 2004. In 2005, Alabama submitted, and EPA approved, a SIP revision to address additional emissions reductions required for the NO_X SIP Call under Phase II. *See* 70 FR 76694 (December 28, 2005).

In 2005, EPA published the Clean Air Interstate Rule (CAIR), which required several eastern states, including Alabama, to submit SIPs that prohibited emissions consistent with revised ozone season NO_X budgets (as well as annual budgets for NO_X and sulfur dioxide). *See* 70 FR 25162 (May 12, 2005); *see also* 71 FR 25328 (April 28, 2006). CAIR addressed the good neighbor provision for the 1997 ozone NAAQS and 1997 fine particulate matter ($PM_{2.5}$) NAAQS and was designed to mitigate the impact of transported NO_X emissions with respect to ozone and $PM_{2.5}$. CAIR established several trading programs that EPA implemented through Federal implementation plans (FIPs) for EGUs greater than 25 MW in each affected state, but not large non-EGUs; states could submit SIPs to replace the FIPs that achieved the required emission reductions from EGUs and/or other types of sources.[3] When the CAIR trading program for ozone season NO_X was implemented beginning in 2009, EPA discontinued administration of the NO_X Budget Trading Program; however, the requirements of the NO_X SIP Call continued to apply.

On October 1, 2007 (72 FR 55659), EPA approved revisions to Alabama's SIP that incorporated requirements for CAIR. Consistent with CAIR's requirements, EPA approved a SIP revision in which Alabama regulations: (1) sunset its NO_X Budget Trading

[1] *See* 63 FR 57356 (October 27, 1998).

[2] As originally promulgated, the NO_X SIP Call also addressed good neighbor obligations under the 1997 8-hour ozone NAAQS, but EPA subsequently stayed and later rescinded the rule's provisions with respect to that standard. *See* 65 FR 56245 (September 18, 2000); 84 FR 8422 (March 8, 2019).

[3] CAIR had separate trading programs for annual sulfur dioxide (SO_2) emissions, seasonal NO_X emissions, and annual NO_X emissions.

Program requirements, and (2) incorporated CAIR annual and ozone season NO_X state trading programs. *See* 72 FR 55659. Participation of EGUs in the CAIR ozone season NO_X trading program addressed the State's obligation under the NO_X SIP Call for those units, and Alabama also chose to require non-EGUs subject to the NO_X SIP Call to participate in the same CAIR trading program. In this manner, Alabama's CAIR rules incorporated into the SIP addressed the State's obligations under the NO_X SIP Call with respect to both EGUs and non-EGUs.

The United States Court of Appeals for the District of Columbia Circuit (D.C. Circuit) initially vacated CAIR in 2008, but ultimately remanded the rule to EPA without vacatur to preserve the environmental benefits provided by CAIR. *See North Carolina* v. *EPA,* 531 F.3d 896, *modified on rehearing,* 550 F.3d 1176 (D.C. Cir. 2008). The ruling allowed CAIR to remain in effect temporarily until a replacement rule consistent with the court's opinion was developed. While EPA worked on developing a replacement rule, the CAIR program continued to be implemented with the NO_X annual and ozone season trading programs beginning in 2009 and the SO_2 annual trading program beginning in 2010.

Following the D.C. Circuit's remand of CAIR, EPA promulgated the Cross-State Air Pollution Rule (CSAPR) to replace CAIR and address good neighbor obligations for the 1997 ozone NAAQS, the 1997 $PM_{2.5}$ NAAQS, and the 2006 $PM_{2.5}$ NAAQS. *See* 76 FR 48208 (August 8, 2011). Through FIPs, CSAPR required EGUs in eastern states, including Alabama, to meet annual and ozone season NO_X emission budgets and annual SO_2 emission budgets implemented through new trading programs. Implementation of CSAPR began on January 1, 2015.[4] CSAPR also contained provisions that would sunset CAIR-related obligations on a schedule coordinated with the implementation of the CSAPR compliance requirements. Participation by a state's EGUs in the CSAPR trading program for ozone season NO_X generally addressed the state's obligation under the NO_X SIP Call for EGUs. CSAPR did not initially contain provisions allowing states to incorporate large non-EGUs into that trading program to meet the requirements of the NO_X SIP Call for non-EGUs. EPA also stopped administering CAIR trading programs with respect to emissions occurring after December 31, 2014.[5]

To comply with CSAPR, Alabama adopted SO_2 and NO_X CSAPR trading program rules, including budgets, in ADEM Administrative Code Chapters 335–3–5 and 335–3–8. On August 31, 2016, EPA approved Alabama's CSAPR annual SO_2 and annual NO_X trading program rules into the SIP.[6] *See* 81 FR 59869. Because EPA stopped administering the CAIR trading programs after 2014, the approved CAIR rules in Alabama's SIP have not been implemented for several years. Furthermore, ADEM repealed all CAIR and CAIR-related regulations from Alabama Administrative Code Chapters 335–3–1, 335–3–5, and 335–3–8 on December 9, 2011.[7] Even though the CAIR programs were not being implemented in Alabama, ozone season NO_X emissions have remained well below the NO_X SIP Call budget levels.

After litigation that reached the Supreme Court, the D.C. Circuit generally upheld CSAPR but remanded several state budgets to EPA for reconsideration. *EME Homer City Generation, L.P.* v. *EPA,* 795 F.3d 118, 129–30 (D.C. Cir. 2015). EPA addressed the remanded ozone season NO_X budgets in the Cross-State Air Pollution Rule Update for the 2008 Ozone NAAQS (CSAPR Update), which also partially addressed eastern states' good neighbor obligations for the 2008 ozone NAAQS. *See* 81 FR 74504 (October 26, 2016). The air quality modeling for the CSAPR Update demonstrated that Alabama contributes significantly to nonattainment and/or interferes with maintenance of the 2008 ozone NAAQS in other states. The CSAPR Update reestablished an option for most states to meet their ongoing obligations for non-EGUs under the NO_X SIP Call by including the units in the CSAPR Update trading program.

The CSAPR Update trading program replaced the original CSAPR trading program for ozone season NO_X for most covered states. On October 6, 2017, EPA approved Alabama's CSAPR Update ozone season NO_X trading program rules for EGUs into Alabama's SIP.[8] *See* 82 FR 46674.[9] Alabama's EGUs participate in the CSAPR Update trading program, generally also addressing the state's obligations under the NO_X SIP Call for EGUs. However, Alabama elected not to include its large non-EGUs in the CSAPR Update ozone season trading program. Because Alabama's large non-EGUs no longer participate in any CSAPR or CSAPR Update trading program for ozone season NO_X emissions, the NO_X SIP Call regulations at 40 CFR 51.121(r)(2), as well as anti-backsliding provisions at 40 CFR 51.905(f) and 40 CFR 51.1105(e), require these non-EGUs to maintain compliance with NO_X SIP Call requirements in some other way.

Under 40 CFR 51.121(f)(2) of the NO_X SIP Call regulations, where a state's implementation plan contains control measures for EGUs and large non-EGU boilers and combustion turbines, the SIP must contain enforceable limits on the ozone season NO_X mass emissions from these sources. In addition, under 40 CFR 51.121(i)(4) of the NO_X SIP Call regulations as originally promulgated, the SIP also had to require these sources to monitor emissions according to the provisions of 40 CFR part 75, which generally entails the use of continuous emission monitoring systems (CEMS). Alabama triggered these requirements by including control measures in its SIP for these types of sources, and the requirements have remained in effect despite the discontinuation of the NO_X Budget Trading Program after the 2008 ozone season.

On March 8, 2019, EPA revised some of the regulations that were originally promulgated in 1998 to implement the NO_X SIP Call.[10] The revision gave states covered by the NO_X SIP Call greater flexibility concerning the form of the NO_X emissions monitoring requirements that the states must include in their SIPs

[4] *See* 79 FR 71663 (December 3, 2014).

[5] *See* 79 FR 71663 (December 3, 2014) and 81 FR 13275 (March 14, 2016).

[6] In the 2016 action, EPA did not act on the portion of Alabama's SIP submittal intended to replace Alabama units' obligations to participate in CSAPR's Federal trading program for ozone-season NO_X emissions.

[7] Although CAIR-related regulations were repealed from ADEM Administrative Code on December 11, 2011, the repeal of the regulations was not effective until February 20, 2015. EPA removed the repealed regulations from the SIP, effective August 6, 2021. *See* 86 FR 35610 (July 7, 2021).

[8] This action approved CSAPR and CSAPR Update-related provisions of Alabama SIP submissions dated October 26, 2015, and May 19, 2017.

[9] In subsequent litigation, the D.C. Circuit upheld the CSAPR Update in virtually all respects but remanded it because it was partial in nature and did not fully eliminate upwind states' significant contribution to nonattainment or interference with maintenance of the 2008 ozone NAAQS by ''the relevant downwind attainment deadlines'' in the CAA. *Wisconsin* v. *EPA,* 938 F.3d 303, 313–15 (D.C. Cir. 2019). To address the remand, in 2021 EPA issued the Revised CSAPR Update, in which the Agency determined (among other things) that the requirements established for Alabama in the CSAPR Update did in fact constitute a full remedy for the State's good neighbor obligations with respect to the 2008 ozone NAAQS. 86 FR 23054, 23054 (April. 30, 2021).

[10] *See* ''Emissions Monitoring Provisions in State Implementation Plans Required Under the NO_X SIP Call,'' 84 FR 8422 (March 8, 2019).

for certain emissions sources. The revision amended 40 CFR 51.121(i)(4) to make part 75 monitoring, recordkeeping, and reporting optional, such that SIPs may establish alternative monitoring requirements for NO_X SIP Call budget units that meet the general requirements of 40 CFR 51.121(f)(1) and (i)(1). Under the updated provision, a state's implementation plan still needs to include some form of emissions monitoring requirements for these types of sources, consistent with the NO_X SIP Call's general enforceability and monitoring requirements at 40 CFR 51.121(f)(1) and (i)(1), respectively, but states are no longer required to satisfy these general NO_X SIP Call requirements specifically through the adoption of 40 CFR part 75 monitoring requirements.

Through a letter to EPA, dated February 27, 2020, ADEM provided a SIP revision to incorporate changes to Alabama's Administrative Code, Chapter 335–3–8, to include Rule 335–3–8–.71, *NO_X Budget Program,* and Rule 335–3–8–.72, *NO_X Budget Program Monitoring and Reporting,* to maintain the State's compliance with the Federal NO_X SIP Call regulations at 40 CFR 51.121 and 51.122, and to provide alternative monitoring options for certain large non-EGUs. Subsequently, on September 15, 2020, ADEM sent a letter requesting that EPA conditionally approve Rule 335–3–8–.72 and committing to provide a SIP revision to EPA by July 7, 2022, to address a deficiency related to misplacement of stack testing requirements within Rule 335–3–8–.72(1).[11] Based on the State's commitment to submit a SIP revision addressing the identified deficiency, EPA conditionally approved the February 27, 2020, submission on July 7, 2021. *See* 86 FR 35610.[12]

In accordance with EPA's conditional approval and ADEM's commitment, the State submitted a SIP revision on October 18, 2021.[13] The submission corrects the deficiency in Rule 335–3–8–.72(1) and requests EPA to convert the previous conditional approval into a full approval. As proposed through a notice of proposed rulemaking (NPRM) published on May 16, 2022, EPA is approving the October 18, 2021, revision to the Alabama SIP and converting the conditional approval to a full approval of ADEM's Rule 335–3–8–.72. For a comprehensive discussion of EPA's analysis and rationale for approving the State's submittal, please refer to EPA's May 16, 2022, NPRM. *See* 87 FR 29707 (May 16, 2022). Comments on the May 16, 2022, NPRM were due on or before June 15, 2022. EPA received one comment on that proposal, and it supports EPA's proposed action.

II. Incorporation by Reference

In this document, EPA is finalizing regulatory text that includes incorporation by reference. In accordance with the requirements of 1 CFR 51.5, and as discussed in Section I of this preamble, EPA is finalizing the incorporation by reference of Alabama's Administrative Code Rule 335–3–8–.72, *NO_X Budget Program Monitoring and Reporting,* which establishes emission monitoring requirements for units subject to the NO_X SIP call, state effective December 13, 2021. EPA has made, and will continue to make, these materials generally available through *www.regulations.gov* and at the EPA Region 4 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information). Therefore, the revised materials as stated above, 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 by the Director of the Federal Register in the next update to the SIP compilation.[14]

III. Final Action

EPA is taking final action to approve Alabama's October 18, 2021, submission, which revises Alabama Rule 335–3–8–.72, *NO_X Budget Program Monitoring and Reporting,* to correct the stack testing requirement by moving it from 335–3–8–.72(1)(c) to 335–3–8–.72(1)(d) and correct language in 335–3–8–.72(d) to refer to NO_X mass emissions. In addition, EPA is taking final action to convert the July 7, 2021, conditional approval of Alabama Rule 335–3–8–.72 to a full approval.

IV. Statutory and Executive Order Reviews

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

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- 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 (Public Law 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

The SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9,

[11] These stack testing requirements were mistakenly added to 335–3–8–.72(1)(c), which allows sources to fulfill NO_X SIP call monitoring requirements by operating a NO_X CEMS outside of part 75 requirements, instead of 335–3–8–.72(1)(d), which uses emissions factors.

[12] In the same action, EPA approved removal of the CAIR trading program, removal of the NO_X Budget Trading Program rules, and the State's renumbering of the existing regulation titled ''New Combustion Sources'' from Rule 335–3–8–.14 to Rule 335–3–8–.05.

[13] EPA notes that the submission was received by the Regional Office on October 20, 2021. However, for clarity, this document refers to the letter date of October 18, 2021.

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

2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law.

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

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 9, 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, Ozone, Reporting and recordkeeping requirements.

Dated: June 30, 2022.

Daniel Blackman,

Regional Administrator, Region 4.

For the reasons stated in the preamble, the EPA amends 40 CFR part 52 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 B—Alabama

§ 52.49 [Removed and Reserved]

■ 2. Remove and reserve § 52.49.

■ 3. In § 52.50(c), amend the table by revising the entry for ''Section 335–3–8–.72'' to read as follows:

§ 52.50 Identification of plan.

* * * * *

(c) * * *

EPA-APPROVED ALABAMA REGULATIONS

State citation	Title/subject	State effective date	EPA approval date	Explanation
*	*	*	*	*
Section 335–3–8–.72	NO_X Budget Program Monitoring and Reporting.	12/13/2021	7/11/2022, [Insert citation of publication].	
*	*	*	*	*

* * * * *

[FR Doc. 2022–14538 Filed 7–8–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R10–OAR–2021–0751: FRL–9211–02–R10]

Air Plan Approval; Washington; Yakima Regional Clean Air Agency, General Air Quality Regulations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving revisions to the Washington State Implementation Plan (SIP) that were submitted by the Department of Ecology (Ecology) in coordination with the Yakima Regional Clean Air Agency (YRCAA). In 2014, 2015, 2016, and 2020, the EPA approved revisions to the General Regulations for Air Pollution Sources promulgated by Ecology in the Washington Administrative Code (WAC). In this action, the EPA is approving an update to the SIP for YRCAA's jurisdiction to reflect these changes to the WAC. We are also approving updates to certain YRCAA regulations currently in the SIP, removing obsolete regulations, and approving a small set of YRCAA regulations to replace or supplement the corresponding WAC regulations for sources in YRCAA's jurisdiction.

DATES: This final rule is effective August 10, 2022.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R10–OAR–2021–0751. 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.,* CBI or other information the disclosure of which is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and is publicly available only in hard copy form. Publicly available docket materials are available at *https://www.regulations.gov,* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

FOR FURTHER INFORMATION CONTACT: Jeff Hunt, EPA Region 10, 1200 Sixth Avenue—Suite 155, Seattle, WA 98101, at (206) 553–0256, or *hunt.jeff@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document wherever ''we,'' ''us,'' or ''our'' is used, it is intended to refer to the EPA.

I. Background Information

On December 7, 2021, the EPA proposed to approve Washington's October 14, 2021, SIP revision for YRCAA's jurisdiction as meeting Clean Air Act (CAA) requirements (86 FR 69200). The public comment period for the proposed action ended on January 6, 2022.

II. Response to Comments

The EPA received three comments on the proposal. We have summarized and responded to the comments below. The full text of the submitted comments may be found in the docket for this action.

Comment—Emission data, as defined by the EPA, and other data used in preparation of plans must be publicly available.

Summary—A commenter requested confirmation that ''emission data'' is not entitled to confidential treatment under YRCAA Regulation 1, section 1.06 *Records.* Specifically, subsection 1.06(D) treats as confidential records ''any information, other than ambient air quality data or emission data'' that is certified by an owner or operator as meeting certain requirements, subject to review by the agency. The commenter noted that Regulation 1 does not contain a definition of ''emission data'' and requested that YRCAA confirm that it will apply section 1.06 consistent with the EPA's definition of ''emissions data'' in 40 CFR 2.301(a)(2). The commenter also states that Regulation 1 cannot exempt information that is ''used in the preparation of each plan or plan revision,'' citing to 40 CFR 51.116. The commenter gave as an example of such information the identification of a manufacturing process that is used to estimate emissions from the facility for purposes of an attainment plan, and notes that this is an example of emission data, which is not entitled to confidential treatment.

Response—In response to the comment, the EPA has evaluated the commenter's concern about the meaning of the term ''emissions data'' in subsection 1.06(D) and verified that the YRCCA uses this term consistent with CAA requirements. YRCAA has submitted a letter confirming that the agency interprets the term ''emission data'' consistent with the EPA's definition of ''emissions data'' in 40 CFR 2.301(a)(2). YRCAA's letter notes that this interpretation is consistent with the language in YRCAA Regulation 1, section 1.06 stating that the application of this provision is ''to provide access to any information available under Federal or state law concerning the business of the agency.'' Although inclusion of a specific definition of ''emissions data'' in section 1.06 could be helpful, the EPA is relying on YRCAA's confirmation of the meaning of this term as part of the basis for this action. A copy of YRCAA's letter is included in the docket for this action.

The EPA agrees that it is important to have clarity about the meaning of the term ''emissions data'' in SIPs. As a specific example of potential ambiguity about what is emissions data, the commenter states: ''One example could be identification of a manufacturing process that is used to estimate emissions from the facility for purposes of an attainment plan. Even if the facility claims the identification of the manufacturing process is confidential, it is used in preparation of the plan and must be disclosed to the public.'' The commenter then correctly notes that in this hypothetical scenario, if identification of the manufacturing process is in fact necessary information in order to estimate the emissions from the source, then this information is ''emissions data'' under the EPA's definition in 40 CFR 2.301(a)(2). The EPA agrees that any information that meets the definition of ''emissions data'' in 40 CFR 2.301(a)(2) must be available to the public and may not be treated as confidential information.

It is unclear whether the commenter's statement that ''Regulation 1 cannot exempt information that is 'used in the preparation of each plan or plan revision''' is limited to ''emission data'' used in the preparation of a plan or plan revision, or whether the commenter is making a broader statement that no information whatsoever used in preparation of a state implementation plan or plan revision may be treated as confidential and withheld from the public. To the extent the commenter is broadly asserting that no information used in preparation of a state implementation plan or plan revision may be treated as confidential, the EPA disagrees with that position.

Section 114(d) of the CAA addresses the extent to which certain information obtained by the EPA under the CAA, including information used for the purpose of developing or assisting in the development of any implementation plan under section 110 of the CAA, is entitled to confidential treatment. There is nothing in 40 CFR part 2, subpart B or part 51, however, to suggest that the EPA intended to require states to make available to the public information used in the preparation of an implementation plan or plan revision that would be entitled to confidential treatment under section 114(d) of the CAA. As noted by the commenter, however, any such claims may not extend to ''emission data,'' as defined in 40 CFR 2.301(a)(2), which YRCAA has confirmed is the case under YRCAA Regulation 1, section 1.06. We therefore are finalizing our proposal to approve section 1.06 into the SIP to replace WAC 173–400–175 Public Information within YRCAA's jurisdiction.

Comment—The EPA must fully disclose the legal effects of its approval of section 4.03 ''Voluntary Limits on Emissions''.

Summary—Section 4.03 *Voluntary Limits on Emissions* of YRCAA Regulation 1, states in subsection (A), ''Upon request by the owner or operator of a new or existing source or stationary source, the agency shall issue a regulatory order that limits the potential to emit any air contaminant or contaminants to a level agreed to by the owner or operator and the agency.'' A commenter noted that the EPA had not stated in its proposed approval whether regulatory orders issued pursuant to section 4.03 can be enforced by the EPA under CAA section 113 or by citizens under CAA section 304. The commenter goes on to explain why it believes regulatory orders issued under YRCAA Region I, section 4.03 are enforceable by the EPA and citizens under the CAA.

Response—YRCAA Regulation 1, section 4.03 is a nearly verbatim adaptation of the state regulation WAC 173–400–091 *Voluntary Limits on Emissions,* which the EPA last approved on October 3, 2014 (79 FR 59653).[1] In 40 CFR 52.2495 *Voluntary limits on potential to emit,* the EPA explicitly stated that the terms and conditions of regulatory orders covering regulated new source review pollutants issued pursuant to WAC 173–400–091 shall be applicable requirements of the federally-approved Washington SIP for the purposes of CAA section 113 and shall be enforceable by the EPA and by any person in the same manner as other requirements of the SIP. We interpret 40 CFR 52.2495 to apply to any local clean air agency corollary regulation approved in lieu of WAC 173–400–091, as well as the Energy Facilities Site Evaluation Council's adoption by reference of WAC 173–400–091. We are revising 40 CFR 52.2495 with this clarification to remove any ambiguity on this issue. With this clarification, we are finalizing our proposal to approve section 4.03 into the SIP to replace WAC 173–400–091 Voluntary Limits on Emissions.

Comment—A commenter questions whether the EPA should approve a SIP for a clean air agency when the commenter asserts there are ongoing complaints about the agency's legitimacy.

Summary—A commenter identifies what it considers to be numerous concerns with YRCAA agency leadership and program implementation and enforcement. The concerns include that the proposed SIP revision was not signed by all YRCAA board members, a board member rarely attends YRCAA board meetings, and that permitting decisions are made by staff and not board members. The letter also summarizes a recent request made by the commenter to the Yakima County Commissioners to dissolve the YRCAA.

[1] Please see the docket for a redline/strikeout comparison of section 4.03 and WAC 173–400–091.

The commenter summarized concerns raised in their dissolution request, including allegations that YRCAA does not address significant air pollution in a part of its jurisdiction that is an environmental justice community, that YRCAA has refused to acknowledge environmental justice, that YRCAA refused to investigate complaints regarding odor and dust when the source is animal agriculture, that YRCAA does not measure levels of ammonia, hydrogen sulfide, methane, oxygen, or other pollutants when citizens complain that they cannot breathe due to air pollution in their homes, that YRCAA ignores Washington laws regulating confined animal feeding operations and that YRCAA does not regulate dairies in Yakima County.

Response— The commenter questions whether the EPA should approve a SIP for YRCAA because the commenter contends there are ongoing concerns about the legitimacy of the YRCAA and states that it has requested Yakima County to dissolve YRCAA. In response to those concerns, we note that YRCAA is established as a local air authority under Revised Code of Washington (RCW) 70A.15.1500 to 70A.15.2040 of the Washington Clean Air Act. The Washington Clean Air Act contains a mechanism for the state to investigate and address concerns with local air agency performance. Specifically, under RCW 70A.15.3100, the Department of Ecology ''may, on its own motion, conduct a hearing held in accordance with chapters 42.30 and 34.05 RCW, to determine whether or not the air pollution prevention and control program of such authority is being carried out in good faith and is as effective as possible. If at such hearing the department finds that such authority is not carrying out its air pollution control or prevention program in good faith, is not doing all that is possible and reasonable to control and/or prevent air pollution within the geographical area over which it has jurisdiction, or is not carrying out the provisions of this chapter, it shall set forth in a report or order to the appropriate authority: (1) Its recommendations as to how air pollution prevention and/or control might be more effectively accomplished; and (2) guidelines which will assist the authority in carrying out the recommendations of the department.'' In letters dated August 31, 2016 and April 8, 2019, included in the docket for this action, Ecology responded to past requests for formal review of YRCAA under RCW 70A.15.3100 (previously codified at RCW 70.94.405) from the commenter based on similar concerns raised by the commenter about the legitimacy of YRCAA. For the reasons set forth in the response letters, Ecology did not initiate a formal review of YRCAA under RCW 70A.15.3100.

With respect to the specific proposed rulemaking update, the Washington Department of Ecology is the Governor's designee for SIP revisions. In March 2021, YRCAA submitted the revised rules to Ecology and requested Ecology submit them to the EPA for review and approval into the SIP. Ecology held two public comment periods from April 8, 2021 to May 20, 2021 and July 30, 2021 to August 6, 2021, with supplemental documentation. During the state public comment periods, the commenter, and other associated commenters, raised concerns similar to those raised during the EPA's public comment period in this action. On October 4, 2021, Ecology's Director, Laura Watson, as the Governor's designee, reviewed the results of the public review process and made the determination to adopt the SIP revision and submit it to the EPA for review and approval. Ecology's response to comments is included in the SIP revision and was reviewed by the EPA prior to our proposed approval. As Ecology notes in its responses, if Ecology does not submit the current YRCAA regulations to the EPA for review and approval, the YRCAA rules that were in place in 1989 would continue to be the rules that the EPA and the public can enforce in Federal court, and would not correspond to the rules YRCAA currently implements, creating uncertainty for the public, regulated community and regulatory agencies. We agree with that assessment.

With respect to the EPA's review of the more specific comments raised by this commenter during the public comment period in this action, many of the concerns, such as the regulation of odor and toxic air pollutants regulated under Chapter 173–460 WAC, are outside the scope of this action. The EPA's authority to approve SIP submissions extends to provisions related to attainment and maintenance of the National Ambient Air Quality Standards through regulation of criteria pollutants and their precursors and carrying out other specific requirements of section 110 and Parts C and D of the CAA. To the extent that the commenter raises concerns regarding YRCAA's regulation of precursors to criteria pollutants, such as ammonia and volatile organic compounds, none of the comments address a specific deficiency in a regulation that the EPA proposed to approve in this action. In this regard, we note that Yakima County is not designated nonattainment for any criteria pollutants and this SIP revision was not submitted to address any outstanding CAA Part D nonattainment requirements.

With respect to the assertion that YRCAA ignores specified Washington laws with respect to confined animal feeding operations, the commenter does not explain the basis for its concerns with any specificity. Several of the provisions cited by the commenter are clearly outside the scope of this action: RCW 70.15.2270 (addressing fees under Washington's title V operating permit program) and WAC 173–460 (toxic air pollutants). RCW 70A.15.1005 (declaration of public policies and purpose), and RCW 70A.15.3150, (penalties) are broad, authorizing legislation, and the commenter does not explain how YRCAA is ignoring these statutes and how such an allegation relates to the EPA's authority to approve the revisions and updates to the Washington SIP. RCW 70A.15.3050 (emission control requirements) provides that local air authorities in Washington must generally have requirements for the control of emissions that are no less stringent than those adopted by the Washington Department of Ecology. The commenter does not explain with any specificity, however, how the YRCAA regulations that the EPA proposed to approve in this action are less stringent than Ecology's regulations. In this regard, the EPA notes that it has proposed to approve subsection 3.08(B) *Dust from Cattle Feeding Operations,* which adds additional requirements to supplement the state requirements in WAC 173–400–040(9) *Fugitive Dust.* Because no equivalent requirements for dust control plans at cattle feeding operations exist in state or Federal regulations, subsection 3.08(B) *Dust from Cattle Feeding Operations* is SIP-strengthening. The commenter also cites to WAC 173–400–100, Washington's registration requirements. This regulation, however, is not in the SIP. See 79 FR 39351 (July 10, 2014) at page 39354.

In summary, the commenter raises broad concerns about YRCAA program implementation and enforcement of air pollution control requirements but does not raise specific Regulation 1 provisions for the EPA to address or specify any action the EPA should take differently with regards to the submitted regulations.

III. Final Action

A. Regulations Approved and Incorporated by Reference Into the SIP

The EPA is approving general air quality regulations for the YRCAA jurisdiction. These regulations impose new source review permitting requirements, source registration requirements, source testing procedures, public participation requirements, control measures for certain source categories such as dust control requirements, and other general provisions as necessary to implement the requirements above, such as definitions and procedures. Specifically, the EPA is approving and incorporating by reference into the Washington SIP at 40 CFR 52.2470(c)—*Table 10—Additional Regulations Approved for the Yakima Regional Clean Air Agency (YRCAA) Jurisdiction,* the following YRCAA Regulation 1 sections effective November 11, 2020:

- 1.01, 1.02, 1.03, 1.04, 1.06, 1.07, 2.04, 3.01, 3.08, 4.01, 4.03, Appendix A, and Appendix B.

The EPA is also approving and incorporating by reference the following Chapter 173–400 WAC sections (state effective as of the date shown below) that YRCAA and Ecology submitted to apply within YRCAA's jurisdiction:

- 173–400–020 (12/29/2012), 173–400–025 (9/16/2018), 173–400–030 (9/16/2018), 173–400–036 (12/29/2012), 173–400–040 (9/16/2018), 173–400–050 (9/16/2018), 173–400–060 (11/25/2018), 173–400–105 (11/25/2018), 173–400–110 (12/29/2012), 173–400–111 (07/01/2016), 173–400–112 (12/29/2012), 173–400–113 (12/29/2012), 173–400–117 (12/29/2012), 173–400–118 (12/29/2012), 173–400–131 (4/1/2011), 173–400–136 (4/1/2011), 173–400–151 (2/10/2005), 173–400–171 (9/16/2018), 173–400–200 (2/10/2005), 173–400–560 (12/29/2012), 173–400–800 (4/1/2011), 173–400–810 (07/01/2016), 173–400–820 (12/29/2012), 173–400–830 (07/01/2016), 173–400–840 (07/01/2016), 173–400–850 (07/01/2016), and 173–400–860 (4/1/2011).

Please see the amendatory text for more detailed information about the provisions submitted and approved in this action, including local agency corollaries which replace certain Chapter 173–400 WAC provisions and exclusions to our approval.

B. Approved But Not Incorporated by Reference Regulations

In addition to the regulations approved and incorporated by reference described in section III.A. of this preamble, the EPA reviews and approves state and local clean air agency submissions to ensure they provide adequate enforcement authority and other general authority to implement and enforce the SIP. However, regulations describing such agency enforcement and other general authority are generally not incorporated by reference so as to avoid potential conflict with the EPA's independent authorities. Therefore, we are approving the following updates to YRCAA's general provisions for inclusion in 40 CFR 52.2470(e), *Table 1—Approved but Not Incorporated by Reference Regulations:* YRCAA Regulation 1, sections 1.05, 2.01, 2.02, 2.05, 5.01, 5.02, and 5.03.

C. Regulations To Remove From the SIP

YRCAA and Ecology's October 14, 2021, submittal included a request to remove several obsolete provisions from the SIP and to remove other provisions that are not required SIP elements under CAA section 110. As discussed in the proposal for this action, we are removing former section 1.03 which was replaced by Appendix A; former section 2.03 which was replaced by the provisions of section 1.07; former section 2.04 which was replaced by the provisions of section 1.06; former section 5.10 which was repealed effective May 1, 2000; former section 5.12 which was replaced by section 3.08 and WAC 173–400–040; former sections 13.01, 13.02, and 13.03 which were replaced by the provisions of section 2.02; former section 12.01 which was replaced by section 2.03 and is not a required SIP element; and former sections 3.11, 4.02, 4.03, 5.06, 5.07, 5.08, and 5.11, for which YRCAA is now relying on Chapter 173–400 WAC. We are also removing from 40 CFR 52.2470(c) the former sections 2.02, 2.05, 3.01, 3.02, 3.03, 3.04, 8.01, 8.02, 8.03, 8.04, and 8.05, related to local agency enforcement and other general authority, now consolidated in sections 1.05, 2.01, 2.02, 2.05, 5.01, 5.02, and 5.03 approved in 40 CFR 52.2470(e), *Table 1—Approved But Not Incorporated By Reference Regulations.* We are removing from the SIP Chapter 173–400 WAC provisions approved by the EPA on June 2, 1995 (60 FR 28726) that we are replacing with the local agency corollaries. These provisions are WAC 173–400–010 (replaced by section 1.03), 173–400–091 (replaced by section 4.03), and 173–400–100 (replaced by section 4.01).

D. Scope of Proposed Action

This revision to the SIP applies specifically to the YRCAA jurisdiction incorporated into the SIP at 40 CFR 52.2470(c), Table 10. As discussed in our proposal, local air agency jurisdiction in Washington is generally defined on a geographic basis; however, there are exceptions. By statute, YRCAA does not have authority for sources under the jurisdiction of the Energy Facilities Site Evaluation Council (EFSEC). See Revised Code of Washington Chapter 80.50. Under the applicability provisions of WAC 173–405–012, 173–410–012, and 173–415–012, YRCAA also does not have jurisdiction for kraft pulp mills, sulfite pulping mills, and primary aluminum plants. For these sources, Ecology retains statewide, direct jurisdiction. Ecology and EFSEC also retain statewide, direct jurisdiction for issuing Prevention of Significant Deterioration (PSD) permits. Therefore, the EPA is not approving into 40 CFR 52.2470(c), Table 10 those provisions of Chapter 173–400 WAC related to the PSD program. Specifically, these provisions are WAC 173–400–116 and WAC 173–400–700 through 173–400–750, which the EPA has already approved as applying statewide under 40 CFR 52.2470(c), Tables 2 and 3.

Jurisdiction to implement the visibility permitting program contained in WAC 173–400–117 varies depending on the situation. Ecology and EFSEC retain authority to implement WAC 173–400–117 as it relates to PSD permits. However, for facilities subject to major nonattainment new source review (NSR) under the applicability provisions of WAC 173–400–800, we are approving YRCAA's implementation of those parts of WAC 173–400–117 as they relate to major nonattainment NSR permits.[2] Therefore, we are modifying the visibility protection Federal Implementation Plan contained in 40 CFR 52.2498 to reflect the approval of WAC 173–400–117 as it applies to implementation of the major nonattainment NSR program in YRCAA's jurisdiction.

Lastly, this SIP revision is not approved to apply on any Indian reservation land within Yakima County and is also not approved to apply in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction.

IV. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, we are finalizing the incorporation

[2] This approval is with respect to the current area designations and classifications in the YRCAA jurisdiction only. New nonattainment designations trigger nonattainment NSR SIP revisions, among other area planning requirements.

by reference of certain provisions as described in section III.A. and removing provisions from the SIP as described in section III.C. of this preamble. The EPA has made, and will continue to make, materials incorporated by reference generally available through *https://www.regulations.gov* and at the EPA Region 10 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information). Therefore, these materials have been approved by the EPA for inclusion in the SIP, have been incorporated by reference by the EPA into that plan, are fully federally-enforceable under sections 110 and 113 of the CAA as of the effective date of the final rule of the EPA's approval, and will be incorporated by reference in the next update to the SIP compilation.[3]

V. Statutory and Executive Order Reviews

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

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

This SIP revision is not approved to apply on any Indian reservation land within Yakima County and is also not approved to apply 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). Consistent with EPA policy, the EPA provided an opportunity to request consultation to the Confederated Tribes and Bands of the Yakama Nation in a letter dated April 5, 2021.

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

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 9, 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, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: June 28, 2022.

Casey Sixkiller,

Regional Administrator, Region 10.

For the reasons set forth in the preamble, 40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart WW—Washington

■ 2. In § 52.2470 amend:

■ a. Paragraph (c) by revising ''Table 10''; and

■ b. Paragraph (e) by adding a new heading for ''Yakima Regional Clean Air Agency Regulations'' and adding new entries ''1.05'', ''2.01'', ''2.02'', ''2.05'', ''5.01'', ''5.02'', and ''5.03'' at the end of Table 1.

The additions and revisions read as follows:

§ 52.2470 Identification of plan.

* * * * *

(c) * * *

[3] 62 FR 27968 (May 22, 1997).

TABLE 10—ADDITIONAL REGULATIONS APPROVED FOR THE YAKIMA REGIONAL CLEAN AIR AGENCY (YRCAA) JURISDICTION

[Applicable in Yakima county, excluding facilities subject to Energy Facilities Site Evaluation Council (EFSEC) jurisdiction; facilities subject to the Washington Department of Ecology's direct jurisdiction under Chapters 173–405, 173–410, and 173–415 Washington Administrative Code (WAC); Indian reservations; any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction; and the Prevention of Significant Deterioration (PSD) permitting of facilities subject to the applicability sections of WAC 173–400–700.]

State/local citation	Title/subject	State/local effective date	EPA approval date	Explanations
Yakima Regional Clean Air Agency Regulations Article 1—General Administrative Provisions				
1.01	Name of Agency	11/09/20	7/11/22, [INSERT **FEDERAL REGISTER** CITATION].	
1.02	Short Title	11/09/20	7/11/22, [INSERT **FEDERAL REGISTER** CITATION].	
1.03	Policy	11/09/20	7/11/22, [INSERT **FEDERAL REGISTER** CITATION].	Except sub-section H. Replaces WAC 173–400–010.
1.04	Applicability	11/09/20	7/11/22, [INSERT **FEDERAL REGISTER** CITATION].	
1.06	Records	11/09/20	7/11/22, [INSERT **FEDERAL REGISTER** CITATION].	Replaces WAC 173–400–175.
1.07	General Provisions	11/09/20	7/11/22, [INSERT **FEDERAL REGISTER** CITATION].	Replaces WAC 173–400–105(6) & (8).
Article 2—General Regulations				
2.04	Public Participation in Permitting	11/09/20	7/11/22, [INSERT **FEDERAL REGISTER** CITATION].	
Article 3—Rules				
3.01	General Rules	11/09/20	7/11/22, [INSERT **FEDERAL REGISTER** CITATION].	Except sub-section D.
3.04	Wood Heaters	11/09/20	1/24/22, 87 FR 3435.	
3.05	Burn Bans	11/09/20	1/24/22, 87 FR 3435.	
3.08	Specific Dust Controls	11/09/20	7/11/22, [INSERT **FEDERAL REGISTER** CITATION].	Except sub-sections 3.08(A)(3)(b) and 3.08(B)(3).

TABLE 10—ADDITIONAL REGULATIONS APPROVED FOR THE YAKIMA REGIONAL CLEAN AIR AGENCY (YRCAA) JURISDICTION—Continued

[Applicable in Yakima county, excluding facilities subject to Energy Facilities Site Evaluation Council (EFSEC) jurisdiction; facilities subject to the Washington Department of Ecology's direct jurisdiction under Chapters 173–405, 173–410, and 173–415 Washington Administrative Code (WAC); Indian reservations; any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction; and the Prevention of Significant Deterioration (PSD) permitting of facilities subject to the applicability sections of WAC 173–400–700.]

State/local citation	Title/subject	State/local effective date	EPA approval date	Explanations
Article 4—Permits and Registration				
4.01	Registration Program	11/09/20	7/11/22, [INSERT **FEDERAL REGISTER** CITATION].	Excluding any provisions related to the regulation of Toxic Air Pollutants.
4.03	Voluntary Limits on Emissions	11/09/20	7/11/22, [INSERT **FEDERAL REGISTER** CITATION].	Replaces WAC 173–400–091 (state effective 4/1/11). The 9/20/93 version of WAC 173–400–091 continues to be approved under the authority of CAA Section 112(l) with respect to Section 112 hazardous air pollutants. See the **Federal Register** of June 2, 1995).
Article V—Emissions Standards and Preventative Measures				
5.01	Outdoor Burning	12/15/95	2/2/98, 63 FR 5269.	Subsections 5.01–5.05 (state effective 12/15/95) were subsequently consolidated and renumbered to subsection 3.03 which will be addressed in a separate action.
5.02	Regulations Applicable to all Outdoor Burning.	12/15/95	2/2/98, 63 FR 5269.	Subsections 5.01–5.05 (state effective 12/15/95) were subsequently consolidated and renumbered to subsection 3.03 which will be addressed in a separate action.
5.03	Regulations Applicable to all Outdoor Burning within Jurisdiction of the Yakima County Clean Air Authority, Local Cities, Towns, Fire Protection Districts and Conservation Districts.	12/15/95	2/2/98, 63 FR 5269.	Subsections 5.01–5.05 (state effective 12/15/95) were subsequently consolidated and renumbered to subsection 3.03 which will be addressed in a separate action.
5.04	Regulations Applicable to Permits Issued by the Yakima County Clean Air Authority for all Other Outdoor Burning.	12/15/95	2/2/98, 63 FR 5269.	Subsections 5.01–5.05 (state effective 12/15/95) were subsequently consolidated and renumbered to subsection 3.03 which will be addressed in a separate action.
5.05	Additional Restrictions on Outdoor Burning.	12/15/95	2/2/98, 63 FR 5269.	Subsections 5.01–5.05 (state effective 12/15/95) were subsequently consolidated and renumbered to subsection 3.03 which will be addressed in a separate action.
Appendices				
Appendix A	Definitions of Words and Phrases	11/09/20	7/11/22, [INSERT **FEDERAL REGISTER** CITATION].	
Appendix B	Definitions of Acronyms and Abbreviations.	11/09/20	7/11/22, [INSERT **FEDERAL REGISTER** CITATION].	
Washington Department of Ecology Regulations Washington Administrative Code, Chapter 173–400—General Regulations for Air Pollution Sources				
173–400–020	Applicability	12/29/12	7/11/22, [INSERT **FEDERAL REGISTER** CITATION].	
173–400–025	Adoption of Federal Rules	9/16/18	7/11/22, [INSERT **FEDERAL REGISTER** CITATION].	

TABLE 10—ADDITIONAL REGULATIONS APPROVED FOR THE YAKIMA REGIONAL CLEAN AIR AGENCY (YRCAA) JURISDICTION—Continued

[Applicable in Yakima county, excluding facilities subject to Energy Facilities Site Evaluation Council (EFSEC) jurisdiction; facilities subject to the Washington Department of Ecology's direct jurisdiction under Chapters 173–405, 173–410, and 173–415 Washington Administrative Code (WAC); Indian reservations; any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction; and the Prevention of Significant Deterioration (PSD) permitting of facilities subject to the applicability sections of WAC 173–400–700.]

State/local citation	Title/subject	State/local effective date	EPA approval date	Explanations
173–400–030(24).	Definitions	3/22/91	6/2/95, 60 FR 28726.	
173–400–030	Definitions	9/16/18	7/11/22, [INSERT **FEDERAL REGISTER** CITATION].	Except: 173–400–030(6); 173–400–030(32); 173–400–030(38); 173–400–030(45); 173–400–030(83); 173–400–030(89); 173–400–030(96); 173–400–030(97); 173–400–030(100); 173–400–030(103); 173–400–030(104).
173–400–036	Relocation of Portable Sources	12/29/12	7/11/22, [INSERT **FEDERAL REGISTER** CITATION].	
173–400–040(1)(a) & (b).	General Standards for Maximum Emissions.	3/22/91	6/2/95, 60 FR 28726.	Subsections 173–400–040(1)(a)&(b) (state effective 3/22/91) were subsequently revised and renumbered to subsection 173–400–040(2) which will be addressed in a separate action.
173–400–040	General Standards for Maximum Emissions.	9/16/18	7/11/22, [INSERT **FEDERAL REGISTER** CITATION].	Except: 173–400–040(2); 173–400–040(3); 173–400–040(5);
173–400–050	Emission Standards for Combustion and Incineration Units.	9/16/18	7/11/22, [INSERT **FEDERAL REGISTER** CITATION].	Except: 173–400–050(2); 173–400–050(4); 173–400–050(5); 173–400–050(6).
173–400–060	Emission Standards for General Process Units.	11/25/18	7/11/22, [INSERT **FEDERAL REGISTER** CITATION].	
173–400–070	Emission Standards for Certain Source Categories.	3/22/91	6/2/95, 60 FR 28726.	Except (7).
173–400–081	Startup and Shutdown	9/20/93	6/2/95, 60 FR 28726.	
173–400–105	Records, Monitoring and Reporting.	11/25/18	7/11/22, [INSERT **FEDERAL REGISTER** CITATION].	Except 173–400–105(6) & (8).
173–400–107	Excess Emissions	9/20/93	6/2/95, 60 FR 28726.	
173–400–110	New Source Review (NSR) for Sources and Portable Sources.	12/29/12	7/11/22, [INSERT **FEDERAL REGISTER** CITATION].	Except: 173–400–110(1)(c)(ii)(C); 173–400–110(1)(e); 173–400–110(2)(d); The part of WAC 173–400–110(4)(b)(vi) that says, • "not for use with materials containing toxic air pollutants, as listed in chapter 173–460 WAC,"; The part of 400–110 (4)(e)(iii) that says, • "where toxic air pollutants as defined in chapter 173–460 WAC are not emitted"; The part of 400–110(4)(f)(i) that says, • "that are not toxic air pollutants listed in chapter 173–460 WAC"; The part of 400–110 (4)(h)(xviii) that says, • ", to the extent that toxic air pollutant gases as defined in chapter 173–460 WAC are not emitted"; The part of 400–110 (4)(h)(xxxiii) that says, • "where no toxic air pollutants as listed under chapter 173–460 WAC are emitted"; The part of 400–110(4)(h)(xxxiv) that says, • ", or ≤1% (by weight) toxic air pollutants as listed in chapter 173–460 WAC"; The part of 400–110(4)(h)(xxxv) that says,

TABLE 10—ADDITIONAL REGULATIONS APPROVED FOR THE YAKIMA REGIONAL CLEAN AIR AGENCY (YRCAA) JURISDICTION—Continued

[Applicable in Yakima county, excluding facilities subject to Energy Facilities Site Evaluation Council (EFSEC) jurisdiction; facilities subject to the Washington Department of Ecology's direct jurisdiction under Chapters 173–405, 173–410, and 173–415 Washington Administrative Code (WAC); Indian reservations; any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction; and the Prevention of Significant Deterioration (PSD) permitting of facilities subject to the applicability sections of WAC 173–400–700.]

State/local citation	Title/subject	State/local effective date	EPA approval date	Explanations
				• "or ≤1% (by weight) toxic air pollutants"; The part of 400–110(4)(h)(xxxvi) that says, • "or ≤1% (by weight) toxic air pollutants as listed in chapter 173–460 WAC"; 400–110(4)(h)(xl), second sentence; The last row of the table in 173–400–110(5)(b) regarding exemption levels for Toxic Air Pollutants.
173–400–111	Processing Notice of Construction Applications for Sources, Stationary.	07/01/16	7/11/22, [INSERT **FEDERAL REGISTER** CITATION].	Except: 173–400–111(3)(h); The part of 173–400–111(8)(a)(v) that says, • "and 173–460–040,"; 173–400–111(9).
173–400–112	Requirements for New Sources in Nonattainment Areas—Review for Compliance with Regulations.	12/29/12	7/11/22, [INSERT **FEDERAL REGISTER** CITATION].	
173–400–113	New Sources in Attainment or Unclassifiable Areas—Review for Compliance with Regulations.	12/29/12	7/11/22, [INSERT **FEDERAL REGISTER** CITATION].	Except: 173–400–113(3), second sentence.
173–400–117	Special Protection Requirements for Federal Class I Areas.	12/29/12	7/11/22, [INSERT **FEDERAL REGISTER** CITATION].	
173–400–118	Designation of Class I, II, and III Areas.	12/29/12	7/11/22, [INSERT **FEDERAL REGISTER** CITATION].	
173–400–131	Issuance of Emission Reduction Credits.	4/1/11	7/11/22, [INSERT **FEDERAL REGISTER** CITATION].	
173–400–136	Use of Emission Reduction Credits (ERC).	12/29/12	7/11/22, [INSERT **FEDERAL REGISTER** CITATION].	
173–400–151	Retrofit Requirements for Visibility Protection.	2/10/05	7/11/22, [INSERT **FEDERAL REGISTER** CITATION].	
173–400–161	Compliance Schedules	3/22/91	6/2/95, 60 FR 28726.	
173–400–171	Public Notice and Opportunity for Public Comment.	9/16/18	7/11/22, [INSERT **FEDERAL REGISTER** CITATION].	Except: The part of 173–400–171(3)(b) that says, • "or any increase in emissions of a toxic air pollutant above the acceptable source impact level for that toxic air pollutant as regulated under chapter 173–460 WAC"; 173–400–171(3)(o); 173–400–171(12).
173–400–190	Requirements for Nonattainment Areas.	3/22/91	6/2/95, 60 FR 28726.	
173–400–200	Creditable Stack Height and Dispersion Techniques.	2/10/05	7/11/22, [INSERT **FEDERAL REGISTER** CITATION].	
173–400–205	Adjustment for Atmospheric Conditions.	3/22/91	6/2/95, 60 FR 28726.	

TABLE 10—ADDITIONAL REGULATIONS APPROVED FOR THE YAKIMA REGIONAL CLEAN AIR AGENCY (YRCAA) JURISDICTION—Continued

[Applicable in Yakima county, excluding facilities subject to Energy Facilities Site Evaluation Council (EFSEC) jurisdiction; facilities subject to the Washington Department of Ecology's direct jurisdiction under Chapters 173–405, 173–410, and 173–415 Washington Administrative Code (WAC); Indian reservations; any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction; and the Prevention of Significant Deterioration (PSD) permitting of facilities subject to the applicability sections of WAC 173–400–700.]

State/local citation	Title/subject	State/local effective date	EPA approval date	Explanations
173–400–210	Emission Requirements of Prior Jurisdictions.	3/22/91	6/2/95, 60 FR 28726.	
173–400–560	General Order of Approval	12/29/12	7/11/22, [INSERT **FEDERAL REGISTER** CITATION].	Except: The part of 173–400–560(1)(f) that says, "173–460 WAC".
173–400–800	Major Stationary Source and Major Modification in a Nonattainment Area.	4/1/11	7/11/22, [INSERT **FEDERAL REGISTER** CITATION].	EPA did not review WAC 173–400–800 through 860 for consistency with the 2016 $PM_{2.5}$ implementation rule (see the **Federal Register** of August 24, 2016); nor does YRCAA have an obligation to submit rule revisions to address the 2016 $PM_{2.5}$ implementation rule at this time.
173–400–810	Major Stationary Source and Major Modification Definitions.	7/1/16	7/11/22, [INSERT **FEDERAL REGISTER** CITATION].	
173–400–820	Determining if a New Stationary Source or Modification to a Stationary Source is Subject to these Requirements.	12/29/12	7/11/22, [INSERT **FEDERAL REGISTER** CITATION].	
173–400–830	Permitting Requirements	7/1/16	7/11/22, [INSERT **FEDERAL REGISTER** CITATION].	
173–400–840	Emission Offset Requirements	7/1/16	7/11/22, [INSERT **FEDERAL REGISTER** CITATION].	
173–400–850	Actual Emissions Plantwide Applicability Limitation (PAL).	7/1/16	7/11/22, [INSERT **FEDERAL REGISTER** CITATION].	
173–400–860	Public Involvement Procedures ...	4/1/11	7/11/22, [INSERT **FEDERAL REGISTER** CITATION].	

* * * * * (e) * * *

TABLE 1—APPROVED BUT NOT INCORPORATED BY REFERENCE REGULATIONS

State/local citation	Title/subject	State/local effective date	EPA approval date	Explanations
*	*	*	*	*
Yakima Regional Clean Air Agency Regulations				
1.05	Roles and Responsibilities	11/09/20	7/11/22, [INSERT **FEDERAL REGISTER** CITATION].	
2.01	Authority and Investigation	11/09/20	7/11/22, [INSERT **FEDERAL REGISTER** CITATION].	
2.02	Authority to Collect Fees	11/09/20	7/11/22, [INSERT **FEDERAL REGISTER** CITATION].	

TABLE 1—APPROVED BUT NOT INCORPORATED BY REFERENCE REGULATIONS—Continued

State/local citation	Title/subject	State/local effective date	EPA approval date	Explanations
2.05	Appeals	11/09/20	7/11/22, [INSERT **FEDERAL REGISTER** CITATION].	
5.01	General Information	11/09/20	7/11/22, [INSERT **FEDERAL REGISTER** CITATION].	
5.02	Additional or Alternative Enforcement Actions	11/09/20	7/11/22, [INSERT **FEDERAL REGISTER** CITATION].	
5.03	Penalties	11/09/20	7/11/22, [INSERT **FEDERAL REGISTER** CITATION].	

* * * * *

■ 3. Amend § 52.2495 by revising paragraph (a) to read as follows:

§ 52.2495 Voluntary limits on potential to emit.

(a) Terms and conditions of regulatory orders covering regulated NSR pollutants (as defined in 40 CFR 52.21(b)), issued pursuant to WAC 173–400–091 ''Voluntary limits on emissions'' and in accordance with the provisions of WAC 173–400–091, WAC 173–400–105 ''Records, monitoring, and reporting,'' and WAC 173–400–171 ''Public involvement,'' shall be applicable requirements of the Federally-approved Washington SIP for the purposes of section 113 of the Clean Air Act and shall be enforceable by the EPA and by any person in the same manner as other requirements of the SIP. Such regulatory orders issued pursuant to WAC 173–400–091 are part of the Washington SIP and shall be submitted to EPA Region 10 in accordance with the requirements of 40 CFR 51.326. This includes any local clean air agency corollary approved by the EPA to act in lieu of WAC 173–400–091 or the adoption by reference of WAC 173–400–091 by any state or local agency. The EPA-approved provisions of the WAC are identified in 40 CFR 52.2470(c).

* * * * *

■ 4. Amend § 52.2498 by revising paragraph (a)(1) to read as follows:

§ 52.2498 Visibility protection.

(a) * * *

(1) Sources subject to the jurisdiction of Olympic Region Clean Air Agency;

* * * * *

[FR Doc. 2022–14389 Filed 7–8–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2014–0204; FRL–9440–02–R3]

Air Plan Approval; Delaware; Sulfur Content of Fuel Oil

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 Delaware. The revision pertains to the reduction of the maximum allowable sulfur content limit for distillate fuels, from a current limit of 3000 parts per million (ppm) (0.3% by weight) to 15 ppm (0.0015% by weight) and residential fuels from a current limit of 1.0% by weight to 0.5% by weight. This revision also adds requirements for sampling and testing along with certification and recordkeeping. Additionally, start up, shut down and malfunction provisions that were previously included in the Delaware SIP have been removed in this revision. EPA has determined that such removal corrects a deficiency identified in the June 12, 2015, SIP call issued to Delaware. EPA is approving the revision to the Delaware SIP in accordance with the requirements of the Clean Air Act (CAA).

DATES: This final rule is effective August 10, 2022.

ADDRESSES: EPA has established a docket for this action under Docket ID Number EPA–R03–OAR–2014–0204. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through *https://www.regulations.gov,* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

FOR FURTHER INFORMATION CONTACT: Mallory Moser, Planning & Implementation Branch (3AD30), Air & Radiation Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. The telephone number is (215) 814–2030. Ms. Moser can also be reached via electronic mail at *moser.mallory@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On January 28, 2022 (87 FR 4528), EPA published a notice of proposed rulemaking (NPRM) for the State of Delaware which proposed to approve a revision to Title 7 of Delaware's Administrative Code (7 DE Admin. Code) 1108—Sulfur Dioxide Emissions from Fuel Burning Equipment into the Delaware SIP. The revision will reduce the amount of sulfur in fuel oils used in fuel burning units.[1] The revised regulation also establishes the date of compliance and adds necessary record keeping and recording provisions to ensure compliance with the regulation. Additionally, the revision removes start up, shut down and malfunction provisions that were previously included in the Delaware SIP. The formal SIP revision was submitted by Delaware on July 10, 2013, and amended on August 19, 2016, by a supplemental letter from Delaware Department of Natural Resources and Environmental Control (DNREC) withdrawing a portion of Section 3.0 of 7 DE Admin. Code 1108. The letter is

[1] A ''fuel burning unit'' is defined as ''each unit, or any combination of units discharging to a common stack used for the burning of fuel or other combustible material for the primary purpose of utilizing the thermal energy released.'' This definition is included in the Delaware SIP at 40 CFR 52.420(c).

available in the docket for this rulemaking and online at *www.regulations.gov.*

II. Summary of SIP Revision and EPA Analysis

The SIP revision incorporates amendments to 7 DE Admin. Code 1108—Sulfur Dioxide Emissions from Fuel Burning Equipment which sets the allowable content of sulfur in fuel oils combusted in Delaware. The amendments reduce the SIP approved maximum allowable sulfur content limit for distillate fuels to 15 ppm, and for residential fuel to 0.5% by weight. For any other fuel, the sulfur content would remain 1.0% by weight.

In addition, the amendments to 7 DE Admin. Code 1108 respond to a SIP call issued by EPA for this provision as part of a national action to address startup, shutdown and malfunction (SSM) SIP provisions which are contrary to the CAA and existing EPA guidance.[2] The SIP submission from Delaware, that is the subject of this action, contains a revised version of 7 DE Admin. Code 1108 to delete the language identified in the 2015 SSM SIP call, formerly at Section 1.2, which allowed for impermissible exemptions from the low sulfur fuel oil provisions.

This SIP revision to implement low sulfur fuel oil provisions is expected to reduce regional haze and visibility impairment in Delaware. Additionally, decreased emissions of sulfur dioxide (SO_2) will contribute to the attainment, maintenance, or both, of the SO_2 and fine particulate matter ($PM_{2.5}$) national ambient air quality standards (NAAQS) in Delaware and the surrounding areas. Other specific requirements of the SIP revision and the rationale for EPA's proposed action are explained in the NPRM and will not be restated here. Relevant support documents for this action are available online at *https://www.regulations.gov,* Docket number EPA–R03–OAR–2014–0204.

III. EPA's Response to Comments Received

EPA received four comments in total, two of which were supportive and can be found in the docket. The remaining two comments EPA received were generally supportive but raised issues beyond the scope of this rulemaking. One comment supported this action generally but suggested additional sulfur reductions should be encouraged by phasing out fossil fuels and investing ''in infrastructure that supports the use of electric cars.'' Another comment approved of this action to the extent that it approved Delaware's revision to correct one of the SSM exemptions identified in the SSM SIP Call, but admonished EPA for not yet taking action to address the other six SSM provisions in Delaware's SIP that were identified in the SSM SIP Call. EPA acknowledges both comments and the feedback provided. However, the concerns expressed by both commenters are beyond the scope of this rulemaking action, and no response by EPA to those comments is required.

IV. Final Action

EPA is approving, as a SIP revision, the State of Delaware's July 10, 2013, submittal reducing the amount of sulfur in fuel oils and removing SSM provisions from this portion of the Delaware SIP. EPA has determined that such approval corrects a deficiency identified in the June 12, 2015, SIP call issued to Delaware. EPA is approving the revision to the Delaware SIP in accordance with the requirements of the CAA.

V. Incorporation by Reference

In this document, EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is finalizing the incorporation by reference of Delaware's Sulfur Dioxide Emissions from Fuel Burning Equipment requirements as described in 7 DE Admin. Code 1108, not including the last sentence of section 3.0, which Delaware withdrew from this SIP revision. EPA has made, and will continue to make, these materials generally available through *https://www.regulations.gov* and at the EPA Region III Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information). Therefore, these materials have been approved by EPA for inclusion in the SIP, have been incorporated by reference by EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of EPA's approval, and will be incorporated by reference in the next update to the SIP compilation.[3]

VI. Statutory and Executive Order Reviews

A. General Requirements

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

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

In addition, this rule does not have tribal implications as specified by

[2] After issuing a statement in 2020 to change aspects of the policy articulated in the 2015 SSM SIP Action, EPA in 2021 reinstated and reaffirmed the 2015 policy (*see* September 30, 2021, memorandum ''Withdrawal of the October 9, 2020, Memorandum Addressing Startup, Shutdown, and Malfunctions in State Implementation Plans and Implementation of the Prior Policy,'' from Janet McCabe, Deputy Administrator). Neither the 2020 nor 2021 guidance memoranda affected the SSM SIP call for Delaware, and, as stated in the McCabe memorandum, EPA intends to implement the 2015 SSM SIP Action, including taking this action on the SIP submittal in partial response to the 2015 SIP call.

[3] 62 FR 27968 (May 22, 1997).

Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the State, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

B. Submission to Congress and the Comptroller General

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

C. Petitions for Judicial Review

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 9, 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 regarding fuel oil sulfur limits for combustion and sale in the State of Delaware 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, Particulate matter, Regional haze, Sulfur oxides.

Adam Ortiz,

Regional Administrator, Region III.

For the reasons stated in the preamble, the EPA amends 40 CFR part 52 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 I—Delaware

■ 2. In § 52.420:

■ a. In the table in paragraph (c) under the heading ''1108 Sulfur Dioxide Emissions from Fuel Burning Equipment'':

■ i. Revise the entries ''Section 1.0'', ''Section 2.0'', and ''Section 3.0''; and

■ ii. Add the entries ''Section 4.0'' and ''Section 5.0'' in numerical order.

The revisions and additions read as follows:

§ 52.420 Identification of plan.

* * * * *

(c) * * *

EPA-APPROVED REGULATIONS AND STATUTES IN THE DELAWARE SIP

State regulation (7 DNREC 1100)	Title/subject	State effective date	EPA approval date	Additional explanation
*	*	*	*	*
1108 Sulfur Dioxide Emissions From Fuel Burning Equipment				
Section 1.0	General Provisions	07/11/2013	7/11/2022, [insert **Federal Register** citation].	
Section 2.0	Limit on Sulfur Content of Fuel	07/11/2013	7/11/2022, [insert **Federal Register** citation].	
Section 3.0	Emissions Control in Lieu of Sulfur Content Limits of 2.0 of this Regulation.	07/11/2013	7/11/2022, [insert **Federal Register** citation].	
Section 4.0	Sampling and Testing Methods and Requirements.	07/11/2013	7/11/2022, [insert **Federal Register** citation].	
Section 5.0	Recordkeeping and Reporting	07/11/2013	7/11/2022, [insert **Federal Register** citation].	
*	*	*	*	*

* * * * *

[FR Doc. 2022–14715 Filed 7–8–22; 8:45 am]

BILLING CODE 6560–50–P

Proposed Rules

Federal Register
Vol. 87, No. 131
Monday, July 11, 2022

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

Office of the Secretary

7 CFR Part 1

[Docket No. APHIS–2015–0008]

RIN 0579–AE68

Privacy Act Regulations

AGENCY: Office of the Secretary, USDA.

ACTION: Proposed rule.

SUMMARY: The U.S. Department of Agriculture (USDA) is proposing to amend its Privacy Act regulations to exempt a system of records, Smuggling Interdiction and Trade Compliance (SITC) National Information Communication Activity System (SNICAS), USDA/APHIS–21, from certain provisions of the Privacy Act. USDA is further proposing to amend its Privacy Act regulations to reflect an administrative change to the list of system of records that are exempt from certain provisions of the Privacy Act.

DATES: We will consider all comments that we receive on or before August 10, 2022.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Enter APHIS–2015–0008 in the Search field. Select the Documents tab, then select the comment button in the list of documents.
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2015–0008, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov* or in our reading room, which is located in room 1620 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: Ms. Tonya Woods, Director, Freedom of Information Act and Privacy Act Staff, 4700 River Road Unit 50, Riverdale, MD 20737; (301) 851–4076.

SUPPLEMENTARY INFORMATION:

Background

The Privacy Act of 1974, as amended, 5 U.S.C. 552a, governs the means by which an agency collects, maintains, uses, and disseminates information about individuals that is maintained in a ''system of records.'' A system of records is any group of records under the control of an agency from which information about an individual is retrieved by the name, identifying number, symbol, or other identifying particular assigned to the individual. The Privacy Act generally grants individuals the right to access Privacy Act records maintained by an agency about themselves, as well as the right to request amendment of those records if they are not accurate, relevant, timely, or complete. The Privacy Act also allows the head of a Federal agency to promulgate rules to exempt a system of records from certain provisions of the Privacy Act, if the system of records contains ''investigatory material compiled for law enforcement purposes, other than material within the scope of [5 U.S.C. 552a(j)(2)]: Provided, however, that if any individual is denied a right, privilege, or benefit that he would otherwise be entitled by Federal law, or for which he would otherwise be eligible, as a result of the maintenance of such material, such material shall be provided to such individual, except to the extent that the disclosure of such material would reveal the identity of a source who furnished information to the Government under an express promise that the identity of the source would be held in confidence, or, prior to the effective date of this section [September 27, 1975], under an implied promise that the identity of the source would be held in confidence.'' 5 U.S.C. 552a(k)(2).

The U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) is proposing to exempt a system of records, Smuggling Interdiction and Trade Compliance (SITC) National Information Communication Activity System (SNICAS), USDA/APHIS–21, from certain provisions of the Privacy Act in order to avoid interference with law enforcement functions. USDA also proposes to update the list of systems exempt from certain provisions of the Privacy Act in accordance with 5 U.S.C. 552a(k)(2) to reflect administrative changes to USDA/APHIS–1.

USDA/APHIS–1

As an administrative matter, this proposal will update the list of previously exempt systems to reflect the agency combining two system of records under Investigative and Enforcement Records Regarding Regulatory Activities, USDA/APHIS–1. In a notice published in the **Federal Register** on November 16, 2001 (66 FR 57698–57700, Docket No. 99–024–1) [1], USDA announced the combination of three system of records (Plant Protection and Quarantine Program-Regulatory Actions, USDA/APHIS–1; Veterinary Services Programs—Animal Quarantine Regulatory Actions, USDA/APHIS–3; and Veterinary Services Programs—Animal Welfare and Horse Protection Regulatory Actions, USDA/APHIS–4) into one system of record: the Investigative and Enforcement Records Regarding Regulatory Activities, USDA/APHIS–1. The reason for combining the system of records was to bring all of the records concerning investigation and enforcement together. USDA's Privacy Act regulations were not previously amended to reflect this consolidation. Accordingly, USDA proposes to modify the list of exempt APHIS systems to reflect the consolidation.

USDA/APHIS–21

USDA also proposes to exempt Smuggling Interdiction and Trade Compliance (SITC) National Information Communication Activity System (SNICAS), USDA/APHIS–21, from certain provisions of the Privacy Act of 1974, as amended, 5 U.S.C. 552a. In a notice published elsewhere in this issue of the **Federal Register**, (Docket No. APHIS–2014–0062) [2], APHIS is publishing a new system of records, entitled Smuggling Interdiction and Trade Compliance (SITC) National Information Communication Activity

[1] To view the notice, go to: *https://www.govinfo.gov/content/pkg/FR-2001-11-16/pdf/01-28727.pdf.*

[2] To view the notice, go to *www.regulations.gov* and enter APHIS–2014–0062 in the Search field.

System (SNICAS), USDA/APHIS–21, to maintain a record of activities conducted by the agency pursuant to its mission and responsibilities authorized by the Plant Protection Act (PPA, 7 U.S.C. 7701 *et seq.*); the Animal Health Protection Act (AHPA, 7 U.S.C. 8301 *et seq.*); and the Honey Bee Act (7 U.S.C. 281 *et seq.*). The purpose of the system is to record data and information about APHIS' Smuggling Interdiction and Trade Compliance activities nationwide. As described in that notice, portions of this system could reveal the identity and contact information of a witness or person who has submitted a complaint concerning potential alleged violations and violations by persons who are subject to the PPA, AHPA, and the Honey Bee Act.

Because this system contains the identity and contact information for witnesses and people who have submitted complaints concerning potential violations by persons who are subject to the acts relevant to the system of records, USDA proposes to exempt this system of records from the following provisions of the Privacy Act: 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G), (H) and (I), and (f).

Paragraph (c)(3) of 5 U.S.C. 552a requires agencies to make the accounting of each disclosure of records available to the individual named in the record upon his or her request. However, release of certain accounting of disclosures could alert an individual who may be under investigation to the existence of the investigation and that he or she is the subject to an investigation. The release of such information to the subject of an investigation could provide him or her with information as to the nature of the investigation, compromise the investigation and any witnesses or people who submitted complaints, and lead to improper influencing or endangerment of these individuals.

Based on 5 U.S.C. 552a(d), (e)(4)(G) and (e)(4)(H), and (f), agencies are required to provide notice and disclosure of individuals that a system contains records pertaining to the individual, as well as providing rights of access and amendment. We believe that granting access to certain records in the previously listed systems could inform the subject of an investigation of the existence of that investigation, the nature and scope of the information and evidence obtained, the identity of witnesses and individuals who have provided information, and could provide information to enable the subject to avoid detection. The release of such information to the subject of an investigation could also lead to improper influencing or endangerment of these individuals.

Paragraph (e)(1) of 5 U.S.C. 552a requires an agency to maintain information about an individual only to the extent that such information is relevant or necessary. In terms of information that is related to an investigation, it is not always possible to know in advance what information is relevant and necessary for an investigation, and this information may contain information from witnesses or people who have submitted complaints that may inadvertently convey the identity of the source of information to the subject.

Paragraph (e)(4)(I) of 5 U.S.C. 552a requires an agency to provide public notice of the categories of sources of records in the system. The application of this section could disclose information provided by sources and could cause sources to refrain from providing information because of fear of reprisal or fear of breach of promise(s) of anonymity and confidentiality. This could compromise USDA's ability to conduct investigations and to identify and detect violators of the acts relevant to the listed system of records.

Executive Orders 12866 and Regulatory Flexibility Act

This proposed rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

In accordance with the Regulatory Flexibility Act, we have analyzed the potential economic effects of this action on small entities. This proposed rule would not impose a requirement for small businesses to report or keep records as a result of any of the provisions contained in this rulemaking. The exemptions to the Privacy Act apply to individuals, not to entities covered under the Regulatory Flexibility Act.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. If this proposed rule is adopted: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This proposed rule contains no new information collection requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 7 CFR Part 1

Administrative practice and procedure, Agriculture, Antitrust, Blind, Claims, Concessions, Cooperatives, Equal access to justice, Federal buildings and facilities, Freedom of information, Lawyers, Privacy.

Accordingly, we propose to amend 7 CFR part 1 as follows:

PART 1—ADMINISTRATIVE REGULATIONS

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

Authority: 5 U.S.C. 301 and 552a; 31 U.S.C. 9701.

■ 2. Section 1.123 is amended by revising the entries under the heading ''Animal and Plant Health Inspection Service'' to read as follows:

§ 1.123 Specific exemptions.

* * * * *

Animal and Plant Health Inspection Service

Investigative and Enforcement Records Regarding Regulatory Activities, USDA/APHIS–1. Veterinary Services Programs-Records of Accredited Veterinarians, USDA/APHIS–2. Smuggling Interdiction and Trade Compliance (SITC) National Information Communication Activity System (SNICAS), USDA/APHIS–21.

* * * * *

Done in Washington, DC, this 6th day of July 2022.

Gary Washington,

Chief Information Officer, United States Department of Agriculture.

[FR Doc. 2022–14707 Filed 7–8–22; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 174, 175, and 177

[Docket No. FDA–2022–F–1108]

Environmental Defense Fund, Maricel Maffini, Breast Cancer Prevention Partners, Clean Water Action/Clean Water Fund, Consumer Reports, Endocrine Society, Environmental Working Group, Healthy Babies Bright Futures, Linda Birnbaum, and the Nicholas School of the Environment at Duke University; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of petition.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that we have filed a petition, submitted by Environmental Defense Fund, Maricel Maffini, Breast Cancer Prevention Partners, Clean Water Action/Clean Water Fund, Consumer Reports, Endocrine Society, Environmental Working Group, Healthy Babies Bright Futures, Linda Birnbaum, and the Nicholas School of the Environment at Duke University, proposing that the food additive regulations be amended to remove or restrict authorizations for the use of bisphenol A (BPA).

DATES: The food additive petition was filed on May 2, 2022. Submit either electronic or written comments on the filing notice by September 9, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 9, 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–2022–F–1108 for ''Environmental Defense Fund, Maricel Maffini, Breast Cancer Prevention Partners, Clean Water Action/Clean Water Fund, Consumer Reports, Endocrine Society, Environmental Working Group, Healthy Babies Bright Futures, Linda Birnbaum, and the Nicholas School of the Environment at Duke University; Filing of Food Additive Petition.'' Received comments, those filed in a timely manner (see **DATES**), 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.'' We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Marissa Santos, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–8160.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 409(b)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(b)(5)), we are giving notice that we have filed a food additive petition (FAP 2B4831), submitted by Environmental Defense Fund, Maricel Maffini, Breast Cancer Prevention Partners, Clean Water Action/Clean Water Fund, Consumer Reports, Endocrine Society, Environmental Working Group, Healthy Babies Bright Futures, Linda Birnbaum, and the Nicholas School of the Environment at Duke University, c/o Mr. Thomas Neltner, 1875 Connecticut Ave. NW, Washington, DC 20009. The petition proposes to amend the food additive regulations in §§ 175.105, 175.300, 177.1440, 177.1580, 177.1585, 177.2280, and 177.2440 (21 CFR 175.105, 175.300, 177.1440, 177.1580, 177.1585, 177.2280, and 177.2440); Indirect Food Additives: General (part 174 (21 CFR part 174)); Indirect Food Additives: Adhesives and Components of Coatings (21 CFR part 175); and

Indirect Food Additives: Polymers (21 CFR part 177), to remove authorizations for the use of BPA in §§ 175.105, 175.300, and 177.2440; establish a migration limit for BPA from the authorized uses of BPA in food contact articles in §§ 177.1440, 177.1580, 177.1585, and 177.2280; and add a new provision to part 174 with a restriction on the use of BPA, stating that the substance is subject to a specific migration limit of 0.5 nanograms per kilogram of food. The petition is available in Docket No. FDA–2022–F–1108.

II. Amendment of §§ 175.105, 175.300, 177.1440, 177.1580, 177.1585, 177.2280, and 177.2440 and Addition of New Provision With BPA Restriction

In accordance with the procedures for amending or repealing a food additive regulation in § 171.130 (21 CFR 171.130), the petition asks us to amend §§ 175.105, 175.300, 177.1440, 177.1580, 177.1585, 177.2280, and 177.2440 to remove authorizations for the use of BPA in §§ 175.105, 175.300, and 177.2440; establish a migration limit for BPA from the authorized uses of BPA in food contact articles in §§ 177.1440, 177.1580, 177.1585, and 177.2280; and add a new provision to part 174 with a restriction on the use of BPA. The petitioners cite, as evidence, a draft opinion by the European Food Safety Authority (EFSA), which analyzed studies related to the health effects of dietary BPA exposure that were published between January 1, 2013, through October 15, 2018. EFSA's draft opinion entitled ''Re-evaluation of the risks to public health related to the presence of bisphenol (BPA) in foodstuffs,'' was published in December 2021 for public comment. Based on the analysis in the draft EFSA opinion, the petitioners conclude that the use of BPA in food and food contact articles is toxic and disrupts the ''proper functioning of the immune and reproductive systems.'' To support their conclusion, the petitioners also cite publications referred to in comments to EFSA on the draft opinion and an epidemiology study that petitioners assert show an association of in utero exposure to BPA with an increased risk of asthma and wheezing in school-age girls.

We invite comments, additional scientific data, and other information related to the issues raised by this petition. If we determine that the available data justify removing authorizations for the use of BPA as listed under §§ 175.105, 175.300, and 177.2440; establishing a migration limit for BPA from authorized uses of BPA in food contact articles as listed under §§ 177.1440, 177.1580, 177.1585, and 177.2280; or adding a new provision with a restriction on the use of BPA, we will publish our decision in the **Federal Register** in accordance with § 171.130.

The petitioners have claimed that this action is categorically excluded under 21 CFR 25.32(m) because this action would prohibit or otherwise restrict the use of a substance in food packaging. In addition, the petitioners have stated that, to their knowledge, no extraordinary circumstances exist. If FDA determines a categorical exclusion applies, neither an environmental assessment nor an environmental impact statement is required. If FDA determines a categorical exclusion does not apply, we will request an environmental assessment and make it available for public inspection.

Dated: July 1, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–14682 Filed 7–8–22; 8:45 am]

BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2021–0342; FRL–9971–01–R4]

Air Plan Approval; Georgia; Vehicle Inspection and Maintenance Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve State Implementation Plan (SIP) revisions submitted by the State of Georgia through the Georgia Department of Natural Resources (GA DNR), Environmental Protection Division (GA EPD) on April 30, 2021. The revisions remove obsolete references and provisions, update and clarify the State's inspection and maintenance (I/M) requirements, and update terminology, in part to reflect advances in test and vehicle technology. EPA has evaluated the SIP revisions and has preliminarily determined the changes will not increase emissions under the Georgia I/M program. EPA is proposing to approve these changes pursuant to the Clean Air Act (CAA).

DATES: Comments must be received on or before August 10, 2022.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R04–OAR–2021–0342 at *www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. 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 *www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Kelly Sheckler, Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. The telephone number is (404) 562–9222. Ms. Sheckler can also be reached via electronic mail at *sheckler.kelly@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. What is the background of Georgia's SIP-approved I/M program?

The CAA requires areas that are designated as moderate, serious, severe, or extreme ozone nonattainment areas to establish a motor vehicle I/M program to ensure regular monitoring of gasoline fueled motor vehicle emissions. *See* CAA sections 182(b)(4), (c)(3). The required monitoring is performed by periodic emissions testing of vehicles. *See* CAA sections 182(a)(2)(B), (c)(3). This emissions testing ensures that vehicles are well maintained, operating as designed, and do not exceed established vehicle pollutant limits. A basic I/M program is required for moderate ozone nonattainment areas, and an enhanced I/M program is required for serious, severe, or extreme ozone nonattainment areas.

In 1991, EPA classified a 13-county area in and around the Atlanta, Georgia, metropolitan area as a serious ozone nonattainment area for the 1979 1-hour ozone national ambient air quality standards (NAAQS), triggering the requirement for the State to establish an

enhanced I/M program for this area.[1] In 1996, Georgia submitted its enhanced I/M program to EPA for incorporation into the SIP. EPA granted interim approval of the State's program in 1997. *See* 62 FR 42916 (August 11, 1997). A few years later, EPA granted full approval.[2] *See* 65 FR 4133 (January 26, 2000). Despite this, the 13-county area failed to attain the 1-hour ozone NAAQS by November 15, 1999. EPA issued a final rulemaking action (68 FR 55469) on September 26, 2003, to reclassify the area to a severe ozone nonattainment area. Subsequently, this area attained the 1-hour ozone NAAQS, and thus EPA redesignated the nonattainment area to attainment for the 1-hour ozone NAAQS. *See* 70 FR 34660 (June 15, 2005). On April 30, 2004, EPA issued a final rulemaking action (69 FR 23951) to revoke the 1979 1-hour ozone NAAQS, effective June 15, 2005.

On July 18, 1997 (62 FR 38856), EPA established an 8-hour ozone NAAQS and subsequently designated areas. On April 30, 2004 (69 FR 23858), EPA designated a 20-county area in and around metropolitan Atlanta as a marginal ozone nonattainment area for the 1997 8-hour ozone NAAQS.[3] EPA reclassified this area as a moderate ozone nonattainment area on March 6, 2008 (73 FR 12013), because the area failed to attain the 1997 8-hour ozone NAAQS by the required attainment date of June 15, 2007. Subsequently, the area attained the 1997 8-hour ozone standard, and on December 2, 2013 (78 FR 72040), EPA redesignated the counties to attainment for the 1997 8-hour ozone NAAQS.

On March 12, 2008, EPA revised the 8-hour ozone NAAQS. *See* 73 FR 16436 (March 27, 2008). EPA designated a 15-county area in and around metropolitan Atlanta as a marginal ozone nonattainment area for the 2008 8-hour ozone NAAQS on April 30, 2012 (effective July 20, 2012).[4] *See* 77 FR 30088 (May 21, 2012). EPA reclassified these counties as a moderate ozone nonattainment area on April 11, 2016 (effective June 3, 2016), because the area failed to attain the 2008 8-hour ozone NAAQS by the required attainment date of July 20, 2015. *See* 81 FR 26697 (May 4, 2016). Subsequently, the area attained the 2008 8-hour ozone standard and EPA redesignated the counties to attainment for the 2008 8-hour ozone NAAQS. *See* 82 FR 25523 (June 2, 2017).

On October 1, 2015, EPA again revised the 8-hour ozone NAAQS. *See* 80 FR 65291 (October 26, 2015). EPA designated a 7-county area in and around metropolitan Atlanta as a marginal ozone nonattainment area for the 2015 8-hour ozone NAAQS on April 30, 2018 (effective August 3, 2018).[5] *See* 83 FR 25776 (June 4, 2018).

II. Background on EPA's I/M Program

After the 1990 amendments, the CAA required EPA to set guidelines for states in designing and running I/M programs.[6] The guidelines were required to distinguish between basic and enhanced I/M programs and clarify how states must meet minimum I/M design requirements set by the CAA. One of the minimum design requirements included Onboard Diagnostic (OBD) system checks as a part of periodic inspections. This design requirement applied to both basic and enhanced I/M programs.

In November of 1992, EPA published an I/M rule at 40 CFR part 51 subpart S. At the time of promulgation however, federal standards for OBD certification had not been published. As a stopgap, EPA reserved sections in the 1992 rule for the CAA's OBD–I/M requirement based on the understanding that these sections would be amended in the future. A federal requirement to incorporate OBD into new vehicles began with the 1994 model year. However, manufacturers could request waivers on vehicles for model years 1994–95, so full compliance for light-duty cars and trucks sold in the United States was not required until model year 1996.

EPA published amendments to the 1992 I/M rule that created OBD–I/M requirements for I/M performance standards and I/M SIPs on August 6, 1996. These amendments included the following requirements: data collection, summary reporting, and analysis requirements for the OBD–I/M testing element. Additionally, the amendments established OBD test equipment requirements, the OBD test result reporting format, and identified conditions to determine if a test resulted in an OBD–I/M pass, failure, or rejection. Finally, these amendments established OBD–I/M as an official performance warranty short test under section 207(b) of the Act by revising 40 CFR part 85, subpart W.

In August 2000, EPA published a study evaluating the use of OBD to detect vehicle malfunctions that caused increased emissions.[7] In this study, EPA concluded that the OBD technology is a viable I/M test for 1996 and newer vehicles. The magnitude of emissions reductions available from basing repairs on OBD were found to be at least as large, if not greater than those resulting from available I/M tailpipe tests. In direct comparison to the IM240,[8] the study found that OBD technology offered a better ability to identify vehicles with tailpipe emissions that exceed certified standards. With some exceptions, the study found that OBD identified the same vehicles as IM240, but additionally identified components which have degraded and may cause future emissions problems. By identifying and repairing these components early, OBD was found to provide a type of preventative maintenance that extended the long-term durability of expensive components (catalytic converter, fuel injectors, oxygen sensors, transmissions). Additionally, repairs based on OBD testing effectively returned vehicles to their proper operating conditions and for a majority, returned tailpipe emissions to below certification levels.

III. What is being proposed?

EPA is proposing to approve changes to the Georgia SIP that were provided to EPA through a cover letter dated April

[1] On November 6, 1991, EPA designated and classified the following counties in and around the Atlanta, Georgia, metropolitan area as a serious ozone nonattainment area for the 1-hour ozone NAAQS: Cherokee, Clayton, Cobb, Coweta, DeKalb, Douglas, Fayette, Forsyth, Fulton, Gwinnett, Henry, Paulding, and Rockdale. *See* 56 FR 56694.

[2] Since granting full approval for the State's I/M program, EPA has approved several SIP revisions concerning the State's I/M program.

[3] The nonattainment area for the 1997 8-hour ozone standard consisted of the following counties: Barrow, Bartow, Carroll, Cherokee, Clayton, Cobb, Coweta, DeKalb, Douglas, Fayette, Forsyth, Fulton, Gwinnett, Hall, Henry, Newton, Paulding, Rockdale, Spalding, and Walton.

[4] The nonattainment area for the 2008 8-hour ozone standard consisted of the following counties: Bartow, Cherokee, Clayton, Cobb, Coweta, DeKalb, Douglas, Fayette, Forsyth, Fulton, Gwinnett, Henry, Newton, Paulding, and Rockdale.

[5] The nonattainment area for the 2015 8-hour ozone standard consists of the following counties: Bartow, Clayton, Cobb, DeKalb, Fulton, Gwinnett, and Henry.

[6] *See* 182(a)(2)(B)(ii); David Sosnowski, Edward Gardetto, *Performing Onboard Diagnostic System Checks as a Part of a Vehicle Inspection and Maintenance Program,* EPA 420–R–01–015, June 2001. This document is available at *https://nepis.epa.gov/Exe/ZyPdf.cgi?Dockey=P1002KRN.pdf.*

[7] *See* Edward Gardetto, Ted Trimble, *Evaluation of On-Board Diagnostics for Use in Detecting Malfunctioning and High Emitting Vehicles,* EPA 420–R–00–13, August 2000. This document is available at *https://nepis.epa.gov/Exe/ZyPDF.cgi/P1002KM8.PDF?Dockey=P1002KM8.PDF.*

[8] The IM240 test is a test that measures emissions while the vehicle is driven on a dynamometer. The vehicle is operated over different speeds to resemble typical city driving and includes tests of the vehicle's acceleration and deceleration. The IM240 test captures the entire exhaust stream emitted during the test and measures the total mass of emissions from the vehicle.

30, 2021.[9] Specifically, GA EPD submitted changes to Georgia's Rule 391–3–20—*Enhanced Inspection and Maintenance* (''Georgia I/M Regulation''), which were adopted by the GA DNR Board of Directors and became state-effective on April 13, 2021.

With regards to revisions to SIPs, CAA section 110(l) provides that EPA shall not approve a revision to a plan if the revision would interfere with any applicable requirement concerning attainment and reasonable further progress (as defined in CAA Section 171), or any other applicable requirement of the CAA. Section 193 of the CAA provides, in part, that:

> No control requirement in effect, or required to be adopted by an order, settlement agreement, or plan in effect before November 16, 1990, in any area for any air pollutant may be modified after November 15, 1990, in any manner unless the modification insures equivalent or greater emission reductions of such air pollutant.

The proposed changes remove obsolete references and provisions, update and clarify the State's inspection and maintenance (I/M) requirements, and update terminology, in part to reflect advances in test and vehicle technology. EPA believes the proposed changes submitted by Georgia will not lead to any increases of any NAAQS pollutant and will not otherwise interfere with any CAA applicable requirement. Additional detail on the changes and EPA's analysis is contained in Section IV, below.

IV. State's Submittal and EPA's Analysis

Georgia's April 30, 2021, SIP submittal modifies the following sections of Georgia's SIP-approved I/M Regulation: Rule 391–3–20–.01—''Definitions''; Rule 391–3–20–.04—''Emission Inspection Procedures''; Rule 391–3–20–.05—''Emission Standards''; Rule 391–3–20–.07—''Inspection Equipment System Specifications''; Rule 391–3–20–.09—''Inspection Station Requirements''; and Rule 391–3–20–.11—''Inspector Qualifications and Certification.'' EPA's analysis of these changes is provided in sections IV.A through IV.F.

Georgia's current SIP-approved I/M regulation covers all gasoline-powered light duty trucks and vehicles 24 model years old and newer. *See* Georgia Rule 391–3–20–.03(1); 62 FR 42916 (August 11, 1997). This means the I/M program currently applies to all gasoline-powered light duty trucks and vehicles with a model year of 1998 or later.

Georgia's current SIP-approved I/M regulation also has specific testing requirements. As mentioned above, all light-duty vehicles and trucks with model years of 1996 or newer are federally required to have an OBD system. As a result, Georgia's SIP-approved rule requires OBD testing for ''newer'' vehicles and Acceleration Simulation Mode (ASM)[10] or 2-speed idle (TSI)[11] tailpipe testing on ''older'' vehicles. The SIP-approved Georgia rule defines ''older vehicles'' as those with a designated model year of 1995 and older and ''newer vehicles'' as those with a designated model year of 1996 and newer. *See* Georgia Rules 391–3–20–.01(mm) and (kk), respectively. As discussed further in this section of the notice, the terms ''older vehicles'' and ''newer vehicles'' are obsolete because Georgia's SIP-approved I/M program only applies to light duty trucks and vehicles that are 24 model years old and newer.

A. Rule 391–3–20–.01, ''Definitions''

Georgia's SIP revisions include the following changes to Rule 391–3–20–.01. All other definitions in this Rule were renumbered accordingly to reflect the changes below.

1. Acceleration Simulation Mode 2525/5015 Exhaust Emission Test

The submittal deletes the term ''Acceleration Simulation Mode 2525/5015 exhaust emission test (ASM test)'' from Rule 391–3–20–.01 as the test is now obsolete. EPA's I/M program requirements stipulate that state and local agencies are free to design their testing protocol as they choose, provided they meet the appropriate performance standard. *See* 40 CFR 51.351(d). EPA approved Georgia's I/M Program SIP revision stipulating that the program would cover all gasoline-powered light duty trucks and vehicles 24 model years old and newer in 1997. *See* 62 FR 42916 (August 11, 1997). As a result, Georgia's I/M program is only required to cover vehicles with a model year of 1998 and later. *See* Georgia Rule 391–3–20–.03(1). The SIP-approved Georgia rules require ASM or TSI testing on ''older'' vehicles and OBD testing for ''newer'' vehicles.[12] *See* Georgia Rules 391–3–20–.04(2)(b) and .04(2)(a), respectively. Because Georgia's I/M program only covers vehicles with a model year of 1998 or newer currently, the provisions of the SIP-approved rule that require ASM testing for older vehicles are no longer applicable.[13]

Since the ASM requirement no longer applies to vehicles covered by Georgia's I/M program for the reason stated above, EPA has made the preliminary determination that the removal of this definition from Rule 391–3–20–.01(b) has no impact on emissions and is consistent with CAA requirements.

2. Calibration

The submittal revises the term ''Calibration'' by removing a reference to the dynamometer, a part of the ASM test. The ASM test uses tailpipe emissions sensing equipment that measures emissions as the vehicle is driven under load at a steady speed on a chassis dynamometer. As stated above, the ASM test is no longer applicable to motor vehicles subject to Georgia's SIP-approved I/M program. Therefore, EPA has made the preliminary determination that this revision to Rule 391–3–20–.01(c) has no impact on emissions and is consistent with CAA requirements.

3. Exhaust Emission Test

The submittal revises the term ''Exhaust Emissions Test'' by removing a reference to the ASM test. As stated above, the ASM test is no longer applicable to motor vehicles subject to the I/M program. An exhaust emission test, when conducted, will now use the TSI test instead of the ASM test to determine the amount of specified gases in a vehicle's exhaust. Inspectors may use the TSI test on non-OBD equipped vehicles when prompted by the Georgia Analyzer System (GAS).[14] Additionally, inspectors must continue to use the TSI test on grandfathered vehicles. EPA has made the preliminary determination that this revision to Rule 391–3–20–.01(r) has no impact on emissions and is consistent with CAA requirements.

4. Malfunction Indicator Light

The submittal revises the term ''Malfunction Indicator Light (MIL)'' by

[9] EPA officially received Georgia's I/M SIP revisions on May 4, 2021.

[10] ASM testing is testing that uses a dynamometer so that the vehicle can be tested under load. The ASM test accelerates the vehicle to 15 miles per hour (mph) with 50% of the vehicle's horsepower, and a second portion of the test accelerates the vehicle to 25 mph with 25% of the vehicle's horsepower. This test is performed while an exhaust gas analyzer measures the vehicle's levels of nitrogen oxide, hydrocarbon, and carbon monoxide during acceleration.

[11] The TSI test is an exhaust emission test where the vehicle is run at an idle revolutions per minute (RPM) speed, and then a higher RPM speed. An analyzer measures the tailpipe exhaust emissions of the vehicles at both settings to determine compliance with motor vehicle emission standards.

[12] Id.

[13] As mentioned previously, OBD testing receives the same emission reduction credit as other forms of enhanced testing (*i.e.,* ASM or TSI) because OBD is more sensitive to problems that might cause emissions to rise above the standard.

[14] For the few vehicles with model years 1996 or newer that are not equipped with OBD, Georgia does not currently require an emissions test.

replacing the term ''newer'' with ''OBD equipped'' to describe vehicles with an MIL. A MIL is a light on the dashboard of OBD equipped vehicles that notifies the driver that an emission related fault has been detected and the vehicle should be repaired as soon as possible. The word ''newer'' previously referred to vehicles with a model year of 1996 or later and is now obsolete because the I/M program only covers those vehicles with a designated model year of 1998 or later. EPA has made the preliminary determination that this revision to Rule 391–3–20–.01(jj) has no impact on emissions and is consistent with CAA requirements.

5. Newer Vehicles

The submittal deletes the term ''Newer Vehicles,'' which refers to vehicles with a designated model year of 1996 and newer, as it is obsolete. All vehicles covered under Georgia's SIP-approved I/M program are necessarily those with a designated model year later than 1996 as the program only covers vehicles as far back as 24 model years old or newer. *See* Georgia Rule 391–3–20–.03(1). Currently, Georgia's I/M program covers those vehicles with a model year of 1998 or newer. As a result, the rules no longer need to distinguish between ''older'' and ''newer'' vehicles since the I/M program only covers those vehicles with a designated model year of 1998 or later. EPA has made the preliminary determination that the removal of this definition from Rule 391–3–20–.01(kk) has no impact on emissions and is consistent with CAA requirements.

6. Older Vehicles

The submittal deletes the term ''Older Vehicles,'' which means vehicles with a designated model year of 1995 and older, as it is obsolete. As mentioned above, the only vehicles covered under Georgia's SIP-approved I/M program currently are those with a designated model year of 1998 or later. EPA has made the preliminary determination that the removal of this definition from Rule 391–3–20–.01(mm) has no impact on emissions and is consistent with CAA requirements.

B. Rule 391–3–20–.04, ''Emission Inspection Procedures''

The submittal amends Rule 391–3–20–.04, ''Emission Inspection Procedures,'' by removing obsolete language referring to outdated requirements and inserting language referring to the OBD test. Specifically, the submittal makes changes to distinguish what emission inspection procedures will be used for OBD equipped vehicles versus non-OBD equipped vehicles. It does this first in Rule 391–3–20–.04(2)(a) by replacing the term ''newer'' with ''OBD equipped'' in reference to vehicles subject to particular emission inspection procedures. In 391–3–20–.04(3)(b) the term ''older'' is replaced with ''non-OBD equipped'' in reference to vehicles subject to a different set of emission inspection procedures. These changes are appropriate delineations between vehicles as the ''older'' and ''newer'' distinction is now obsolete for the reasons described above.

The submittal also adds a new provision to the emission inspection procedures for newer non-OBD equipped vehicles.[15] Specifically, for those non-OBD equipped vehicles that are not grandfathered in, inspectors may use the TSI test when prompted by GAS.[16] EPA has made the preliminary determination that the revisions to Rule 391–3–20–.04 have no impact on emissions and are consistent with CAA requirements.

C. Rule 391–3–20–.05, ''Emission Standards''

The submittal amends Rule 391–3–20–.05, ''Emission Standards,'' to delete an outdated reference to the ASM test. Specifically, the submittal deletes 391–3–20–.05(2)(b)(2), which describes the standard under which a vehicle would pass an ASM test. As the ASM test is no longer applicable, this provision is no longer necessary. Rule 391–3–20–.05 is renumbered to adjust for the removal of this provision. EPA has made the preliminary determination that this revision to Rule 391–3–20–.05 has no impact on emissions and is consistent with CAA requirements.

D. Rule 391–3–20–.07, ''Inspection Equipment System Specification''

The submittal amends Rule 391–3–20–.07, ''Inspection Equipment System Specification'' by deleting language referring to newer vehicles, older vehicles, and the ASM test as this language is outdated and obsolete. This is consistent with the changes to the definitions portion of the rule which removed those terms. The ASM test is replaced with the TSI test in 391–3–20–.07 (b) and (d) as the ASM test is no longer applicable. The change to paragraph (b) has substantively made it identical to SIP-approved paragraph (c), so paragraph (c) has been removed completely. Rule 391–3–20–.07 is renumbered thereafter to account for this change.

The submittal also deletes language in 391–3–20–.07 that refers to distinctions between ''newer'' and ''older'' vehicles. First, in 391–3–20–.07(a), the submittal deletes language that gave station owners the option to apply for a Certificate of Authorization as either a regular inspection station or a newer-vehicle only inspection station. This distinction is now obsolete and the Certificate of Authorization was optional originally. Additionally, the submittal deletes language in 391–3–20–.07(d) referring to ''newer and older'' vehicles and removes a requirement from the same provision that only applied previously to fleet station inspection stations with respect to ''newer'' vehicles. The removal of this language has resulted in a requirement that all fleet inspection station owners have an EPD-approved GAS which meets the OBD and TSI requirements of Chapter 391–3–20. EPA has made the preliminary determination that these revisions to Rule 391–3–20–.07 have no impact on emissions and are consistent with CAA requirements.

E. Rule 391–3–20–.09, ''Inspection Station Requirements''

The April 30, 2021, submittal amends Rule 391–3–20–.09, ''Inspection Station Requirements,'' by removing language that makes distinctions between older and newer stations as the delineation between older and newer vehicles is obsolete. The removal of requirements that depended upon this distinction has resulted in two classes of stations, regular inspection stations and fleet inspection stations. The removal of ''Newer-Vehicle Only Inspection Stations'' will not result in any emissions impact as all vehicles that were required to be covered by the I/M program will still be subject to inspections under the new classes of stations. Rule 391–3–20–.09 is renumbered to account for the removal of this section.

In addition to the changes described above, the submittal removes references and requirements related to the ASM test. One particular requirement that has been removed is a requirement for inspection station owners to provide proof of a bond or garage owner's liability insurance for any damage to a vehicle during inspection. This requirement was primarily directed towards damage that would be caused using dynamometers during ASM testing. As TSI testing, which is performed at idle instead of on a

[15] As mentioned previously, Georgia does not currently require an emissions test for the few vehicles with model years 1996 or newer that are not equipped with OBD.

[16] For those vehicles that are grandfathered in, inspectors must continue to use the TSI test in lieu of the ASM test.

dynamometer, will be used instead of ASM testing, the requirement is no longer necessary because the risks that gave rise to it no longer exist. No emissions impact will result from these changes.

EPA has made the preliminary determination that these revisions to Rule 391–3–20–.09 have no impact on emissions and are consistent with CAA requirements.

F. Rule 391–3–20–.11, ''Inspector Qualifications and Certification''

The April 30, 2021, submittal amends Rule 391–3–20–.11, ''Inspector Qualifications and Certification,'' to remove references to ''newer'' vehicles, specifically in 391–3–20–.11(4) and (7). As described above, the distinction between ''newer'' and ''older'' vehicles is obsolete. The submittal specifically removes language that specifies requirements for inspectors who hold certificates that authorize them to only work on ''newer'' vehicles. As ''newer'' vehicle only certificates will no longer exist, the result of this removal will mean that inspectors will receive a certificate that authorizes them to inspect all vehicles.

EPA has made the preliminary determination that this revision to Rule 391–3–20–.11 has no impact on emissions and is consistent with CAA requirements.

V. Incorporation by Reference

In this document, EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with the requirements of 40 CFR 51.5, and as explained in Sections I through IV of this preamble, EPA is proposing to incorporate by reference Georgia Rules 391–3–20–.01—*Definitions;* 391–3–20–.04—*Emission Inspection Procedures;* 391–3–20–.05—*Emission Standards;* 391–3–20–.07—*Inspection Equipment System Specifications;* 391–3–20–.09—*Inspection Station Requirements;* and 391–3–20–.11—*Inspector Qualifications and Certification,* all of which have an effective date of April 13, 2021, into the Georgia SIP. EPA has made, and will continue to make, these materials generally available through *www.regulations.gov* and at the EPA Region 4 office (please contact the person identified in the ''For Further Information Contact'' section of this preamble for more information).

VI. Proposed Action

EPA is proposing to approve the aforementioned changes to the Georgia SIP. Specifically, EPA is proposing to approve the changes to Georgia Rules 391–3–20–.01—*Definitions;* 391–3–20–.04—*Emission Inspection Procedures;* 391–3–20–.05—*Emission Standards;* 391–3–20–.07—*Inspection Equipment System Specifications;* 391–3–20–.09—*Inspection Station Requirements;* and 391–3–20–.11—*Inspector Qualifications and Certification* into the Georgia SIP. EPA has made the preliminary determination that these changes have no impact on emissions and are consistent with CAA requirements.

VII. Statutory and Executive Order Reviews

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

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

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

List of Subjects in 40 CFR Part 52

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

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

Dated: June 30, 2022.

Daniel Blackman,

Regional Administrator, Region 4.

[FR Doc. 2022–14537 Filed 7–8–22; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 697

[Docket No. 220701–0149]

RIN 0648–BF01

Fisheries of the Northeastern United States; Atlantic Coastal Fisheries Cooperative Management Act Provisions; American Lobster Fishery

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

ACTION: Proposed rule; request for comments.

SUMMARY: Based on the Atlantic States Marine Fisheries Commission's recommendations, we are proposing to establish individual and aggregate trap caps in Lobster Conservation Management Areas 2 and 3, and institute mandatory coastwide electronic harvester reporting for all Federal lobster vessels. The proposed ownership caps and trap cap reduction measures are intended to reduce fishing exploitation and latent effort in the trap fishery by scaling the fishery to the size of the Southern New England lobster

stock. The proposed harvester reporting requirement is intended to improve the spatial resolution of harvester data, and improve and expand the collection of fishery effort data. This action is necessary to ensure fishery regulations for the lobster fishery in Federal waters remain compatible with the intent of the Commission's Interstate Fishery Management Plan for American Lobster and consistent with the Atlantic Coastal Fisheries Cooperative Management Act.

DATES: Comments must be received on or before August 10, 2022.

ADDRESSES: You may submit comments, identified by NOAA–NMFS–2022–0032, by any one of the following methods:

• *Electronic Submissions:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *https://www.regulations.gov* and enter ''NOAA–NMFS–2022–0032'' in the Search box. Click on the ''Comment'' icon, complete the required fields, and enter or attach your comments.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personally identifiable information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields, if you wish to remain anonymous).

Written comments regarding the burden-hour estimates or other aspects of the collection-of-information requirements contained in this proposed rule may be submitted to (enter office name) and to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Allison Murphy, Fishery Policy Analyst, (978) 281–9122.

SUPPLEMENTARY INFORMATION:

Background

Statutory Authority

The proposed regulations would modify Federal lobster fishery management measures in the Exclusive Economic Zone (EEZ) under the authority of section 803(b) of the Atlantic Coastal Fisheries Cooperative Management Act (16 U.S.C. 5101 *et seq.*), which states, in the absence of an approved and implemented Fishery Management Plan under the Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1801 *et seq.*) and, after consultation with the appropriate fishery management council(s), the Secretary of Commerce may implement regulations to govern fishing in the EEZ, from 3 to 200 nautical miles offshore. The regulations must be: (1) Compatible with the effective implementation of an Interstate Fishery Management Plan developed by the Atlantic States Marine Fisheries Commission; and (2) consistent with the National Standards set forth in section 301 of the Magnuson-Stevens Act.

Purpose and Need for Management

The purpose of the proposed action is to manage the American lobster fishery in a manner that maximizes resource sustainability, recognizing that Federal management occurs in concert with state management, and thus, that compatibility between state and Federal measures is crucial to the overall success of American lobster management. To achieve this purpose, we are responding to state management measures to address poor stock conditions and persistent recruitment failure of the Southern New England (SNE) American lobster stock. We are also responding to efforts to improve the spatial resolution of harvester data, and improve and expand the collection of fishery effort data. We request public comment and data on the potential impact of the proposed provisions given the need for compatibility with state measures and the need to address the declining SNE American lobster stock.

Background

The American lobster fishery is managed by the Commission under Amendment 3 to the Interstate Fishery Management Plan for American Lobster. Since 1997, the Commission has coordinated the efforts of the states and Federal Government toward sustainable management of the American lobster fishery. We manage the portion of the fishery conducted in Federal waters from 3 to 200 miles offshore, based on management recommendations made by the Commission.

The American lobster management unit is divided between two lobster stocks and seven Lobster Conservation Management Areas. There have been a number of stock assessments over the last decade—the most recent being in 2020—but the 2009 stock assessment was a critical starting point for much of what is being proposed in this action. The 2009 stock assessment indicated that the SNE American lobster stock, which includes all or part of six Areas, was at a low level of abundance and was experiencing persistent recruitment failure caused by a combination of environmental factors and continued fishing mortality. The 2015 and 2020 assessments have since yielded similar results.

To address the poor condition of the SNE stock, the Commission adopted Addenda XXI and XXII in 2013 as part of an attempt to scale the SNE fishery to the diminished size of the SNE resource. These addenda were developed to address latent effort in the fishery and, by reducing trap limits to reduce harvest, allow for potential stock rebuilding. We temporarily delayed this rulemaking action from 2016 through 2017 because the Commission was contemplating additional measures to address the poor condition of the SNE stock in Addendum XXV. We did not want to initiate a regulatory regime that the Commission might eventually seek to rescind. Ultimately, the Commission abandoned Addendum XXV. We again began development of Federal waters Addenda XXI and XXII measures.

While we were developing this action, the Commission adopted Addendum XXVI in February 2018, which aimed at improving harvester reporting and biological data collection in state and Federal waters. Addendum XXVI intends to improve the spatial resolution of harvester data, improve and expand the collection of fishery effort data, and obtain better data on the offshore fishery and lobster stock through increased biological sampling. This proposed rule also seeks to implement elements of Addendum XXVI into Federal regulations. Copies of the addenda are available on the Commission's website at: *https://www.asmfc.org.*

Proposed Measures

Area 2 Measures

In Area 2, we propose an ownership cap that would restrict a Federal permit holder to 800 active Area 2 traps, effective on May 1, 2024. This measure complements the Commission's Area 2 recommendations in Addendum XXI, but does not propose the specific Area 2 measures as originally envisioned. The Commission intended Addendum XXI measures be implemented in conjunction with the 2016–2021 Area 2 trap reductions, which were completed as of May 1, 2021. We request comment on whether these proposed measures meet the Commission's intent, given the current state of the Area 2 fishery.

When approved by the Commission in 2013, Addendum XXI included three main provisions for the Area 2 fishery:

1. A 'single ownership or individual permit cap' that would allow an entity, in this case a Federal vessel, an allocation of no more than 1,600 traps (800 active traps and 800 banked traps). In effect, this would allow for the banking of traps above and beyond the Area's maximum trap cap under one permit.

2. An 'aggregate ownership cap' intended to reduce the chance of any entity exerting significant control over the markets and to maintain cultural and geographic diversity in the fishery that would limit each entity to an allocation of not more than 1,600 Area 2 lobster traps (800 active and 800 banked), regardless of the overall number of permits held by a single entity. The addendum did not provide a specific definition of an entity, but we propose below to use a definition that is consistent with the definition used in other federally managed Greater Atlantic Regional Fisheries Office (GARFO) fisheries; and

3. A 'sunset provision' for the single ownership cap, which would revert the allocation cap to no more than 800 Area 2 traps, effective two years after the last Addendum XVIII trap reduction (May 1, 2023).

The Commission intended its Area 2 measures to allow a permit holder the ability to acquire a total of 1,600 Area 2 lobster traps (800 active and 800 'banked') on one permit by purchasing traps in excess of the 800 active-trap limit through the annual trap transfer program. As the Area 2 allocations were reduced by annual 2016–2021 trap cuts, the permit holder could activate these excess or 'banked' traps to maintain their vessel's former allocation of fishable traps, without incurring a repeated 10-percent conservation tax associated with the trap transfer program (although the 10-percent conservation tax would nevertheless apply when initially purchased). When the trap reductions were completed, the sunset clause was intended to give permit holders two years to make any final adjustments to their active allocations using banked traps. After the two-year adjustment period, banked traps would be eliminated and a permit holder would be limited to the active allocations associated with their Area 2 permits, not to exceed 800 Area 2 traps, as the ownership cap would revert to 800 traps. This was intended to eliminate from the fishery any unused or latent traps that had been banked and revert Area 2 to an owner/operator fishery. Permit holders could still use the Trap Transfer Program after banking is eliminated to make further adjustments to their active trap allocations through purchase or sale agreements with other Federal lobster permit holders.

Given that the annual 2016–2021 trap reductions are complete, trap 'banking' provisions of Addendum XXI are no longer a necessary element of the Area 2 management plan. Our proposed ownership cap of 800 active Area 2 traps, effective on May 1, 2024, incorporates elements of the Addendum XXI within the current context of the fishery. Despite excluding the now-moot banking recommendation, this proposed cap makes an effort to realize the ultimate desired outcome of Addendum XXI: Implementing the 'aggregate ownership cap' by restricting an entity holding an Area 2 permit, defined as persons who are shareholders in a vessel owned by a corporation, who are partners (general or limited) to a vessel owner, or who, in any way, partly own a vessel, to 800 active Area 2 traps at the end of a two-year adjustment period. The Addendum also included a provision whereby an entity owning two or more permits (*i.e.,* 1,600 traps) would be allowed to retain those permits and traps, but may not own or share ownership of any additional permits.

The provisions of Addendum XXI allow a two-year sunset clause, whereby all banked allocation is eliminated. With banking no longer a necessary element of the Area 2 plan, the sunset clause will not act to eliminate residual allocation, but here we consider its implementation as a means of offering another tool for adjusting allocations prior to finalizing the active ownership cap. Therefore, the proposed rule would cap all entities at 800 active traps two years after the last wave of trap reductions (*i.e.,* May 1, 2024), regardless of the number of individual permits owned. This option would further restrict the fishery by establishing a *de facto* owner/operator fishery. That is, a single entity would be restricted to fish no more than 800 traps, regardless of how many permits they owned. In other words, this action would not take away federal lobster permits, but an entity would be limited to fishing no more than 800 traps no matter how many Federal lobster permits the entity owned.

Addendum XXI originally included a provision that would allow an entity owning two or more permits (*i.e.,* 1,600 traps) as of 2003 to retain those permits and traps, but they would not be allowed to expand further by owning or sharing ownership of any additional permits. Our analysis indicates that, as of 2018, only five entities with Area 2 permits exceeded this limit of two or more permits. Given that the vast majority of the Area 2 fishery remains owner/operator, these five entities are an extremely small portion of the fishery and allowing them to fish at status quo levels will not undermine the purpose and need for this rule. We propose to allow all five entities to retain these permits and traps, but prevent these entities from ownership in additional permits and traps. We believe these proposed Area 2 measures are consistent with the Commission's intent to maintain an owner/operator fishery without unnecessarily restricting entry and exit of operators or negatively affecting fishing communities in Area 2 and request specific comment on this proposal.

Area 3 Measures

In Area 3, we propose a reduction of the existing active trap cap from 1,945 traps to 1,548 traps, over the course of three fishing years (*i.e.,* 2023, 2024, and 2025). We also propose establishing an aggregate ownership cap that would continue to allow a permit holder to accumulate and hold as many permits as they desired, but that would nevertheless cap the number of traps a permit holder could fish to the equivalent of five times the active trap cap. The aggregate ownership cap would be reduced over three years, in proportion to the active trap cap reduction, as summarized in Table 1. For permit holders who currently exceed the proposed limits, we propose to cap their allocations at current levels as of the publication of this proposed rule and prohibit them from exceeding this level.

TABLE 1—AREA 3 ACTIVE TRAP CAP AND AGGREGATE OWNERSHIP CAP REDUCTIONS

Fishing year	Active trap cap	Aggregate ownership cap
2021 (current limits)	1,945	n/a
2023	1,805	9,025
2024	1,629	8,145
2025	1,548	7,740

These measures would complement the Commission's recommendations in Addenda XXI and XXII, but do not propose the Area 3 measures as originally envisioned. The differences are minor and are due to the addenda's intention to be implemented in conjunction with the 2016–2020 Area 3 trap reductions, which were completed

on May 1, 2020. We request comment on whether these proposed measures meet the Commission's intent given the current state of the Area 3 fishery.

Addenda XXI and XXII included the following provisions for Area 3:

1. A reduction in the active trap cap of 5 percent per year over five years, from 2,000 traps to 1,548 traps. (The current Federal Area 3 active trap cap is 1,945 traps and would start from this slightly lower trap level.)

2. An 'individual permit cap' that would allow a permit holder to bank traps in excess of the active trap cap for one permit. The individual permit cap would be lowered over five years, proportionate to the active trap cap reductions; and

3. An 'aggregate ownership cap' that would limit each entity to an allocation of not more than 5 times the individual permit cap. The addendum did not provide a specific definition of an entity, but we propose below to use a definition that is consistent with the definition used in other federally managed GARFO fisheries. The aggregate ownership cap would be lowered over five years, commensurate with the active trap cap reductions.

The Commission intended the active trap cap reductions to scale the size of the Area 3 fishery to the stock and to prevent consolidation. As with Area 2, the Commission intended its Area 3 individual permit cap to allow harvesters the ability to acquire traps in excess of the active trap limit through the annual trap transfer program and activate ''banked'' traps during the 2016–2020 trap cuts, thus maintaining the permit's former allocation of fishable traps, without incurring an additional 10-percent conservation tax associated with the initial trap transfer. Finally, the aggregate ownership cap was intended as another tool to help prevent excessive consolidation of the Area 3 fishery.

Given that the annual 2016–2020 trap reductions are complete, the individual permit cap or trap 'banking' provisions of Addendum XXII are no longer a necessary element of the Area 3 management plan. Further, because of other proposed Area 3 measures that will limit the number of total traps a permit holder can own, a limit on the number of permits is no longer necessary. Therefore, we are not proposing an individual permit cap.

Instead, we propose only the active trap cap reductions, with an aggregate ownership cap that is equal to five times the active trap cap. This differs slightly from the Commission's original recommendation, but it nevertheless remains consistent with the Commission's intent to limit future consolidation. And more to the point, it acts upon Addenda XXI and XXII recommendations within the current context of the fishery. If approved, permit holders would be allowed to use transferability to adjust their allocations.

Understanding the desire by industry to implement these reductions as soon as possible, and being aware that these reductions count toward Area 3 risk reduction measures implemented in the Atlantic Large Whale Take Reduction Plan final rule (86 FR 51970, September 17, 2021), we propose to implement these reductions on an accelerated schedule relative to the Commission's recommendation, achieving the reductions over three years instead of five years. We request comment on this reduction schedule.

Mandatory Reporting

Currently, all commercial and for-hire fishing vessels permitted by GARFO, except Federal lobster permit holders, are required to submit vessel trip reports electronically within 48 hours of the end of a trip. We are proposing expand the mandatory electronic harvester reporting requirements to Federal lobster permit holders and add the collection of several additional data elements in the electronic form, no earlier than January 1, 2023, as recommended by the Commission. The submission of electronic vessel trip reports (eVTR) is being proposed to align the reporting requirements for Federal lobster permit holders with the existing reporting requirements for all other fisheries permitted by GARFO. As discussed above, the Commission adopted Addendum XXVI in February 2018 to improve the spatial resolution of harvester data, to improve and expand the collection of fishery effort data, and to obtain better data on the offshore fishery and lobster stock through improved biological sampling. More specifically, it recommends that we implement a Federal mandatory reporting requirement as soon as possible, and develop and use a specialized, fixed-gear reporting form that includes data fields for improved spatial fishery data and fishing effort information. It also provides specific recommendations for expanded sea sampling and biological sampling requirements. We published an advance notice of proposed rulemaking in 2018 (83 FR 27747, June 14, 2018) to inform the public that we were considering implementing a mandatory harvester reporting requirement and analyzing it within this action. We do not intend to take action on biological and sea sampling recommendations at this time.

Since that time, the New England and Mid Atlantic Fishery Management Councils completed, and we implemented, a joint action requiring all vessels holding permits under their management authority to submit mandatory eVTRs. In addition to changing the submission method, the Council's joint action advanced the submission requirement for all Federal fisheries under Council jurisdiction to 48 hours following the completion of a trip. We published a final rule (85 FR 71575) requiring electronic submission of VTRs for Council-managed fisheries on November 10, 2020, and implemented this requirement for all limited access commercial fisheries managed by the Councils, which eliminated the option to submit VTRs using a paper form, on November 10, 2021. These actions, and the recommendations of the Commission and others to expand harvester reporting to the lobster fleet, have prompted us to consider a universal approach to revising harvester reporting requirements.

Therefore, we are proposing to implement mandatory trip-level electronic harvester reporting of existing data elements for all Federal lobster permit holders, beginning January 1, 2023, using the requirements outlined above. This action would implement consistent reporting requirements, methods, and timing of submission across all GARFO fisheries. We specifically request comment on the timing of this requirement. We recognize that mandating the collection of this data as soon as possible is essential to improve the science and management of the lobster fishery, to understand the co-occurrence of the fishery with protected species, and to support our ability to determine impacts from other marine activities. However, this requirement constitutes a change for Federal lobster permit holders. Providing sufficient time between this notice and implementation will be essential to ensure compliance with this new requirement. Thus, we request comment on an implementation date that balances the need for this data with sufficient time for industry to prepare.

This rule also proposes the collection of several additional data elements in the electronic form, no earlier than January 1, 2023. In addition to the existing reporting elements of the Federal VTR, Addendum XXVI recommended that we collect Lobster Management Area fished, 10-minute square fished, number of traps hauled, trip length, and total number of buoy lines in the water. As states and NMFS moved to consider modifying databases

to accommodate the collection of these elements, the Commission convened a Data Working Group during 2020, consisting of state and Federal partners, Atlantic Coastal Cooperative Statistics Program (ACCSP) staff, and the Commission's lobster policy staff. The Working Group provided guidance for how jurisdictions should collect these data, which resulted in a March 8, 2021, letter recommending the collection of additional data elements, including: Total number of traps hauled by chart area; total number of traps in the water in each chart area fished; average number of traps per string hauled in each chart area fished; total number of buoy lines in each chart area fished; and total number of buoy lines in the water.

We are able to derive the lobster management area and 10-minute square fished using the latitude/longitude information already collected on the eVTR. Similarly, trip length can be derived using the difference between date/time landed and date/time sailed, fields that are already collected on the eVTR. We believe that the collection of this information is redundant and therefore contrary to public interest to collect. Therefore, we are not proposing to collect these data elements; however, these derived data could be made available to the ACCSP data warehouse. We specifically request comment on the utility of these data elements and on the proposal to not collect these data elements.

Given Addendum XXVI and the March 8, 2021, recommendations, we propose the collection of the following additional information:

Data element	Description
Total number of traps hauled by chart area.	This data element includes the direct collection of the number of traps hauled in a chart area. This data element could be calculated from data that is currently collected, but has been recommended for direct collection.
Number of traps in chart area fished.	In addition to total number of traps in the water already on the VTR, this data element includes the direct collection of the number of traps in a given chart area at the beginning of each trip.
Average number of traps per string hauled in the chart area fished.	In addition to average number of traps per string already on the VTR, this data element includes the average number of traps per string in the chart area fished.
Number of buoy lines in the chart area fished.	This data element includes the direct collection of the number of buoy lines in a given chart area at the beginning of each trip.
Total number of buoy lines in the water.	This data element includes the direct collection of the total number of buoy lines in the water.

We are proposing to require the additional data elements no sooner than January 1, 2023. A potential delay in implementation may be necessary to provide sufficient time to complete regional and ACCSP database and programming modifications by vendors for all currently approved and pending eVTR applications. We request comment on this delay in data collection for Federal lobster permit holders.

Proposed Corrections

We intend to use this rule to make several regulatory corrections. We intend to remove several regulations that are no longer necessary, including:

- Area 1 participation requirements at § 697.4(a)(7)(vi);
- Outer Cape Area participation requirements at § 697.4(a)(7)(vii);
- Area 2 participation requirements at § 697.4(a)(7)(viii);
- Outdated lobster size restrictions at § 697.20(a)(5) and (6); and
- Outdated gear marking requirements at § 697.21(a)(1).

In addition, we propose to make corrections to several regulations, including:

- Updating the Greater Atlantic Regional Fisheries Office name and address in several locations;
- Correcting management area coordinates at § 697.18 and § 697.23; and
- Trap transferability requirements at § 697.27(a)(1)(vi), allowing traps in any increment to be transferred.

Classification

The NMFS Assistant Administrator has determined that this proposed rule is consistent with the Atlantic Coastal Fisheries Cooperative Management Act, applicable provisions of the Magnuson-Stevens Fishery Conservation and Management Act, and other applicable law, subject to further consideration after public comment.

This proposed rule has been determined to be significant for purposes of Executive Order 12866.

Regulatory Flexibility Act

An initial regulatory flexibility analysis (IRFA) was prepared, as required by section 603 of the Regulatory Flexibility Act (RFA). The IRFA describes the economic impact this proposed rule, if adopted, would have on small entities. A description of the action, why it is being considered, and the legal basis for this action are contained at the beginning of this section in the preamble and in the **SUMMARY** section of the preamble. A summary of the analysis follows. A copy of this analysis is available from NMFS (see **ADDRESSES**).

Description of the Reasons Why Action by the Agency is Being Considered

In response to the continued decline of the SNE lobster stock, the Commission approved Addenda XXI and XXII to revise the Areas 2 and 3 management programs. In addition, the Commission approved Addendum XXVI to improve data collection programs. The Commission recommended that Federal government to implement measures consistent with these addenda. To the extent practicable, we aim to implement regulations consistent with Commission recommendations, and those promulgated by our partner states.

Statement of the Objectives of, and Legal Basis for, this Proposed Rule

The objective of this action is to adjust American lobster management in response Addenda XXI, XXII, and XXVI to the American Lobster Plan. The purpose of the proposed measures is to manage the Federal lobster fishery in a manner consistent with:

- The Atlantic Coastal Act;
- the National Standards of the Magnuson-Stevens Act;
- the Jonah Crab Plan;
- states laws and regulations;
- and other applicable Federal laws.

The legal basis for the proposed action is the American Lobster Plan and promulgating regulations at part 697.

Description and Estimate of the Number of Small Entities to Which This Proposed Rule Would Apply

As of June 1, 2021, NMFS had issued 2,291 Federal American lobster permits that are potentially regulated by this action. The Area 2 preferred alternative would apply to 131 Federal permits, and the Area 3 preferred alternatives would apply to 82 Federal permits. The reporting requirements preferred alternative would apply to all 2,291 Federal American lobster permits, though many of these permit holders are already subject to electronic trip reporting pursuant to the Council action described above.

Each vessel may be individually owned or part of a larger corporate ownership structure, and for RFA purposes, it is the ownership entity that is ultimately regulated by the proposed action. Ownership entities are identified on June 1st of each year based on the list of all permit numbers, for the most recent complete calendar year, that have applied for any type of Greater Atlantic Region Federal fishing permit. The current ownership data set is based on calendar year 2020 permits and contains gross sales associated with those permits for calendar years 2018 through 2020.

For RFA purposes only, NMFS has established a small business size standard for businesses, including their affiliates, whose primary industry is commercial fishing (see 50 CFR 200.2). A business primarily engaged in commercial fishing (NAICS code 11411) is classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including its affiliates), and has combined annual receipts not in excess of $11 million for all its affiliated operations worldwide. The Small Business Administration (SBA) has established size standards for all other major industry sectors in the U.S., including for-hire fishing (NAICS code 487210). These entities are classified as small businesses if combined annual receipts are not in excess of $8.0 million for all its affiliated operations. Similar to permit data, the annual average of the three most recent years (2018–2020) is used in determining annual receipts for fishing and for-hire businesses.

Ownership data collected from permit holders indicates that there are 2,025 distinct business entities that hold at least one Federal permit regulated by the proposed action. All 2,025 business entities identified could be directly regulated by this proposed action. Of these 2,025 entities, 1,685 are commercial fishing entities, 6 are for-hire entities, and 334 did not have revenues (*i.e.,* were inactive in 2020). Of the 1,685 commercial fishing entities, 1,677 are categorized as small entities and 8 are categorized as large entities, per the NMFS guidelines. All six for-hire entities are categorized as small businesses.

The proposed Area 2 cap of 800 traps is at or higher than most entities' trap allocations, and all entities in excess of the preferred cap will be able to retain their current allocation. Thus, no costs are expected. The proposed Area 3 ownership caps are similarly largely set higher than most entities' allocations and all entities in excess of the preferred cap will be able to retain their current allocation. The active trap cap reduction may result in the loss of some traps, reducing fishing revenues and profits for fishing businesses. The loss in fishing profit from retired traps is estimated to be between $307,000 and $419,000, assuming a profit margin of 5 percent. For harvester reporting, the GARFO supported application for eVTRs is free of charge, and most individuals in the fishery own a device which can be used to submit eVTRs, wage hours are summarized below. We request comments on the assumptions underlying losses due to the proposal, including assumptions that no entities will go out of business due to the proposal and that entities are able to cover fixed costs on diminished revenues.

Description of the Projected Reporting, Record-Keeping, and Other Compliance Requirements of This Proposed Rule

This action contains a new reporting and recordkeeping requirements for Federal American lobster permit holders that would involve costs to vessels to catch lobsters. Vessels would be required to complete a Federal vessel trip report at sea and submit the report electronically to GARFO within 48 hours of returning to port. Costs in terms of burden is estimated to be 7 minutes per report, or 10,065 burden hours total. With a mean hourly wage of $14.49 dollars, total wage burden costs are $155,586.

Federal Rules Which May Duplicate, Overlap, or Conflict With This Proposed Rule

This action does not duplicate, overlap, or conflict with any other federal laws.

Description of Significant Alternatives to the Proposed Action Which Accomplish the Stated Objectives of Applicable Statutes and Which Minimize Any Significant Economic Impact on Small Entities

Most alternatives analyzed in the draft environmental assessment minimize impacts of the proposed action on small entities. A no action alternative was analyzed for Area 2, Area 3 and reporting measures, all of which maintain the status quo and do not increase costs. Non-preferred alternatives were also proposed for each measures. For Area 2, the non-preferred alternative of implementing an ownership trap cap of 1,600 traps was expected to have similar impacts, and thus no costs. For Area 3, non-preferred alternatives included alternate ownership caps and applying historic control dates to the implementation of the ownership caps. The alternative ownership caps are expected to result in similar impacts, as the same entities exceed both the preferred and non-preferred ownership caps. The application of historic control dates would be more costly, as they would have impacted more traps. For harvester reporting, the non-preferred alternative included a paper reporting option which would have increased costs (associated with mailing forms).

Given the current state of the Area management programs, the alternatives remain consistent with the Commission's recommendations but do not consider implemented outdated management measures (*i.e.,* trap banking). Further, the preferred reporting alternative would leverage technology to minimize the burden of completing and submitting/mailing paper Federal vessel trip reports. We request public comment on all alternatives.

Paperwork Reduction Act

This proposed rule contains a collection-of-information requirement subject to review and approval by OMB under the Paperwork Reduction Act (PRA). This rule includes a temporary information collection. The collection-of-information requirement in this proposed rule relates to the collection under Control Number 0648–0212, ''Greater Atlantic Region Logbook Family of Forms.'' However, due to multiple concurrent actions for that collection, the collection-of-information requirement in this proposed rule will be assigned a temporary Control Number that will later be merged into Control Number 0648–0212. Public reporting burden for eVTRs is estimated to average 7 minutes (0.117 hours), including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Public comment is sought regarding: Whether this 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 burden estimate; 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, including through the use of automated collection techniques or other forms of information technology. Submit comments on these or any other aspects of the collection of information at *www.reginfo.gov/public/do/PRAMain.*

Notwithstanding any other provisions 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.

List of Subjects in 50 CFR Part 697

Fisheries, Fishing, Reporting and recordkeeping requirements.

Dated: July 5, 2022.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 697 is proposed to be amended as follows:

PART 697—ATLANTIC COASTAL FISHERIES COOPERATIVE MANAGEMENT

■ 1. The authority citation for part 697 continues to read as follows:

Authority: 16 U.S.C. 1501 *et seq.*

■ 2. In § 697.2, remove the definition for ''Qualifying Year'' and revise the definition for ''Regional Administrator'' to read as follows:

§ 697.2 Definitions.

* * * * *

Regional Administrator, means Regional Administrator, Greater Atlantic Region, NMFS, or Regional Administrator, Southeast Region, NMFS, whichever has the applicable jurisdiction, or a respective designee.

* * * * *

■ 3. In § 697.4,

■ a. Revise paragraph (a)(1) introductory text, and paragraphs (a)(7)(i) and (ii), and (d)(1);

■ b. Remove and reserve paragraphs (a)(7)(vi) through (viii);

■ c. Revise paragraph (f)(1)(i);

■ d. Remove paragraph (f)(1)(v); and

■ e. Add paragraph (q).

The revisions and addition read as follows:

§ 697.4 Vessel permits and trap tags.

(a) * * *

(1) *Eligibility.* To be eligible for issuance or renewal of a Federal limited access lobster permit, a vessel must:

* * * * *

(7) * * *

(i) It is unlawful for vessels issued a limited access American lobster permit fishing with traps, to retain on board, land, or possess American lobster in or from the management areas specified in § 697.18, unless such fishing vessel has been issued a valid management area designation certificate or valid limited access American lobster permit specifying such management area(s).

(ii) Each owner of a fishing vessel that fishes with traps capable of catching lobster must declare to NMFS in his/her annual application for permit renewal which management areas, as described in § 697.18, the vessel will fish in for lobster with trap gear during that fishing season. A permit federal lobster permit holder may declare into Lobster Conservation Management Areas 1, 2, 3, 4, 5, and/or the Outer Cape Management Area to fish with traps, only in the following two circumstances:

(A) The NOAA Regional Administrator previously qualified the permit into the requested area as part of the Area 1, 2, 3, 4, 5 and/or Outer Cape Cod Limited Access Program during the initial limited access area qualification process; and/or

(B) The permit holder, even if the permit has not qualified as described in paragraph (a)(7)(ii)(A) of this section, is seeking access to Area 2, 3, and/or the Outer Cape Area based upon ownership of traps acquired as part of the Trap Transfer Program, described in § 697.27, that the NOAA Regional Administrator has previously qualified and allocated under the Area 2, 3, and/or Outer Cape Cod Limited Access Programs.

* * * * *

(d) * * *

(1) Any lobster trap fished in Federal waters must have a valid Federal lobster trap tag permanently attached to the trap bridge or central cross-member, unless exempt under § 697.26.

* * * * *

(f) * * *

(1) * * *

(i) The applicant has failed to submit a complete application. An application is complete when all requested forms, information, documentation, and fees, if applicable, have been received and the applicant has submitted all applicable reports specified in paragraph (q) of this section.

* * * * *

(q) *Fishing Vessel Trip Reports*—(1) *Information to be Submitted.* All federally permitted lobster vessels must maintain onboard the vessel, and submit an electronic fishing log to NMFS for each fishing trip. Both the vessel permit owner and the vessel permit operator are responsible for ensuring the report is accurate and is filed. The report must be filed regardless of species fished for or taken during the trip and this report-must be entered into and submitted through a software application approved by NMFS. The report must contain the following information:

(i) Vessel name;

(ii) USCG documentation number (or state registration number, if undocumented);

(iii) Permit number;

(iv) Date/time left port on fishing trip;

(v) Date/time returned from port on fishing trip;

(vi) Trip type (commercial, recreational, party, or charter);

(vii) Number of crew;

(viii) Number of anglers (if a charter or party boat);

(ix) Gear fished;

(x) Lobster trawl/string information;

(A) Total number of trawls/strings in the water;

(B) Average number of pots per trawl/string;

(C) Total number of pots in the water;

(xi) Entrance (ring/hoop) size;

(xii) Chart area fished, based on the location of the start of haul back begins;

(xiii) Latitude/longitude where the majority of fishing effort occurred;

(xiv) Average depth where the majority of fishing effort occurred;

(xv) Total number of strings hauled per chart area per trip;

(xvi) Average soak time per trawl/string;

(xvii) Hail weight, in pounds (or count of individual fish, if a party or charter vessel), by species, of all species, or parts of species;

(xviii) Dealer permit number;

(xix) Dealer name;

(xx) Date sold, port and state landed; and

(xxi) Vessel operator's name, signature, and operator's permit number (if applicable).

(xxii) Total number of traps hauled by chart area;

(xxiii) Number of traps in chart area fished;

(xxiv) Average number of traps per string hauled in the chart area fished;

(xxv) Number of buoy lines in the chart area fished; and

(xxvi) Total number of buoy lines in the water.

(2) *When to fill out a vessel trip report.* Vessel trip reports required by paragraph (q)(1)(i) of this section must be filled out with all required information, except for information not yet ascertainable, prior to entering port. Information that may be considered unascertainable prior to entering port includes dealer name, dealer permit number, and date sold. Vessel trip reports must be completed as soon as the missing information is ascertained.

(3) *Inspection.* All persons required to submit reports under this part must make these reports and their underlying information available for inspection immediately upon the request of an

authorized officer or an employee of NMFS designated by the Regional Administrator to make such inspections.

(4) *Submitting reports*—(i) For any vessel issued a valid lobster permit, or eligible to renew a limited access permit under this part, fishing vessel trip reports, required by paragraph (b)(1) of this section, must be submitted within 48 hours at the conclusion of a trip.

(ii) For the purposes of paragraph (q)(4)(i) of this section, the date when fish are offloaded from a commercial vessel will establish the conclusion of a commercial trip.

(iii) For the purposes of paragraph (q)(4)(i) of this section, the date a charter/party vessel enters port will establish the conclusion of a for-hire trip.

* * * * *

■ 4. In § 697.6, revise paragraph (n)(1)(ii)(B) to read as follows:

§ 697.6 Dealer permits.

* * * * *

(n) * * *

(1) * * *

(ii) * * *

(B) When purchasing or receiving fish from a vessel landing in a port located outside of the Greater Atlantic Region (Maine, New Hampshire, Massachusetts, Connecticut, Rhode Island, New York, New Jersey, Pennsylvania, Maryland, Delaware, Virginia and North Carolina), only purchases or receipts of species managed by the Greater Atlantic Region under this part (American lobster or Jonah crab), and part 697 of this chapter, must be reported. Other reporting requirements may apply to those species not managed by the Greater Atlantic Region, which are not affected by this paragraph (n); and

* * * * *

■ 5. Revise § 697.18 to read as follows:

§ 697.18 Lobster management areas.

The following lobster management areas are established for purposes of implementing the management measures specified in this part. (A copy of a chart showing the American lobster EEZ management areas is available upon request to the Office of the Regional Administrator, NMFS, 55 Great Republic Drive, Gloucester, MA 01930.)

(a) *EEZ Nearshore Management Area 1.* EEZ Nearshore Management Area 1 includes state and federal waters nearshore in the Gulf of Maine that are bounded on the west and north by the coastlines of Massachusetts (including the southwestern extent of the Cape Cod Canal), New Hampshire, and Maine, bounded on the east by the U.S.-Canada Maritime Boundary, and bounded on the southeast by the following points connected in the order listed by straight lines:

Point	Latitude	Longitude	Notes
A	43°58.25′ N	67°21.44′ W	(1)
B	43°41′ N	68°00′ N	.....
C	43°12′ N	69°00′ W	.....
D	42°49′ N	69°40′ W	.....
E	42°15.5′ N	69°40′ W	.....
F	42°10′ N	69°56′ W	.....
G	42°05.5′ N	70°14′ W	.....
H	42°04.25′ N	70°17.22′ W	.....
I	42°02.84′ N	70°16.1′ W	.....
J	42°03.4′ N	70°14.2′ W	.....

(1) Point A is intended to fall on the U.S./Canada Maritime Boundary.

(b) *EEZ Nearshore Management Area 2.* EEZ Nearshore Management Area 2 includes state and federal waters nearshore in Southern New England that are bounded on the north by the coastlines of Massachusetts (including the northeastern extent of the Cape Cod Canal) and Rhode Island, and bounded on all other sides by the following points connected in the order listed by straight lines:

Point	Latitude	Longitude	Notes
A	41°40′ N	70°05′ W	.....
B	41°15′ N	70°05′ W	.....
C	41°21.5′ N	69°16′ W	.....
D	41°10′ N	69°06.5′ W	.....
E	40°55′ N	68°54′ W	.....
F	40°27.5′ N	72°14′ W	.....
G	40°45.5′ N	71°34′ W	.....
H	41°07′ N	71°43′ W	.....
I	41°06.5′ N	71°47′ W	.....
J	41°11.5′ N	71°47.25′ W	.....
K	41°18.5′ N	71°54.5′ W	(1)

(1) From Point K, the EEZ Nearshore Management Area 2 follows the maritime boundary between Connecticut and Rhode Island to the coastal Connecticut/Rhode Island boundary.

(c) *Area 2/3 Overlap.* The Area 2/3 Overlap is defined by the area, comprised entirely of Federal waters, bounded by straight lines connecting the following points, in the order stated:

Point	Latitude	Longitude
A	41°10′ N	69°06.5′ W
B	40°55′ N	68°54′ W
C	40°27.5′ N	72°14′ W
D	40°45.5′ N	71°34′ W
A	41°10′ N	69°06.5′ W

(d) *EEZ Offshore Management Area 3.* EEZ Offshore Management Area 3 is defined by the area, comprised entirely of Federal waters, bounded by straight lines connecting the following points, in the order stated:

Point	Latitude	Longitude	Notes
A	43°58.25′ N	67°21′ W	(1),(2)
B	43°41′ N	68°00′ W	.....
C	43°12′ N	69°00′ W	.....
D	42°49′ N	69°40′ W	.....
E	42°15.5′ N	69°40′ W	.....
F	42°10′ N	69°56′ W	.....
G	42°21.5 N	69°16′ W	.....
H	41°10′ N	69°06.5′ W	.....
I	40°45.5′ N	71°34′ W	.....
J	40°27.5′ N	72°14′ W	.....
K	40°12.5′ N	72°48.5′ W	.....
L	39°50′ N	73°01′ W	.....
M	38°39.5′ N	73°40′ W	.....
N	38°12′ N	73°55′ W	.....
O	37°12′ N	74°44′ W	.....
P	35°34′ N	74°51′ W	.....
Q	35°14.5′ N	75°31′ W	.....
R	35°14.5′ N	71°24′ W	(2)

(1) Point A is intended to fall on the U.S.-Canada Maritime Boundary.

(2) From Point R back to Point A along the outer limit of the US EEZ and the U.S.-Canada Maritime Boundary.

(e) *EEZ Nearshore Management Area 4.* EEZ Nearshore Management Area 4 includes state and federal waters nearshore in the northern Mid-Atlantic, bounded on the west and north by the coastlines of New Jersey and New York (crossing the East River at 74°W), and bounded on all other sides by the following points connected in the order listed by straight lines, unless otherwise noted:

Point	Latitude	Longitude	Notes
A	41°0.7′ N	72°00′ W	.....
B	40°57.33′ N	72°00′ W	(1),(2)
C	41°06.5′ N	71°47′ W	(2),(3)
D	41°07′ N	71°43′ W	.....
E	40°45.5′ N	71°34′ W	.....
F	41°27.5′ N	72°14′ W	.....
G	40°12.5′ N	72°48.5′ W	.....
H	39°50′ N	73°01′ W	.....
I	39°50′ N	72°09.2′ W	.....

(1) Point B is intended to fall along the Three Nautical Mile line.

(2) From Point B to Point C following the Three Nautical Mile line.

(3) Point C is intended to fall along the Three Nautical Mile line.

(f) *EEZ Nearshore Management Area 5.* EEZ Nearshore Management Area 5 includes state and Federal waters nearshore in the southern Mid-Atlantic, bounded on the west by the coastline of the United States, and bounded on all other sides by the following points connected in the order listed by straight lines:

Point	Latitude	Longitude
A	39°50′ N	74°09.2′ W
B	39°50′ N	72°55′ W
C	38°38.2′ N	73°33.8′ W
D	38°10.4′ N	73°49′ W
E	37°10.6′ N	74°38′ W
F	35°31.9′ N	74°45.5′ W
G	35°14.5′ N	75°19.3′ W
H	35°14.5′ N	75°31.5′ W

(g) *Area 3/5 Overlap.* The Area 3/5 Overlap includes state and Federal waters in the southern Mid-Atlantic bounded by the following points connected in the order listed by straight lines:

Point	Latitude	Longitude
A	39°50′ N	73°01′ W
B	39°50′ N	72°55′ W
C	38°38.2′ N	73°33.8′ W
D	38°10.4′ N	73°49′ W
E	37°10.6′ N	74°38′ W
F	35°31.9′ N	74°45.5′ W
G	35°14.5′ N	75°19.3′ W
H	35°14.5′ N	75°31′ W
I	35°34′ N	74°51′ W
J	37°12′ N	74°44′ W
K	38°12′ N	73°55′ W
L	38°39.5′ N	73°40′ W
A	39°50′ N	73°01′ W

(h) *Nearshore Management Area 6.* The Nearshore Management Area 6 includes New York and Connecticut state waters, bounded by the Long Island Sound coastlines of both states (including the East River until 74° W, and the northern extent of the Harlem River), and bounded on the east by the following points connected in the order listed by straight lines:

Point	Latitude	Longitude	Notes
A	41°0.7′ N	72°00′ W	.....
B	40°57.33′ N	72°00′ W	(1)(2)
C	41°06.5′ N	71°47′ W	(2)(3)
D	41°11.5″ N	71°47.25″ W	.....
E	41°18.5″ N	71°54.5″ W	(4)

(1) Point B is intended to fall along the Three Nautical Mile line.
(2) From Point B to Point C following the Three Nautical Mile line.
(3) Point C is intended to fall along the Three Nautical Mile line.
(4) From Point E, the Nearshore Management Area 6 follows the maritime boundary between Connecticut and Rhode Island to the coastal Connecticut/Rhode Island boundary.

(i) *EEZ Nearshore Outer Cape Lobster Management Area.* EEZ Nearshore Outer Cape Lobster Management Area includes state and Federal waters off Cape Cod, bounded by the following points connected in the order listed by straight lines, unless otherwise noted:

Point	Latitude	Longitude	Notes
A	41°54.46′ N	70°03.99′ W	(1)
B	41°52′ N	70°07.49′ W	.....
C	42°02.84′ N	70°16.1′ W	.....
D	42°04.25′ N	70°17.22′ W	.....
E	42°05.5′ N	70°14′ W	.....
F	42°10′ N	69°65′ W	.....
G	41°21.5′ N	69°16′ W	.....
H	41°15′ N	70°05′ W	.....
I	41°40′ N	70°05′ W	(1)

(1) From Point I back to Point A following the outer coastline of Cape Cod.

(j) *Area management.* NMFS may, consistent with § 697.25, implement management measures necessary for each management area, in order to end overfishing and rebuild stocks of American lobster.

■ 6. In § 697.19, revise the section heading, paragraph (c), and add paragraph (m).

§ 697.19 Trap limits, ownership caps, and trap tag requirements for vessels fishing with lobster traps.

* * * * *

(c) *Area 3 trap limits.*—(1) Effective May 1, 2023, the Area 3 trap limit is 1,805 traps. Federally permitted lobster fishing vessels may only fish with traps that have been previously qualified and allocated into Area 3 by the Regional Administrator, as part of the Federal Area 3 Limited Access Program. This allocation may be modified by trap cuts and/or trap transfers, but in no case shall the allocation exceed the trap limit.

(2) Effective May 1, 2024, the Area 3 trap limit is 1,629 traps. Federally permitted lobster fishing vessels may only fish with traps that have been previously qualified and allocated into Area 3 by the Regional Administrator, as part of the Federal Area 3 Limited Access Program. This allocation may be modified by trap cuts and/or trap transfers, but in no case shall the allocation exceed the trap limit.

(3) Effective May 1, 2025, the Area 3 trap limit is 1,548 traps. Federally permitted lobster fishing vessels may only fish with traps that have been previously qualified and allocated into Area 3 by the Regional Administrator, as part of the Federal Area 3 Limited Access Program. This allocation may be modified by trap cuts and/or trap transfers, but in no case shall the allocation exceed the trap limit.

* * * * *

(m) *Ownership caps.* (1) Area 2—(i) The Area 2 ownership cap shall be restricted to no more than 1,600 allocated traps. An entity is prohibited from possessing Area 2 trap allocations in excess of 1,600 traps. An entity shall be defined as any person having an ownership interest, including, but not limited to, persons who are shareholders in a vessel owned by a corporation, who are partners (general or limited) to a vessel owner, or who, in any way, partly own a Federally permitted lobster vessel. In determining an entity's ownership cap allocation, NMFS will not attribute based upon an entity's percentage ownership interest, but will attribute the full amount of a permit's allocation to the entity upon a finding of any ownership interest in the permit. An entity with an ownership interest above this cap on May 1, 2022 shall not be reduced to this 1,600 trap cap, but may not expand their ownership interest beyond that which existed on May 1, 2022.

(ii) Effective May 1, 2024, the Area 2 ownership cap shall be restricted to no more than 800 allocated traps. An entity is prohibited from possessing Area 2 trap allocations in excess of 800 traps. An entity shall be defined as any person having an ownership interest, including, but not limited to, persons who are shareholders in a vessel owned by a corporation, who are partners (general or limited) to a vessel owner, or who, in any way, partly own a Federally permitted lobster vessel. In determining an entity's ownership cap allocation, NMFS will not attribute based upon an entity's percentage ownership interest, but will attribute the full amount of a permit's allocation to the entity upon a finding of any ownership interest in the permit. An entity with an ownership interest above this cap on May 1, 2022 shall not be reduced to this 1,600 cap, but may not expand their ownership interest beyond that which existed on May 1, 2022.

(iii) Vessel owners with an Area 2 lobster permit in confirmation of permit history, and in compliance with the ownership restrictions in paragraph (m)(2)(ii) of this section, are eligible to renew such permits(s) and/or confirmation(s) of permit history, but will be bound by the trap limits in paragraphs (m)(1)(i) or (ii) of this section.

(2) Area 3.—(i) Effective May 1, 2023, the Area 3 ownership cap shall be restricted to no more than 9,025 allocated traps. An entity is prohibited from possessing Area 3 trap allocations in excess of 9,025 traps. An entity shall be defined as any person having an ownership interest, including, but not limited to, persons who are shareholders in a vessel owned by a corporation, who are partners (general or limited) to a vessel owner, or who, in any way, partly own a Federally permitted lobster vessel. In determining an entity's ownership cap allocation, NMFS will not attribute based upon an entity's percentage ownership interest, but will attribute the full amount of a permit's allocation to the entity upon a finding of any ownership interest in the permit.

(ii) Effective May 1, 2024, the Area 3 ownership cap shall be restricted to no more than 8,145 allocated traps. An entity is prohibited from possessing Area 3 trap allocations in excess of 8,145 traps. An entity shall be defined as any person having an ownership

interest, including, but not limited to, persons who are shareholders in a vessel owned by a corporation, who are partners (general or limited) to a vessel owner, or who, in any way, partly own a Federally permitted lobster vessel. In determining an entity's ownership cap allocation, NMFS will not attribute based upon an entity's percentage ownership interest, but will attribute the full amount of a permit's allocation to the entity upon a finding of any ownership interest in the permit.

(iii) Effective May 1, 2025, the Area 3 ownership cap shall be restricted to no more than 7,740 allocated traps. An entity is prohibited from possessing Area 3 trap allocations in excess of 7,740 traps. An entity shall be defined as any person having an ownership interest, including, but not limited to, persons who are shareholders in a vessel owned by a corporation, who are partners (general or limited) to a vessel owner, or who, in any way, partly own a Federally permitted lobster vessel. In determining an entity's ownership cap allocation, NMFS will not attribute based upon an entity's percentage ownership interest, but will attribute the full amount of a permit's allocation to the entity upon a finding of any ownership interest in the permit.

(iv) Vessel owners with an Area 3 lobster permit in confirmation of permit history, and in compliance with the ownership restrictions in paragraph (m)(2)(ii) of this section, are eligible to renew such permits(s) and/or confirmation(s) of permit history, but will be bound by the trap limits in paragraphs (m)(1)(i) or (ii) of this section.

(v) Paragraphs (m)(2)(i) through (iii) of this section do not apply to an entity's Area 3 lobster trap permits and/or confirmations of permit history if that entity's trap allocation exceeded 7,740 traps as of May 1, 2022. The trap allocations of all such entities will be capped at their May 1, 2022 trap allocation.

* * * * *

■ 7. In § 697.20, revise paragraphs (a)(5) through (7), and remove paragraphs (8) and (9), to read as follows:

§ 697.20 Size, harvesting and landing requirements.

(a) * * *

(5) The minimum carapace length for all American lobsters harvested in or from the Offshore Management Area 3 is 3 17/32 inches (8.97 cm).

(6) The minimum carapace length for all American lobsters landed, harvested, or possessed by vessels issued a Federal limited access American lobster permit fishing in or electing to fish in EEZ Offshore Management Area 3 is 3 17/32 inches (8.97 cm).

(7) No person may ship, transport, offer for sale, sell, or purchase, in interstate or foreign commerce, any whole live American lobster that is smaller than the minimum size specified in paragraph (a) of this section.

* * * * *

■ 8. In § 697.21, revise paragraphs (a)(1), (b)(4)(i) through (iii), (c)(3) and (4), (e), and (f), and remove paragraphs (a)(2) and (c)(5), to read as follows:

§ 697.21 Gear identification and marking, escape vent, maximum trap size, and ghost panel requirements.

(a) * * *

(1) *Identification and trap tagging.* Lobster gear must be marked with a trap tag (as specified in § 697.19) with the following code of identification:

(i) A number assigned by the Regional Administrator; or

(ii) Whatever positive identification marking is required by the vessel's home-port state.

* * * * *

(b) * * *

(4) * * *

(i) *Gulf of Maine gear area.* Gulf of Maine gear area is defined as all waters of the EEZ north of 42°20′ N lat. seaward of the outer boundary of the territorial sea (12 nautical miles (22.2 km) from the baseline);

(ii) *Georges Bank gear area.* Georges Bank gear area is defined as all waters of the EEZ south of 42°20′ N lat. and east of 70°00′ W long. or the outer boundary of the territorial sea (12 nautical miles (22.2 km) from the baseline), whichever lies farther east;

(iii) *Southern New England gear area.* Southern New England gear area is defined as all waters of the EEZ west of 70°00′ W long., east of 71°30′ W long., and north of 36°33′ N lat. at a depth greater than 25 fathoms (45.72 m); and

* * * * *

(c) * * *

(3) All American lobster traps deployed or possessed in the EEZ Offshore Management Area 3, or deployed or possessed by a person on or from a vessel issued a Federal limited access American lobster permit fishing in or electing to fish in the EEZ Offshore Management Area 3, must include either of the following escape vents in the parlor section of the trap, located in such a manner that it will not be blocked or obstructed by any portion of the trap, associated gear, or the sea floor in normal use:

(i) A rectangular portal with an unobstructed opening not less than 2 1/16 inches (5.24 cm) × 5 3/4 inches (14.61 cm);

(ii) Two circular portals with unobstructed openings not less than 2 11/16 inches (6.82 cm) in diameter.

(4) The Regional Administrator may, at the request of, or after consultation with, the Commission, approve and specify, through a technical amendment, any other type of acceptable escape vent that the Regional Administrator finds to be consistent with paragraph (c) of this section.

* * * * *

(e) *Maximum trap size*—(1) *EEZ Nearshore Management Area maximum trap size.* American lobster traps deployed or possessed in the EEZ, or, deployed or possessed by a person on or from a vessel issued a Federal limited access American lobster permit as specified under § 697.4, if deployed or possessed by a person or vessel permitted to fish in any EEZ Nearshore Management Area (Area 1, Outer Cape, Area 2, Area 4, Area 5, or Area 6) and the Area 2/3 Overlap, or only in the Area 2/3 Overlap, shall not exceed 22,950 cubic inches (376,081 cubic centimeters) in volume as measured on the outside portion of the trap, exclusive of the runners.

(2) *EEZ Offshore Management Area maximum trap size.* American lobster traps deployed or possessed in the EEZ, or, deployed or possessed by a person on or from a vessel issued a Federal limited access American lobster permit as specified under § 697.4, if deployed or possessed by a person or vessel permitted to fish only in EEZ Offshore Management Area 3 or only in EEZ Offshore Management Area 3 and the Area 2/3 Overlap, shall not exceed 30,100 cubic inches (493,249 cubic centimeters) in volume as measured on the outside portion of the trap, exclusive of the runners.

(f) *Enforcement action.* Unidentified, unmarked, unvented, or improperly-vented American lobster traps, or any untagged American lobster traps, or any lobster traps subject to the requirements and specifications of § 697.21, which fail to meet such requirements and specifications may be seized and disposed of in accordance with the provisions of 15 CFR part 904.

* * * * *

■ 9. In § 697.23, revise paragraphs (b)(2), (c)(2), (d)(2), and (e)(2) to read as follows:

§ 697.23 Restricted gear areas.

* * * * *

(b) * * *

(2) *Definition of Restricted Gear Area I.* Restricted Gear Area I is defined by

the following points connected in the order listed by straight lines (points followed by an asterisk are shared with an adjacent Restricted Gear Area):

Point	Latitude	Longitude	Note
AA	40°02.75′ N	70°16.10′ W	(*)
AB	40°02.45′ N	70°14.10′ W	(*)
AC	40°05.20′ N	70°10.90′ W	(*)
AD	40°03.75′ N	70°10.15′ W	(*)
AE	40°00.70′ N	70°08.70′ W	(*)
AF	39°59.20′ N	70°04.90′ W	(*)
AG ...	39°58.25′ N	70°03.00′ W	(*)
AH	39°56.90′ N	69°57.45′ W	(*)
AI	39°57.40′ N	69°55.90′ W	(*)
AJ	39°57.55′ N	69°54.05′ W	(*)
AK	39°56.70′ N	69°53.60′ W	(*)
AL	39°55.75′ N	69°41.40′ W	(*)
AM ...	39°56.20′ N	69°40.20′ W	(*)
AN	39°58.80′ N	69°38.45′ W	(*)
AO ...	39°59.15′ N	69°37.30′ W	(*)
AP	40°00.90′ N	69°37.30′ W	(*)
AQ ...	40°00.65′ N	69°36.50′ W	(*)
AR	39°57.85′ N	69°35.15′ W	(*)
AS	39°56.80′ N	69°34.10′ W	(*)
AT	39°56.50′ N	69°26.35′ W	(*)
AU	39°56.75′ N	69°24.40′ W	(*)
AV	39°57.80′ N	69°20.35′ W	(*)
AW ...	40°00.05′ N	69°14.60′ W	(*)
AX	40°02.65′ N	69°11.15′ W	(*)
AY	40°02.00′ N	69°08.35′ W	(*)
AZ	40°02.65′ N	69°05.60′ W	(*)
BA	40°04.10′ N	69°03.90′ W	(*)
BB	40°05.65′ N	69°03.55′ W	(*)
BC	40°08.45′ N	69°03.60′ W	(*)
BD	40°09.75′ N	69°04.15′ W	(*)
BE	40°10.25′ N	69°04.40′ W	(*)
BF	40°11.60′ N	69°05.40′ W	(*)
BG ...	40°11.00′ N	69°03.80′ W	(*)
BH	40°08.90′ N	69°01.75′ W	(*)
BI	40°05.30′ N	69°01.10′ W	(*)
BJ	40°05.20′ N	69°00.50′ W	(*)
BK	40°04.35′ N	69°00.50′ W	(*)
BL	40°03.65′ N	69°00.00′ W	(*)
BM ...	40°03.60′ N	68°57.20′ W	(*)
BN	40°05.70′ N	68°52.40′ W	(*)
BO ...	40°08.10′ N	68°51.00′ W	(*)
BP	40°08.70′ N	68°49.60′ W	(*)
BQ ...	40°06.90′ N	68°46.50′ W	(*)
BR	40°07.20′ N	68°38.40′ W	(*)
BS	40°07.90′ N	68°36.00′ W	(*)
BT	40°06.40′ N	68°35.80′ W	.....
BU	40°05.25′ N	68°39.30′ W	.....
BV	40°05.40′ N	68°44.50′ W	.....
BW ...	40°06.00′ N	68°46.50′ W	.....
BX	40°07.40′ N	68°49.60′ W	.....
BY	40°05.55′ N	68°49.80′ W	.....
BZ	40°03.90′ N	68°51.70′ W	.....
CA	40°02.25′ N	68°55.40′ W	.....
CB	40°02.60′ N	69°00.00′ W	.....
CC ...	40°02.75′ N	69°00.75′ W	.....
CD ...	40°04.20′ N	69°01.75′ W	.....
CE	40°06.15′ N	69°01.95′ W	.....
CF	40°07.25′ N	69°02.00′ W	.....
CG ...	40°08.50′ N	69°02.25′ W	.....
CH ...	40°09.20′ N	69°02.95′ W	.....
CI	40°09.75′ N	69°03.30′ W	.....
CJ	40°09.55′ N	69°03.85′ W	.....
CK	40°08.40′ N	69°03.40′ W	.....
CL	40°07.20′ N	69°03.30′ W	.....
CM ...	40°06.00′ N	69°03.10′ W	.....
CN ...	40°05.40′ N	69°03.05′ W	.....
CO ...	40°04.80′ N	69°03.05′ W	.....
CP	40°03.55′ N	69°03.55′ W	.....
CQ ...	40°01.90′ N	69°03.95′ W	.....
CR ...	40°01.00′ N	69°04.40′ W	.....
CS	39°59.90′ N	69°06.25′ W	.....
CT	40°00.60′ N	69°10.05′ W	.....
CU ...	39°59.25′ N	69°11.15′ W	.....
CV	39°57.45′ N	69°16.05′ W	.....
CW ...	39°56.10′ N	69°20.10′ W	.....
CX	39°54.60′ N	69°25.65′ W	.....
CY	39°54.65′ N	69°26.90′ W	.....
CZ	39°54.80′ N	69°30.95′ W	.....
DA	39°54.35′ N	69°33.40′ W	.....
DB	39°55.00′ N	69°34.90′ W	.....
DC ...	39°56.55′ N	69°36.00′ W	.....
DD ...	39°57.95′ N	69°36.45′ W	.....
DE	39°58.75′ N	69°36.30′ W	.....
DF	39°58.80′ N	69°36.95′ W	.....
DG ...	39°57.95′ N	69°38.10′ W	.....
DH ...	39°54.50′ N	69°38.25′ W	.....
DI	39°53.60′ N	69°46.50′ W	.....
DJ	39°54.70′ N	69°50.00′ W	.....
DK	39°55.25′ N	69°51.40′ W	.....
DL	39°55.20′ N	69°53.10′ W	.....
DM ...	39°54.85′ N	69°53.90′ W	.....
DN ...	39°55.70′ N	69°54.90′ W	.....
DO ...	39°56.15′ N	69°55.35′ W	.....
DP	39°56.05′ N	69°56.25′ W	.....
DQ ...	39°55.30′ N	69°57.10′ W	.....
DR ...	39°54.80′ N	69°58.60′ W	.....
DS	39°56.05′ N	70°00.65′ W	.....
DT	39°55.30′ N	70°02.95′ W	.....
DU ...	39°56.90′ N	70°11.30′ W	.....
DV	39°58.90′ N	70°11.50′ W	.....
DW ...	39°59.60′ N	70°11.10′ W	.....
DX	40°01.35′ N	70°11.20′ W	.....
DY	40°02.60′ N	70°12.00′ W	.....
DZ	40°00.40′ N	70°12.30′ W	.....
EA	39°59.75′ N	70°13.05′ W	.....
EB	39°59.30′ N	70°14.00′ W	(*)
AA	40°02.75′ N	70°16.10′ W	(*)

* * * * *

(c) * * *

(2) *Definition of Restricted Gear Area II.* Restricted Gear Area II is defined by the following points connected in the order listed by straight lines (points followed by an asterisk are shared with an adjacent Restricted Gear Area):

Point	Latitude	Longitude	Note
AA	40°02.75′ N	70°16.10′ W	(*)
EB	39°59.30′ N	70°14.00′ W	(*)
EC	39°58.85′ N	70°15.20′ W	.....
ED	39°59.30′ N	70°18.40′ W	.....
EE	39°58.10′ N	70°19.40′ W	.....
EF	39°57.00′ N	70°19.85′ W	.....
EG ...	39°57.55′ N	70°21.25′ W	.....
EH	39°57.50′ N	70°22.80′ W	.....
EI	39°57.10′ N	70°25.40′ W	.....
EJ	39°57.65′ N	70°27.05′ W	.....
EK	39°58.58′ N	70°27.70′ W	.....
EL	40°00.65′ N	70°28.80′ W	.....
EM ...	40°02.20′ N	70°29.15′ W	.....
EN	40°01.00′ N	70°30.20′ W	.....
EO ...	39°58.58′ N	70°31.85′ W	.....
EP	39°57.05′ N	70°34.35′ W	.....
EQ ...	39°56.42′ N	70°36.80′ W	.....
ER	39°58.15′ N	70°48.00′ W	.....
ES	39°58.30′ N	70°51.10′ W	.....
ET	39°58.10′ N	70°52.25′ W	.....
EU	39°58.05′ N	70°53.55′ W	.....
EV	39°58.40′ N	70°59.60′ W	.....
EW ...	39°59.80′ N	71°01.05′ W	.....
EX	39°58.20′ N	71°05.85′ W	.....
EY	39°57.45′ N	71°12.15′ W	.....
EZ	39°57.20′ N	71°15.00′ W	.....
FA	39°56.30′ N	71°18.95′ W	.....
FB	39°51.40′ N	71°36.10′ W	.....
FC	39°51.75′ N	71°41.50′ W	.....
FD	39°50.05′ N	71°42.50′ W	.....
FE	39°50.00′ N	71°45.00′ W	.....
FF	39°48.95′ N	71°46.05′ W	.....
FG	39°46.60′ N	71°46.10′ W	.....
FH	39°43.50′ N	71°49.40′ W	.....
FI	39°41.30′ N	71°55.00′ W	.....
FJ	39°39.00′ N	71°55.60′ W	.....
FK	39°36.72′ N	71°58.25′ W	.....
FL	39°35.15′ N	71°58.55′ W	.....
FM ...	39°34.50′ N	72°00.75′ W	.....
FN	39°32.20′ N	72°02.25′ W	.....
FO	39°32.15′ N	72°04.10′ W	.....
FP	39°28.50′ N	72°06.50′ W	.....
FQ	39°29.00′ N	72°09.25′ W	.....
FR	39°29.75′ N	72°09.80′ W	(*)
FS	39°32.65′ N	72°06.10′ W	(*)
FT	39°35.45′ N	72°02.00′ W	(*)
FU	39°41.15′ N	71°57.10′ W	(*)
FV	39°46.95′ N	71°49.00′ W	(*)
FW ...	39°53.10′ N	71°42.70′ W	(*)
FX	39°52.60′ N	71°40.35′ W	(*)
FY	39°53.10′ N	71°36.10′ W	(*)
FZ	39°57.50′ N	71°20.60′ W	(*)
GA ...	40°00.70′ N	71°19.80′ W	(*)
GB ...	39°59.30′ N	71°18.40′ W	(*)
GC ...	40°02.00′ N	71°01.30′ W	(*)
GD ...	40°00.50′ N	70°57.60′ W	(*)
GE ...	40°00.10′ N	70°45.10′ W	(*)
GF	39°58.90′ N	70°38.65′ W	(*)
GG ...	39°59.15′ N	70°34.45′ W	(*)
GH ...	40°00.55′ N	70°32.10′ W	(*)
GI	40°03.85′ N	70°28.75′ W	(*)
GJ	39°59.75′ N	70°25.50′ W	(*)
GK ...	39°59.80′ N	70°21.75′ W	(*)
GL	40°00.70′ N	70°18.60′ W	(*)
AA	40°02.75′ N	70°16.10′ W	(*)

* * * * *

(d) * * *

(2) *Definition of Restricted Gear Area III.* Restricted Gear Area III is defined by the following points connected in the order listed by straight lines (points followed by an asterisk are shared with an adjacent Restricted Gear Area):

Point	Latitude	Longitude	Note
AA	40°02.75′ N	70°16.10′ W	(*)
GL	40°00.70′ N	70°18.60′ W	(*)
GK ...	39°59.80′ N	70°21.75′ W	(*)
GJ	39°59.75′ N	70°25.50′ W	(*)
GI	40°03.85′ N	70°28.75′ W	(*)
GH ...	40°00.55′ N	70°32.10′ W	(*)
GG ...	39°59.15′ N	70°34.45′ W	(*)
GF	39°58.90′ N	70°38.65′ W	(*)
GE ...	40°00.10′ N	70°45.10′ W	(*)
GD ...	40°00.50′ N	70°57.60′ W	(*)
GC ...	40°02.00′ N	71°01.30′ W	(*)
GB ...	39°59.30′ N	71°18.40′ W	(*)
GA ...	40°00.70′ N	71°19.80′ W	(*)
FZ	39°57.50′ N	71°20.60′ W	(*)
FY	39°53.10′ N	71°36.10′ W	(*)
FX	39°52.60′ N	71°40.35′ W	(*)
FW ...	39°53.10′ N	71°42.70′ W	(*)
FV	39°46.95′ N	71°49.00′ W	(*)
FU	39°41.15′ N	71°57.10′ W	(*)

Point	Latitude	Longitude	Note
FT	39°35.45′ N	72°02.00′ W	(*)
FS	39°32.65′ N	72°06.10′ W	(*)
FR	39°29.75′ N	72°09.80′ W	(*)
GM ...	39°33.65′ N	72°15.00′ W	.....
GN ...	39°47.20′ N	72°01.60′ W	.....
GO ...	39°53.75′ N	71°52.25′ W	.....
GP ...	39°55.85′ N	71°45.00′ W	.....
GQ ...	39°55.60′ N	71°41.20′ W	.....
GR ...	39°57.90′ N	71°28.70′ W	.....
GS ...	40°10.70′ N	71°10.25′ W	.....
GT	40°12.75′ N	70°55.05′ W	.....
GU ...	40°11.05′ N	70°45.80′ W	.....
GV ...	40°06.50′ N	70°40.05′ W	.....
GW ..	40°05.60′ N	70°17.70′ W	.....
AA	40°02.75′ N	70°16.10′ W	(*)

* * * * *

(e) * * *

(2) *Definition of Restricted Gear Area IV.* Restricted Gear Area IV is defined by the following points connected in the order listed by straight lines (points followed by an asterisk are shared with an adjacent Restricted Gear Area):

Point	Latitude	Longitude	Note
AA	40°02.75′ N	70°16.10′ W	(*)
GX ...	40°07.80′ N	70°09.20′ W	.....
GY ...	40°07.60′ N	70°04.50′ W	.....
GZ	40°02.10′ N	69°45.00′ W	.....
HA	40°01.30′ N	69°45.00′ W	.....
HB	40°00.50′ N	69°38.80′ W	.....
HC ...	40°01.70′ N	69°37.40′ W	.....
HD ...	40°01.70′ N	69°35.40′ W	.....
HE	40°00.40′ N	69°35.20′ W	.....
HF	39°57.30′ N	69°25.10′ W	.....
HG ...	40°05.50′ N	69°09.00′ W	.....
HH ...	40°14.30′ N	69°05.80′ W	.....
HI	40°14.00′ N	69°04.70′ W	.....
HJ	40°11.60′ N	68°53.00′ W	.....
HK	40°13.60′ N	68°40.60′ W	.....
BS	40°07.90′ N	68°36.00′ W	(*)
BR	40°07.20′ N	68°38.40′ W	(*)
BQ ...	40°06.90′ N	68°46.50′ W	(*)
BP	40°08.70′ N	68°49.60′ W	(*)
BO ...	40°08.10′ N	68°51.00′ W	(*)
BN	40°05.70′ N	68°52.40′ W	(*)
BM ...	40°03.60′ N	68°57.20′ W	(*)
BL	40°03.65′ N	69°00.00′ W	(*)
BK	40°04.35′ N	69°00.50′ W	(*)
BJ	40°05.20′ N	69°00.50′ W	(*)
BI	40°05.30′ N	69°01.10′ W	(*)
BH	40°08.90′ N	69°01.75′ W	(*)
BG ...	40°11.00′ N	69°03.80′ W	(*)
BF	40°11.60′ N	69°05.40′ W	(*)
BE	40°10.25′ N	69°04.40′ W	(*)
BD	40°09.75′ N	69°04.15′ W	(*)
BC	40°08.45′ N	69°03.60′ W	(*)
BB	40°05.65′ N	69°03.55′ W	(*)
BA	40°04.10′ N	69°03.90′ W	(*)
AZ	40°02.65′ N	69°05.60′ W	(*)
AY	40°02.00′ N	69°08.35′ W	(*)
AX	40°02.65′ N	69°11.15′ W	(*)
AW ...	40°00.05′ N	69°14.60′ W	(*)
AV	39°57.80′ N	69°20.35′ W	(*)
AU	39°56.75′ N	69°24.40′ W	(*)
AT	39°56.50′ N	69°26.35′ W	(*)
AS	39°56.80′ N	69°34.10′ W	(*)
AR	39°57.85′ N	69°35.15′ W	(*)
AQ ...	40°00.65′ N	69°36.50′ W	(*)
AP	40°00.90′ N	69°37.30′ W	(*)
AO ...	39°59.15′ N	69°37.30′ W	(*)
AN	39°58.80′ N	69°38.45′ W	(*)
AM ...	39°56.20′ N	69°40.20′ W	(*)
AL	39°55.75′ N	69°41.40′ W	(*)
AK	39°56.70′ N	69°53.60′ W	(*)
AJ	39°57.55′ N	69°54.05′ W	(*)
AI	39°57.40′ N	69°55.90′ W	(*)
AH	39°56.90′ N	69°57.45′ W	(*)
AG ...	39°58.25′ N	70°03.00′ W	(*)
AF	39°59.20′ N	70°04.90′ W	(*)
AE	40°00.70′ N	70°08.70′ W	(*)
AD	40°03.75′ N	70°10.15′ W	(*)
AC	40°05.20′ N	70°10.90′ W	(*)
AB	40°02.45′ N	70°14.10′ W	(*)
AA	40°02.75′ N	70°16.10′ W	(*)

* * * * *

■ 10. Revise § 697.24 to read as follows:

§ 697.24 Exempted waters for Maine State American lobster permits.

A person or vessel holding a valid permit or license issued by the State of Maine that lawfully permits that person to engage in commercial fishing for American lobster may, with the approval of the State of Maine, engage in commercial fishing for American lobsters in the following areas designated as EEZ, if such fishing is conducted in such waters in accordance with all other applicable Federal and State regulations:

(a) West of Monhegan Island in the federal waters located north of the line from 43°42.17′ N lat., 69°34.27′ W long. to 43°42.25′ N lat., 69°19.30′ W long.

(b) East of Monhegan Island in the federal waters located northwest of the line from 43°44′ N lat., 69°15.08′ W long. to 43°48.17′ N lat., 69°8.02′ W long.

(c) South of Vinalhaven in the federal waters located west of the line from 43°52.61′ N lat., 68°40.00′ W long. to 43°58.12'N lat., 68°32.95′ W long.

(d) South of Boris Bubert Island in the federal waters located northwest of the line from 44°19.27′ N lat., 67°49.50′ W long. to 44°23.67′ N lat., 67°40.50′ W long.

■ 11. In § 697.27, revise paragraph (a)(2)(vi) to read as follows:

§ 697.27 Trap transferability.

(a) * * *

(2) * * *

(vi) Trap allocations may be transferred in any increment.

* * * * *

[FR Doc. 2022–14596 Filed 7–8–22; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register
Vol. 87, No. 131
Monday, July 11, 2022

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

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Doc. No. AMS–FGIS–22–0019]

Process for the Evaluation of Technology for Official Grain Inspection

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice; request for comments.

SUMMARY: The Agricultural Marketing Service (AMS) currently evaluates and approves technology for use in official grain inspection on a case-by-case basis. AMS proposes a new internal process that is meant to facilitate the introduction of new and improved inspection technology that promotes competition and transparency. AMS is seeking public comment on the proposed process.

DATES: Comments must be received by September 9, 2022.

ADDRESSES: Additional technical information on the evaluation process can be found in the ''Procedure and Submission Guidelines for the Evaluation of Technology for Official Grain Inspection'' at *https://www.ams.usda.gov/sites/default/files/media/FGISUserGuidefor Manufacturers.pdf.*

Interested persons are invited to submit written comments concerning this Notice using either of the following procedures:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. You can access this Notice and instructions for submitting public comments by searching for document number, AMS–FGIS–22–0019.
- *Mail:* Dr. Timothy D. Norden, National Grain Center, 10383 N. Ambassador Drive, Kansas City, Missouri 64153.

All submissions received must include the docket number AMS–FGIS–22–0019. All comments received will be included in the record and will be posted without change, including any personal information provided. Comments will be made available for public inspection at the above address during regular business hours or via the at *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Timothy D. Norden, Chief Scientist, Technology and Science Division, Federal Grain Inspection Service, AMS, USDA; Telephone: (816) 702–3803, or Email: *Timothy.D.Norden@usda.gov.*

SUPPLEMENTARY INFORMATION: AMS provides grain inspection services under the authority of the United States Grain Standards Act (7 U.S.C. 71–87k) (USGSA), as amended, and the Agricultural Marketing Act of 1946 (7 U.S.C. 1621–1627), as amended. USGSA at 7 U.S.C. 74 states that the primary objective of the United States standards for grain is to certify the quality of grain as accurately as practicable and to accommodate scientific advances in testing and new knowledge concerning factors related to, or highly correlated with, the end-use performance of grain. The primary focus of the proposed Inspection Technology Evaluation (ITE) Process is on the need and suitability of the technology for official grain inspection. Below is a description of the proposed ITE Process.

''Technology'' refers to instrumentation, equipment, and the associated methods for measuring grain quality factors. ''Factor'' means a measurable grain quality attribute. This evaluation process does not apply to the research and development effort before the technology is deemed fit-for-purpose; that is, the instrument or method has already been developed so that it generates factor-specific results with sufficient accuracy for official grain inspection.

ITE Process Description

The ITE process starts with the submission of a written proposal by a manufacturer of technology for a specific inspection factor. Manufacturers provide an overview of the technology for which they seek approval. This overview should describe the technology solution, indicate to which grains and inspection factor, or factors the technology applies, and the steps the technology uses to analyze a sample. The proposal should address six criteria, which will form the basis of the initial evaluation. These criteria are: (1) need; (2) accuracy; (3) quality control; (4) automation; (5) testing time; and (6) testing cost.

An AMS review team conducts an initial evaluation of the proposal to determine if it meets these criteria. When the review team completes the initial evaluation, AMS decides whether to accept the proposal. This decision is documented and communicated to the manufacturer. If a proposal is not accepted, the manufacturer is informed of the specific deficiencies and the requirements for resubmission. If accepted, the proposal enters a queue, and the manufacturer is notified and provided with an estimate for the start date along with various factors that may affect the length of the evaluation process.

The remaining steps of the evaluation process focus on validating the performance of the submitted technology using AMS' developed criteria or specifications for the specific inspection factor. This allows for refinement of the initial review criteria to account for specific inspection needs and for a statistically sound evaluation of accuracy of the technology. If not already established, AMS develops performance criteria and specifications and determines whether a **Federal Register** notice is needed to finalize the criteria.

With established performance criteria and specifications, AMS requests that the manufacturer provides information and data supporting the criteria and specifications. When all requested information has been submitted and accepted, AMS conducts an independent verification that focuses on accuracy. AMS will also determine if the submitted technology delivers results that are equivalent to currently approved technology. If this process shows that the technology is accurate and it passes the equivalence test, AMS notifies stakeholders and provides them with the implementation plan. If AMS is unable to verify the accuracy or the technology is not equivalent, the manufacturer is notified of the deficiencies and the requirements for resubmission.

If AMS approves the technology, an AMS certificate of conformance (COC) is issued that allows for use in official grain inspection. If any alterations to the

technology are made that could affect measurement results, the manufacturer should inform AMS in writing to determine the significance. In addition, if the manufacturer finds that the technology is not meeting AMS performance criteria, they should immediately inform AMS. Failure to inform AMS, may result in cancellation of the COC.

Evaluation Criteria

Need. AMS assesses the need criterion through a review of the manufacturer-provided information, input from stakeholders including the Grain Inspection Advisory Committee, and from internal information. AMS evaluates the demand for the testing technology from AMS customers and stakeholders and compares the demand to the costs of providing the testing service, including standardization, calibration, and quality control efforts. AMS recommends that manufacturers provide information from a market assessment of the technology that supports this demand. For existing inspection factors, a successful technology should be compatible with existing official procedures such as subsample size requirements. For a test factor with an existing single approved instrument model, a successful new instrument should offer an added benefit to official inspection and provide results in terms of accuracy that are equivalent to, or better than the currently approved instrument model. If pertinent, manufacturers should provide national or international regulatory requirements the technology addresses. This may include, but is not limited to, maximum levels for toxic substances.

Accuracy and Quality Control. Manufacturers should provide relevant data that support both the accuracy and quality control criteria. Manufacturers and other interested parties are encouraged to review the specific requirements and additional technical information at [insert hyperlink to technical document].

Automation. If the technology generates an electronic result, the manufacturer should provide procedures for automatic data capture and the method to modify the output.

Testing Time. Manufacturers should provide the estimated testing time required from sample receipt to final result. The testing time will be assessed by comparison to existing or similar technologies. Longer testing times should be justified by providing a significant advantage over existing technology.

Testing Cost. The manufacturer should provide itemized cost estimates for the technology, maintenance, consumables, and all materials and equipment needed to perform the test. AMS evaluates the estimated costs of the recommended quality control, calibration, and standardization procedures. The testing cost is compared to existing or similar technologies. Higher testing costs should provide significant advantages over existing technologies.

Melissa R. Bailey,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2022–14671 Filed 7–8–22; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

The Department of Agriculture will submit the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13 on or after the date of publication of this notice. Comments are requested regarding: (1) 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; (2) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding these information collections are best assured of having their full effect if received by August 10, 2022. Written comments and recommendations for the proposed information collection should be submitted, identified by docket number 0535–0264, within 30 days of the publication of this notice by any of the following methods:

- *Email: ombofficer@nass.usda.gov.* Include docket number above in the subject line of the message.
- *E-fax:* 855–838–6382.
- *Mail:* Mail any paper, disk, or CD–ROM submissions to: Richard Hopper, NASS Clearance Officer, U.S. Department of Agriculture, Room 5336 South Building, 1400 Independence Avenue SW, Washington, DC 20250–2024.
- *Hand Delivery/Courier:* Hand deliver to: Richard Hopper, NASS Clearance Officer, U.S. Department of Agriculture, Room 5336 South Building, 1400 Independence Avenue SW, Washington, DC 20250–2024.

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 (NASS)

Title: Land Leasing Survey in Oklahoma.

OMB Control Number: 0535–0264.

Summary of Collection: The primary objectives of the National Agricultural Statistics Service (NASS) are to prepare and issue official State and national estimates of crop and livestock production, disposition and prices, economic statistics, and environmental statistics related to agriculture and to conduct the Census of Agriculture and its follow-on surveys. NASS will conduct a survey of agricultural operations in Oklahoma. Selected farmers will be asked to provide data on rent & acreage as well as form of the lease agreement for operations with the following lease agreements: (1) cash rent for selected crops, (2) share rent, (3) pasture leases, winter grazing, and recreational leases. General authority for these data collection activities is granted under U.S.C. Title 7, Section 2204.

Need and Use of the Information: Oklahoma State University, as well as many farmers and ranchers in Oklahoma, have been interested in land rental rates for agricultural operations in greater detail than what is provided in the Cash Rents and Leases Survey used to satisfy the requirement originally specified in the 2008 Farm Bill and conducted under Office of Management and Budget approval number 0535–0002.

To assist producers with this data need, the Oklahoma State University, Department of Agricultural Economics (OSU–DAE), has been collecting and publishing statistical estimates biennially for more than 30 years—before USDA–NASS was tasked with the Cash Rents County Estimates. The OSU–DAE obtained statistics to assist producers in making sound rental agreements. Due to the diverse nature of the state, OSU–DAE felt it necessary to provide more descriptive land breakouts

such as pasture estimates into native pasture and improved pasture due to large price differences and input costs associated with each type of pasture.

A data request highlighted this limit: A data user (landlord) was trying to re-negotiate the rental rate with their lessee on a large amount of Bermuda grass pastureland. They were given the pasture rate from the USDA–NASS 2017 Cash Rents Survey for the county ($10/ac), district ($12/ac), and the State ($13/ac). The data user was able to find the OSU–DAE pasture rates for 2016/2017 for Bermuda (Improved Pasture) in his Region ($24.55) and at the State level ($22.79). The data user would have lost $12 to $14/per acre if used only the USDA–NASS Cash Rents Survey data alone.

Description of Respondents: Farmers and ranchers in Oklahoma.

Number of Respondents: 2,700.

Frequency of Responses: Reporting: One a year.

Total Burden Hours: 1,022.

Levi S. Harrell,

Departmental Information Collection Clearance Officer.

[FR Doc. 2022–14660 Filed 7–8–22; 8:45 am]

BILLING CODE 3410–20–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2014–0062]

Privacy Act of 1974; System of Records

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of a new system of records.

SUMMARY: The Animal and Plant Health Inspection Service proposes to add a system of records to its inventory of records systems subject to the Privacy Act of 1974, as amended. The system of records is the Smuggling Interdiction and Trade Compliance (SITC) National Information Communication Activity System (SNICAS), USDA/APHIS–21. This notice is necessary to meet the requirements of the Privacy Act to publish in the **Federal Register** notice of the existence and character of record systems maintained by the agency.

DATES: In accordance with 5 U.S.C. 552a(e)(4) and (11), this notice is applicable upon publication, subject to a 30-day notice and comment period in which to comment on the routine uses described below. Please submit any comments by August 10, 2022.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Enter APHIS–2014–0062 in the Search field. Select the Documents tab, then select the comment button in the list of documents.
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2014–0062, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov* or in our reading room, which is located in room 1620 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: For general questions, please contact Mr. Kristian Rondeau, Director Field Operations, District 6, 2150 Centre Avenue, Building B, Fort Collins, CO 80526; (970) 494–7563. For Privacy Act questions concerning this system of records notice, please contact Ms. Tonya Woods, Director, Freedom of Information and Privacy Act Staff, 4700 River Road Unit 50, Riverdale, MD 20737; (301) 851–4076; email: *APHISPrivacy@usda.gov.* For USDA Privacy Act questions, please contact the USDA Chief Privacy Officer, Information Security Center, Office of Chief Information Officer, USDA, Jamie L. Whitten Building, 1400 Independence Ave. SW, Washington, DC 20250; email: *USDAPrivacy@usda.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to the provisions of the Privacy Act of 1974 (5 U.S.C. 552a), notice is given that the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture (USDA) is proposing to add a new system of records, entitled USDA/APHIS–21, Smuggling Interdiction and Trade Compliance (SITC) National Information Communication Activity System (SNICAS), to maintain a record of activities conducted by the agency pursuant to its mission and responsibilities authorized by the Plant Protection Act (7 U.S.C. 7701 *et seq.*); the Animal Health Protection Act (7 U.S.C. 8301 *et seq.*); and the Honey Bee Act (7 U.S.C. 281 *et seq.*). The purpose of the system is to record data and information about APHIS' SITC activities nationwide. SITC is within APHIS' Plant Protection and Quarantine program.

SNICAS supports the mission of SITC programs by providing, to SITC and other agency personnel, information that can be used to assist with detecting and preventing the unlawful entry and distribution into the United States of prohibited and/or non-compliant products that may harbor exotic plant and animal pests, diseases, or invasive species. SITC focuses on anti-smuggling and trade compliance efforts at ports of entry in the United States and in commerce to prevent the establishment of plant and animal pests and diseases, while maintaining the safety of U.S. ecosystems and natural resources. SITC is responsible for collecting, maintaining, and reviewing information to successfully and efficiently meet its mission.

SNICAS consists of a web-based system and paper records and contains information related to commodities that have been physically inspected and/or surveyed by SITC. The system contains records pertaining to U.S. ports of entry and commerce locations that are inspected or surveyed during daily operations. SNICAS also maintains and communicates information associated with SITC operational and administrative activities.

SITC officials use the information in SNICAS to identify and close pathways used for the introduction of prohibited commodities and those regulated commodities that lack the necessary certificates and permits to enter into U.S. commerce. SITC officials also use SNICAS to perform activities such as legal and regulatory actions; scientific research; risk, trend, pathway and targeting analyses; trade support; administrative and budgetary support; supervision and program management; and overall decision support services. Additionally, SITC officials use SNICAS to generate reports to evaluate the risk status of the commercial sites where regulated commodities are seized, the effectiveness of the program, and quality control of the data.

APHIS will share information from the system pursuant to the requirements of the Privacy Act and, in the case of its routine uses, when the disclosure is compatible with the purpose for which the information was compiled. However, APHIS proposes to exempt some records in the system from certain Privacy Act requirements in accordance with 5 U.S.C. 552a(k)(2). APHIS proposes to exempt the system from Privacy Act requirements including subsections (c)(3); (d); (e)(1); (e)(4)(G),

(H), and (I); and (f). A proposed rule has been promulgated in accordance with the requirements of 5 U.S.C. 553(b), (c), and (d) and has been published in today's **Federal Register** [1]. An individual who is the subject of a record in this system may seek access to those records that are not exempt from the access provisions. A determination whether a record may be accessed will be made at the time a request is received.

A report on the new system of records, required by 5 U.S.C. 552a(r), as implemented by Office of Management and Budget Circular A–108, was sent to the Chairman, Committee on Homeland Security and Governmental Affairs, United States Senate; the Chairwoman, Committee on Oversight and Reform, House of Representatives; and the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget.

Done in Washington, DC, this 21st day of June 2022.

Anthony Shea,

Administrator, Animal and Plant Health Inspection Service.

SYSTEM NAME AND NUMBER:

USDA/APHIS–21, Smuggling Interdiction and Trade Compliance (SITC) National Information Communication Activity System (SNICAS)

SECURITY CLASSIFICATION:

Sensitive but unclassified.

SYSTEM LOCATION:

The Animal and Plant Health Inspection Service (APHIS), within the U.S. Department of Agriculture (USDA), maintains records in a Government-approved cloud server accessed through secure data centers in the continental United States. Paper files are held at various Plant Protection and Quarantine (PPQ) Smuggling Interdiction and Trade Compliance national, district, and field offices.

SYSTEM MANAGER:

Deputy Administrator of Plant Protection and Quarantine, APHIS, USDA, 4700 River Road, Riverdale, MD 20737.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The Plant Protection Act (7 U.S.C. 7701 *et seq.*); the Animal Health Protection Act (7 U.S.C. 8301 *et seq.*); and the Honey Bee Act (7 U.S.C. 281 *et seq.*).

[1] To view the proposed rule, go to *www.regulations.gov* and enter APHIS–2015–0008 in the Search field.

PURPOSES OF THE SYSTEM:

SITC focuses on anti-smuggling and trade compliance efforts at ports of entry in the United States and in commerce to prevent the establishment of plant and animal pests and diseases, while maintaining the safety of U.S. ecosystems and natural resources. SITC is responsible for collecting, maintaining, and reviewing information to successfully and efficiently meet its mission.

The purpose of SNICAS is to record data and information about SITC activities nationwide. SNICAS supports the mission of SITC programs by providing, to SITC and other agency personnel, information that can be used to assist with detecting and preventing the unlawful entry and distribution into the United States of prohibited and/or non-compliant products that may harbor exotic plant and animal pests, diseases, or invasive species.

SNICAS contains records pertaining to the U.S. ports of entry and commerce locations that are inspected or surveyed during daily operations. SNICAS also maintains and communicates information associated with SITC operational and administrative activities. The personally identifiable information within SNICAS is used by SITC officials to identify and close pathways used for the introduction of prohibited commodities and those regulated commodities that lack the necessary certificates and permits to enter into U.S. commerce.

SITC officials also use SNICAS to perform activities such as legal and regulatory actions; scientific research; risk, trend, pathway and targeting analyses; trade support; administrative and budgetary support; supervision and program management; and overall decision support services. Additionally, SITC officials use SNICAS to generate reports to evaluate the risk status of the commercial sites where regulated commodities are seized, the effectiveness of the program, and quality control of the data.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

SNICAS contains personal and business identifiable information about individuals and companies who are associated with the importation, interstate, and/or intrastate movement of prohibited or restricted agricultural products along with any actions taken against said individual or company. The system also includes SITC employee information.

CATEGORIES OF RECORDS IN THE SYSTEM:

The categories of records maintained in the system consist of company/business or individual's name; contact information that includes address, telephone and fax numbers, and email address; personal identification number, which may include Social Security number or tax identification number; date of birth; gender; business affiliation; criminal history; inspection or survey date; conveyance type and identification (license plate, vehicle identification number); geospatial data of trade activity; identification of product(s) to include product name, photographs of seized product(s), country of origin, identification number, and bar codes; U.S. port of entry, crossing, or import location; witness statements; and any other supporting documentation. As required, SITC may also collect other information associated with products, seizures, trace requests, product pathways, recall activities, and intelligence or analysis background reviews.

SITC employee information included in the system consists of name, title, work and email addresses, telephone number, badge number, SITC work unit, and area of coverage.

As required, other information associated with products, seizures, trace requests, product pathways, recall activities, and intelligence or analysis background reviews may be saved in the system.

RECORD SOURCE CATEGORIES:

SNICAS collects much of its information directly from individuals, Federal, State, Tribal, or local government and agencies, commercial entities, and companies/individuals that import, handle, distribute, or consume products that may be associated with the importation and/or interstate movement of prohibited or restricted agricultural products.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, records maintained in the system may be disclosed outside USDA, as follows, to the extent that such disclosures are compatible with the purposes for which the information was collected:

(1) To Department of Homeland Security's Customs and Border Protection in conjunction with their cooperative mission to protect U.S. agriculture and natural resources;

(2) To other Federal agencies, agricultural contractors, and Tribal,

State, county, and local government officials, to correlate activities due to overlapping authorities and functions in areas of agriculture, environment, human health, biological sciences, and consumer safety;

(3) To cooperating Federal, Tribal, State, county, and local government officials or other individuals or entities performing or working on a contract, service, grant, cooperative agreement, or other assignment for USDA, when necessary to accomplish an agency function related to this system of records;

(4) To appropriate law enforcement agencies, entities, and persons, whether Federal, foreign, State, local, or Tribal, or other public authority responsible for enforcing, investigating, or prosecuting an alleged violation or a violation of law or charged with enforcing, implementing, or complying with a statute, rule, regulation, or order issued pursuant thereto, when a record in this system on its face, or in conjunction with other records, indicates a violation or potential violation of law, whether civil, criminal, or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule, or court order issued pursuant thereto, if the information disclosed is relevant to any enforcement, regulatory, investigative, or prosecutive responsibility of the receiving entity;

(5) To the Department of Justice when the agency, or any component thereof, or any employee of the agency in his or her official capacity, or any employee of the agency in his or her individual capacity where the Department of Justice has agreed to represent the employee, or the United States, in litigation, where the agency determines that litigation is likely to affect the agency or any of its components, is a party to litigation or has an interest in such litigation, and the use of such records by the Department of Justice is deemed by the agency to be relevant and necessary to the litigation; provided, however, that in each case, the agency determines that disclosure of the records to the Department of Justice is a use of the information contained in the records that is compatible with the purpose for which the records were collected;

(6) To a court or adjudicative body in administrative, civil, or criminal proceedings when: (a) The agency or any component thereof; or (b) any employee of the agency in his or her official capacity; or (c) any employee of the agency in his or her individual capacity where the agency has agreed to represent the employee; or (d) the United States Government, is a party to litigation or has an interest in such litigation, and by careful review, the agency determines that the records is therefore deemed by the agency to be for a purpose that is compatible with the purpose for which the agency collected the records;

(7) To appropriate agencies, entities, and persons when: (a) USDA suspects or has confirmed that there has been a breach of the system of records; (b) USDA has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, USDA (including its information systems, programs, and operations), the Federal Government, or national security; and (c) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with USDA's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm;

(8) To another Federal agency or Federal entity, when the USDA determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (a) responding to a suspected or confirmed breach or (b) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach;

(9) To USDA contractors and other parties engaged to assist in administering the program, analyzing data, and conducting audits. Such contractors and other parties will be bound by the nondisclosure provisions of the Privacy Act;

(10) To USDA contractors, partner agency employees or contractors, or private industry employed to identify patterns, trends, or anomalies indicative of fraud, waste, or abuse;

(11) To a Congressional office from the record of an individual in response to any inquiry from that Congressional office made at the written request of the individual to whom the record pertains; and

(12) To the National Archives and Records Administration (NARA) or to the General Services Administration for records management activities conducted under 44 U.S.C. 2904 and 2906.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

None.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Electronic and paper records are stored at locations listed under ''System Location'' above. All documentation that exists in paper form is maintained by PPQ SITC officials nationwide, while electronic data are stored on hard disks within their work units or on the Azure cloud hosted by APHIS.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

SNICAS users can query and retrieve records on the following fields: Permit or emergency action notification form serial number, name of individual or business, address, and telephone number. Users can also search for records using a global search engine, quick list drop-down menu, or using the reports section of the system.

Records cannot be retrieved by Social Security number, birthdate, vehicle identification number, and tax identification numbers. However, this information may be contained in attached documents. These attached documents can only be accessed through associated parent records, and these documents can only be viewed by authorized SITC officials.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

APHIS is in the process of requesting records disposition authority from NARA, and these records will be retained until appropriate disposition authority is obtained from NARA.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

SNICAS is a web-based system that can be accessed by individuals authorized by PPQ on a need-to-know basis. Authorized users can gain access to SNICAS records via a secure government network, which is only accessible after a user is added to the system by a system administrator and when the user logs onto the password-protected network. If the end user is away from their designated workstation, they can connect through the internet via a secure virtual private network connection. Security measures are in place to prevent outsiders from entering the system. Integrated Network Authentication is required for access to the system. The access control list for the database validates against the network identification of the user creating a 2-layer authentication scheme. PPQ SITC personnel have access to all of the data in the system but are limited to certain actions based on their assigned role. Non-SITC personnel within the agency may be provided ''read-only'' access allowing

users to view all data within SNICAS but restricts editing or downloading data. These accounts use integrated network authentication to validate the end user and restrict access.

Electronic records are stored on secure file servers. SNICAS users gain access to the system through the system administrator with designated user-defined roles and level of access. SNICAS users obtain user -identification accounts that allow password-protected access through the intranet. Access is only available to computers logged onto the APHIS network. Domain network logon credentials are used to validate a user's access against a list of allowed SNICAS logons kept within the database, creating a 2-tier validation strategy. The web-based service identifies and validates USDA customers before they can access SNICAS.

Paper files are maintained in a safeguarded environment with controlled access only by authorized personnel. SITC officers, analysts, and supervisors are in positions of public trust that require background investigations and security clearances. Employees are also required to complete appropriate training to learn requirements for safeguarding records maintained under the Privacy Act.

SNICAS safeguards records and ensures that privacy requirements are met in accordance with Federal cyber security mandates. SNICAS provides continuous storage management, security administration, regular dataset backups, and contingency planning/disaster recovery.

RECORD ACCESS PROCEDURES:

All requests for access to records must be in writing and should be submitted to the APHIS Privacy Act Officer, 4700 River Road Unit 50, Riverdale, MD 20737; or by facsimile (301) 734–5941; or by email *APHISPrivacy@usda.gov.* In accordance with 7 CFR 1.112 (Procedures for requests pertaining to individual records in a record system), the request must include the full name of the individual making the request; the name of the system of records; and preference of inspection, in person or by mail. In accordance with 7 CFR 1.113, prior to inspection of the records, the requester shall present sufficient identification (*e.g.,* driver's license, employee identification card, Social Security card, credit cards) to establish that the requester is the individual to whom the records pertain. In addition, if an individual submitting a request for access wishes to be supplied with copies of the records by mail, the requester must include with his or her request sufficient data for the agency to verify the requester's identity.

CONTESTING RECORD PROCEDURES:

Individuals seeking to contest or amend records maintained in this system of records must direct their request to the address indicated in the ''RECORD ACCESS PROCEDURES'' paragraph, above and must follow the procedures set forth in 7 CFR 1.116 (Request for correction or amendment to record). All requests must state clearly and concisely what record is being contested, the reasons for contesting it, and the proposed amendment to the record.

NOTIFICATION PROCEDURES:

Individuals may be notified if a record in this system of records pertains to them when the individuals request information utilizing the same procedures as those identified in the ''RECORD ACCESS PROCEDURES'' paragraph above.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

The Agency has exempted this system from subsections (c)(3); (d); (e)(1); (e)(4)(G), (H), and (I); and (f) of the Privacy Act pursuant to 5 U.S.C. 552a(k)(2). The exemptions will be applied only to the extent that the information in the system is subject to exemption pursuant to 5 U.S.C. 552a(k)(2). A proposed rule has been promulgated in accordance with the requirements of 5 U.S.C. 553(b), (c), and (e) and has been published in today's **Federal Register** [1].

HISTORY:

Not Applicable.

[FR Doc. 2022–14704 Filed 7–8–22; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Agency Information Collection Activities: Proposed Collection; Comment Request—Serving SNAP Applicants and Participants With Limited English Proficiency (LEP)

AGENCY: Food and Nutrition Service (FNS), USDA.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice invites the general public and other public agencies to comment on this proposed information collection. This is a new information collection for the contract Serving Supplementation Nutrition Assistance Program (SNAP) Applicants and Participants with Limited English Proficiency (LEP). The purpose of the Servicing SNAP LEP study is to provide FNS with a comprehensive understanding of the language landscapes in which SNAP and Nutrition Assistance Program (NAP) agencies operate, as well as the LEP policy and operations landscapes.

DATES: Written comments must be received on or before September 9, 2022.

ADDRESSES: Comments may be sent to: Eric Williams, Food and Nutrition Service, U.S. Department of Agriculture, 1320 Braddock Place, 5th Floor, Alexandria, VA 22314. Comments may also be submitted or via email to *eric.williams@usda.gov.* Comments will also be accepted through the Federal eRulemaking Portal. Go to *http://www.regulations.gov,* and follow the online instructions for submitting comments electronically.

All responses to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will be a matter of public record.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of this information collection should be directed to Eric Williams at 703–305–2640.

SUPPLEMENTARY INFORMATION: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions that were used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Title: Serving SNAP Applicants and Participants with Limited English Proficiency (LEP).

Form Number: N/A.

OMB Number: 0584–NEW.

Expiration Date: Not yet determined.

Type of Request: New collection.

Abstract: The Supplemental Nutrition Assistance Program (SNAP) provides a monthly benefit to eligible households

[1] To view the proposed rule, go to *www.regulations.gov* and enter APHIS–2015–0008 in the Search field.

to spend on food so that households and individuals with low incomes have access to enough nutritious food to lead healthy, active lives. The U.S. Department of Agriculture's (USDA) Food and Nutrition Service (FNS) administers SNAP in partnership with 53 State agencies (the 50 States, the District of Columbia [DC], Guam, and the U.S. Virgin Islands [USVI]). In three U.S. Territories—American Samoa, the Commonwealth of the Northern Mariana Islands (CNMI), and Puerto Rico—nutrition assistance to low-income individuals and households is provided through the Nutrition Assistance Program (NAP).

As Federally assisted programs, both SNAP and NAP are required to comply with Title VI of the Civil Rights Act of 1964 (Title VI) and its implementing regulations for the USDA at 7 CFR 15. (U.S. Department of Justice Civil Rights Division n.d.). Title VI prohibits entities that receive Federal financial assistance from discriminating against or otherwise excluding individuals on the basis of race, color, or national origin. In order to avoid discrimination against LEP persons on the ground of national origin, administrators of Federal financial assistance programs must take reasonable steps to ensure that LEP persons receive the language assistance necessary to afford them meaningful access to SNAP or NAP as applicable, free of charge. LEP individuals are defined as those who do not speak English as their primary language and have a limited ability to read, speak, write, or understand English (USDA 2014, p. 70775). Meaningful access requires that State agencies provide language assistance services that allow equal participation in and access to the benefits of a given program. To support meaningful access, language assistance must be provided at a time and place that avoids the effective denial of the service, benefit, or right at issue or the imposition of an undue burden on or delay in important rights, benefits, or services to the LEP person (USDA 2014, p. 70779–70780).

As the agency responsible for providing oversight and monitoring for both SNAP and NAP, it is critical that FNS understands whether and how SNAP and NAP agencies are complying with LEP requirements. The LEP study will provide FNS with actionable insights about how States and Territories operate language access policies and requirements. The study will gather detailed data from all 53 State SNAP agencies via a web-based survey, the three Territories that operate NAP via in-depth interviews, and will conduct case studies in four States. The study will provide FNS with a comprehensive summary of findings on policies and practices related to LEP access. It will increase FNS' understanding of SNAP LEP access policies and practices across the nation, including how States make decisions about these policies and practices, how they train staff on them, and their perceptions of Federal regulations. The findings from the study will help inform policymakers efforts to provide more meaningful access to SNAP and NAP.

Affected Public: Members of the public affected by the data collection include State, Local, and Tribal Governments from 53 State agencies and three Territories. Respondent groups identified include: (1) State or local agency directors/managers; (2) NAP directors (3) Local agency frontline staff.

Estimated Number of Respondents: The total estimated number of unique respondents is 100, with zero nonrespondents. This includes: 53 State or territory SNAP directors; 3 NAP directors, 12 local SNAP agency directors; 12 local SNAP office managers, and 20 local SNAP agency frontline staff. The State or territory SNAP agency directors include respondents from 53 U.S. States and territories, (50 U.S. States, the District of Columbia, the U.S. Virgin Islands, and Guam). These respondents will respond to a web survey. The NAP directors include three U.S. Territory NAP agencies (American Samoa, Commonwealth of the Northern Mariana Islands, and Puerto Rico). The three NAP agency directors will participate in an in-depth interview (IDI). Four States will be selected for the case study. Here is a summary of the respondents for the case study:

- 4 State SNAP directors (one from each of the four States)
- 12 local SNAP agency directors (three from each of the four States)
- 12 local SNAP office managers (three from each of the four States)
- 20 local SNAP agency frontline staff (5 from each of the four States). Twelve of these staff will participate in in-depth interviews and 8 of these staff will participate in simulations.

Estimated Number of Responses per Respondent: Across all respondents, the average number of responses is 7.56. State or territory SNAP directors will respond once to a web-based survey with eight modules. State or territory SNAP directors will receive a FNS State outreach email to notify them about the web survey. Mathematica will then email the States a study description and invitation to complete the web survey. State or territory SNAP directors who have not completed the survey will be emailed biweekly to complete the survey (for a total of five possible emails). Those who have not completed in the last four weeks of data collection will receive an urgent survey reminder email every week (for a total of four possible emails). State or territory SNAP directors will be asked to submit documents related to their language access procedures via the survey. If they do not submit their documents then they will be sent reminder emails (for a total of nine possible emails). Starting in week six of data collection, State or territory SNAP directors will receive reminder phone calls.

One NAP director from each of three selected Territory NAP agencies will be asked to complete one IDI. The NAP directors will be provided with a definitions handout to assist in answering the questions during the IDI. Prior to the IDI, Mathematica will administer one pre-interview questionnaire that will allow the IDI protocol to be tailored to their respective territory. We may break the interviews into multiple sessions to reduce the burden of the IDI. The IDI will focus on understanding the development and implementation of language access policies. NAP directors will receive an email from FNS to notify them about the IDI. Mathematica will then send an email to NAP directors to invite them to do the IDI. Following the invitation email, Mathematica will send another email that coordinates the scheduling of the IDI. NAP directors that have not scheduled their IDI will be sent a reminder email (for a total of two possible emails). NAP directors will be asked to submit documents related to their language access procedures. If they do not submit their documents then they will be sent reminder emails (for a total of two possible document reminder emails).

Lastly, four State SNAP agencies that participated in the initial survey will be selected in collaboration with FNS for a case study. The case study will involve interviews with four State SNAP directors, 12 local SNAP agency directors, 12 local SNAP office managers, and 12 local SNAP agency frontline staff. Eight local SNAP agency frontline staff will complete a participant experience simulation. The State or territory SNAP directors will receive an initial email from FNS notifying them about the case studies. Following that, an email will come from the research team introducing them to the case studies and asking to schedule a call with them to discuss the case studies. State SNAP directors that do not respond to this initial email will

receive a reminder email. The State SNAP directors will then participate in a one hour call to discuss the case study. They will be provided with an email template to use to reach out to three local areas in their State. The research team will then follow up with the local agencies by email to schedule their portions of the site visit.

Estimated Total Annual Responses: 756.

Estimated Time per Response: The estimated time of response varies from 0.03 hours for activities related to reading email reminders for the survey, case studies, and in-depth interivews to 2.5 hours for completing the survey and document request, as well as, the NAP agency interview protocol and document request. Variation of response time is dependent on the respondent group, as shown in the attached table, with an average estimated time of 18.9 minutes (0.315 hours).

Estimated Total Annual Burden on Respondents: The total estimated burden on respondents is 14,308.2 minutes (238.47 hours). See the table attached for estimated total annual burden for each type of respondent.

Affected public	Type of respondents	Instruments	Sample size	Respondents					Non-respondents					Grand total annual burden estimate (hours)
				Number of respondents	Frequency of response	Total annual responses	Hours per response	Annual burden (hours)	Number of non-respondents	Frequency of response	Total annual responses	Hours per response	Annual burden (hours)	
State, local, and Tribal government.	State or territory SNAP director.	Survey	53	53	1	53	2.50	132.50	0	0	0	0	0	132.50
	State or territory SNAP director.	Survey FNS State outreach email.	53	53	1	53	0.07	3.53	0	0	0	0	0	3.53
	State or territory SNAP director.	Survey study team outreach email with study description.	53	53	1	53	0.10	5.30	0	0	0	0	0	5.30
	State or territory SNAP director.	Survey biweekly survey reminder email #1.	53	47	1	47	0.03	1.57	0	0	0	0	0	1.57
	State or territory SNAP director.	Survey biweekly survey reminder email #2.	53	41	1	41	0.03	1.37	0	0	0	0	0	1.37
	State or territory SNAP director.	Survey biweekly survey reminder email #3.	53	35	1	35	0.03	1.17	0	0	0	0	0	1.17
	State or territory SNAP director.	Survey biweekly survey reminder email #4.	53	29	1	29	0.03	0.97	0	0	0	0	0	0.97
	State or territory SNAP director.	Survey biweekly survey reminder email #5.	53	23	1	23	0.03	0.77	0	0	0	0	0	0.77
	State or territory SNAP director.	Urgent survey reminder email #1.	53	17	1	17	0.03	0.57	0	0	0	0	0	0.57
	State or territory SNAP director.	Urgent survey reminder email #2.	53	11	1	11	0.03	0.37	0	0	0	0	0	0.37
	State or territory SNAP director.	Urgent survey reminder email #3.	53	5	1	5	0.03	0.17	0	0	0	0	0	0.17
	State or territory SNAP director.	Urgent survey reminder email #4.	53	1	1	1	0.03	0.03	0	0	0	0	0	0.03
	State or territory SNAP director.	Survey document reminder email #1.	53	47	1	47	0.03	1.57	0	0	0	0	0	1.57
	State or territory SNAP director.	Survey document reminder email #2.	53	41	1	41	0.03	1.37	0	0	0	0	0	1.37
	State or territory SNAP director.	Survey document reminder email #3.	53	35	1	35	0.03	1.17	0	0	0	0	0	1.17
	State or territory SNAP director.	Survey document reminder email #4.	53	29	1	29	0.03	0.97	0	0	0	0	0	0.97
	State or territory SNAP director.	Survey document reminder email #5.	53	23	1	23	0.03	0.77	0	0	0	0	0	0.77
	State or territory SNAP director.	Survey document reminder email #6.	53	17	1	17	0.03	0.57	0	0	0	0	0	0.57
	State or territory SNAP director.	Survey document reminder email #7.	53	11	1	11	0.03	0.37	0	0	0	0	0	0.37
	State or territory SNAP director.	Survey document reminder email #8.	53	5	1	5	0.03	0.17	0	0	0	0	0	0.17
	State or territory SNAP director.	Survey document reminder email #9.	53	1	1	1	0.03	0.03	0	0	0	0	0	0.03
	State or territory SNAP director.	Survey reminder call script.	53	53	1	53	0.08	4.42	0	0	0	0	0	4.42
	State or territory SNAP director.	FNS case study outreach email.	4	4	1	4	0.07	0.27	0	0	0	0	0	0.27
	State or territory SNAP director.	Study team case study outreach email.	4	4	1	4	0.03	0.13	0	0	0	0	0	0.13
	State or territory SNAP director.	Case study reminder email.	4	4	1	4	0.03	0.13	0	0	0	0	0	0.13
	State or territory SNAP director.	Case study call script	4	4	1	4	1.00	4.00	0	0	0	0	0	4.00
	State or territory SNAP director.	Case study site visit protocol.	4	4	3	12	1.00	12.00	0	0	0	0	0	12.00
	Local SNAP agency director.	Case study outreach email.	12	12	1	12	0.03	0.40	0	0	0	0	0	0.40

	Local SNAP agency director.	Case study reminder email.	12	12	1	12	0.03	0.40	0	0	0	0	0	0.40
	Local SNAP agency director.	Case study site visit protocol.	12	12	1	12	1.00	12.00	0	0	0	0	0	12.00
	Local SNAP office manager.	Case study site visit protocol.	12	12	1	12	1.00	12.00	0	0	0	0	0	12.00
	Subtotal of State, territory or local agency SNAP director/manager		77	77	9.17	706	0.28	201.02	0	0	0	0	0.00	201.02
	NAP director	FNS interview email to Territory NAP agency.	3	3	1	3	0.03	0.10	0	0	0	0	0	0.10
	NAP director	Study team interview outreach email toTerritory NAP agency.	3	3	1	3	0.10	0.30	0	0	0	0	0	0.30
	NAP director	Interview scheduling to Territory NAP agency.	3	3	1	3	0.08	0.25	0	0	0	0	0	0.25
	NAP director	Interview reminder email to Territory NAP agency #1.	3	3	1	3	0.08	0.25	0	0	0	0	0	0.25
	NAP director	Interview reminder email to Territory NAP agency #2.	3	3	1	3	0.08	0.25	0	0	0	0	0	0.25
	NAP director	NAP agency document reminder email #1.	3	3	1	3	0.03	0.10	0	0	0	0	0	0.10
	NAP director	NAP agency document reminder email #2.	3	3	1	3	0.03	0.10	0	0	0	0	0	0.10
	NAP director	NAP agency pre-interview questionnaire.	3	3	1	3	0.17	0.50	0	0	0	0	0	0.50
	NAP director	NAP agency interview protocol.	3	3	1	3	2.50	7.50	0	0	0	0	0	7.50
	NAP director	NAP agency interview definitions handout.	3	3	1	3	0.03	0.10	0	0	0	0	0	0.10
	Subtotal of NAP director		3	3	10.00	30	0.32	9.45	0	0	0	0	0.00	9.45
	Local SNAP agency frontline staff.	Case study site visit protocol.	12	12	1	12	1.50	12.00	0	0	0	0	0	12.00
	Local SNAP agency frontline staff.	Case study simulation guide.	8	8	1	8	2.00	16.00	0	0	0	0	0	16.00
	Subtotal of local agency frontline staff		20	20	1.00	20	1.40	28.00	0	0	0	0	0.00	28.00
	Subtotal unique State, local, and Tribal government		100	100	7.56	756	0.315	238.47	0	0	0	0	0.00	238.47
	Grand total		100	100	7.56	756	0.315	238.47	0	0	0	0	0.00	238.47

Cynthia Long,

Administrator, Food and Nutrition Service.

[FR Doc. 2022–14662 Filed 7–8–22; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

Foreign Agricultural Service

Fiscal Year 2022 Raw Cane Sugar Tariff-Rate Quota Increase and Extension of the Entry Period

AGENCY: Foreign Agricultural Service, U.S. Department of Agriculture.

ACTION: Notice.

SUMMARY: The Foreign Agricultural Service is providing notice of an increase in the fiscal year (FY) 2022 raw cane sugar tariff-rate quota (TRQ) of 90,718 metric tons raw value (MTRV) and an extension of the TRQ entry period.

DATES: The increase and extension are effective July 11, 2022.

FOR FURTHER INFORMATION CONTACT: Souleymane Diaby, Multilateral Affairs Division, Trade Policy and Geographic Affairs, Foreign Agricultural Service, U.S. Department of Agriculture, Stop 1070, 1400 Independence Avenue SW, Washington, DC 20250–1070; by telephone (202) 720–2916; or by email *Souleymane.Diaby@usda.gov.*

SUPPLEMENTARY INFORMATION: On September 13, 2021, the Foreign Agricultural Service established the FY 2022 TRQ for raw cane sugar at 1,117,195 MTRV, the minimum to which the United States is committed under the World Trade Organization (WTO) Uruguay Round Agreements. Pursuant to Additional U.S. Note 5 to Chapter 17 of the U.S. Harmonized Tariff Schedule (HTS) and Section 359k of the Agricultural Adjustment Act of 1938, as amended, the Secretary has authority to modify the raw and refined sugar WTO TRQs. The Secretary's authority under Additional U.S. Note 5 and Section 359(k) has been delegated to the Under Secretary for Trade and Foreign Agricultural Affairs (7 CFR 2.26). The Under Secretary has subsequently delegated this authority to the Administrator, Foreign Agricultural Service (7 CFR 2.601). The Foreign Agricultural Service gives notice today of an increase in the quantity of raw cane sugar eligible to enter at the lower rate of duty during FY 2022 by 90,718 MTRV. The conversion factor is 1 metric ton raw value equals 1.10231125 short tons raw value. With this increase, the overall FY 2022 raw sugar TRQ is now 1,207,913 MTRV. Raw cane sugar under this quota must be accompanied by a certificate for quota eligibility. The Office of the U.S. Trade Representative (USTR) will allocate this increase among supplying countries and customs areas.

The Foreign Agricultural Service also today announces that all sugar entering the United States under the FY 2022 WTO raw sugar TRQ will be permitted to enter U.S. Customs territory through October 31, 2022, a month later than the usual last entry date. Additional U.S. Note 5(a)(iv) of Chapter 17 of the HTS provides: ''(iv) Sugar entering the United States during a quota period established under this note may be charged to the previous or subsequent quota period with the written approval of the Secretary.'' These actions are being taken after a determination that additional supplies of raw cane sugar are required in the U.S. market. USDA will closely monitor stocks, consumption, imports and all sugar market and program variables on an ongoing basis and may make further program adjustments during FY 2022 if needed.

Daniel Whitley,

Administrator, Foreign Agricultural Service.

[FR Doc. 2022–14834 Filed 7–7–22; 4:15 pm]

BILLING CODE 3410–10–P

DEPARTMENT OF AGRICULTURE

Foreign Agricultural Service

Determination of Total Amounts of Fiscal Year 2023 WTO Tariff-Rate Quotas for Raw Cane Sugar

AGENCY: Foreign Agricultural Service, U.S. Department of Agriculture.

ACTION: Notice.

SUMMARY: The Foreign Agricultural Service announces the establishment of the Fiscal Year (FY) 2023 (October 1, 2022–September 30, 2023) in-quota aggregate quantity of raw cane sugar at 1,117,195 metric tons raw value (MTRV).

DATES: This notice is applicable on July 11, 2022.

FOR FURTHER INFORMATION CONTACT: Souleymane Diaby, Multilateral Affairs Division, Trade Policy and Geographic Affairs, Foreign Agricultural Service, U.S. Department of Agriculture, Stop 1070, 1400 Independence Avenue SW, Washington, DC 20250–1070; by telephone (202) 720–2916; or by email *Souleymane.Diaby@usda.gov.*

SUPPLEMENTARY INFORMATION: The provisions of paragraph (a)(i) of the Additional U.S. Note 5, Chapter 17 in the U.S. Harmonized Tariff Schedule (HTS) authorize the Secretary to establish the in-quota tariff-rate quota (TRQ) amounts (expressed in terms of raw value) for imports of raw cane sugar and certain sugars, syrups, and molasses that may be entered under the subheadings of the HTS subject to the lower tier of duties during each fiscal year. The Office of the U.S. Trade Representative (USTR) is responsible for the allocation of these quantities among supplying countries and areas.

Section 359(k) of the Agricultural Adjustment Act of 1938, as amended, requires that at the beginning of the quota year the Secretary of Agriculture establish the TRQs for raw cane sugar and refined sugars at the minimum levels necessary to comply with obligations under international trade agreements, with the exception of specialty sugar.

The Secretary's authority under paragraph (a)(i) of the Additional U.S. Note 5, Chapter 17 in the HTS and Section 359(k) of the Agricultural Adjustment Act of 1938, as amended, has been delegated to the Under Secretary for Trade and Foreign Agricultural Affairs (7 CFR 2.26). The Under Secretary has subsequently delegated this authority to the Administrator, Foreign Agricultural Service (7 CFR 2.601).

Notice is hereby given that I have determined, in accordance with paragraph (a)(i) of the Additional U.S. Note 5, Chapter 17 in the HTS and section 359(k) of the 1938 Act, that an aggregate quantity of up to 1,117,195 MTRV of raw cane sugar may be entered or withdrawn from warehouse for consumption during FY 2023. This is the minimum amount to which the United States is committed under the WTO Uruguay Round Agreements. The conversion factor is 1 metric ton raw value equals 1.10231125 short tons raw value. The Office of the United Trade Representative will allocate these quantities among supplying countries and customs areas.

Daniel Whitley,

Administrator, Foreign Agricultural Service.

[FR Doc. 2022–14840 Filed 7–7–22; 4:15 pm]

BILLING CODE 3410–10–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Louisiana Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the Louisiana Advisory Committee (Committee) to the U.S. Commission on Civil Rights will hold project planning meetings via WebEx on the following dates and times:

- Wednesday, July 20, at 2:00 p.m. ET
- Wednesday, August 17, at 2:00 p.m. ET
- Wednesday, September 21, at 2:00 p.m. ET
- Wednesday, October 19, at 2:00 p.m. ET

The purpose of these meetings is to discuss and vote to select the topic for the Committee's civil rights project. Each planning meeting will last for approximately one hour.

DATES: Wednesday, July 20, at 2:00 p.m. ET; Wednesday, August 17, at 2:00 p.m. ET; Wednesday, September 21, at 2:00 p.m. ET; and Wednesday, October 19, at 2:00 p.m. ET.

Meeting Link: https://tinyurl.com/5n75rk8x.

Telephone (Audio Only): Dial 1–800–360–9505 USA Toll Free; Access code: 2761 303 1881.

FOR FURTHER INFORMATION CONTACT: Ivy Davis, DFO, and Director of the Eastern Regional Office (ERO, at *ero@usccr.gov* or 1–202–539–8468).

SUPPLEMENTARY INFORMATION: Members of the public can listen to these discussions.

Committee meetings are available to the public through the above call-in number. Any interested member of the public may call this number and listen to the meeting. An open comment period will be provided to allow members of the public to make a statement as time allows. Callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Individuals who are deaf, deafblind and hard of hearing may follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the conference call number and conference ID number.

Members of the public are also entitled to submit written comments via email. The comments must be received in the regional office within 30 days following the meeting. Written comments may be emailed. The email subject line should state: Atten: LA and sent to this email address: *ero@usccr.gov.* Persons who desire additional information may contact the Eastern Regional Office at *ero@usccr.gov.*

Records generated from this meeting may be inspected and reproduced at the Eastern Regional Programs, as they become available, both before and after the meeting. Records of the meeting will be available via *www.facadatabase.gov* under the Commission on Civil Rights, West Virginia Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's website, *http://www.usccr.gov,* or may contact the Eastern Regional Office at the above email address.

Agenda

I. Roll Call
II. Welcome
III. Project Planning
IV. Other Matters
V. Next Meeting
VI. Public Comments
VII. Adjourn

Dated: July 5, 2022.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2022–14623 Filed 7–8–22; 8:45 am]

BILLING CODE 6335–01–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meetings of the Kansas Advisory Committee

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the Kansas Advisory Committee (Committee) will hold a meeting via web conference on, July 19, 2022, at 12:00 p.m. Central Time. The purpose of the meeting is for the committee to discuss potential topics and panelists for the upcoming briefing(s).

DATES: The meeting will be held on:

- Tuesday, July 19, 2022, at 12:00 p.m. Central Time *https://civilrights.webex.com/civilrights/j.php?MTID=m02f042b5252c2c361a17afcf0ea748fd.*

Or Join by phone: 800–360–9505 USA Toll Free, Access code: 2764 461 8644#.

FOR FURTHER INFORMATION CONTACT: David Barreras, Designated Federal Officer, at *dbarreras@usccr.gov* or (202) 656–8937.

SUPPLEMENTARY INFORMATION: Members of the public may listen to this discussion through the above call-in number. An open comment period will be provided to allow members of the public to make a statement as time allows. Callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Individuals who are deaf, deafblind and hard of hearing may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the conference call number and conference ID number.

Members of the public are entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be emailed to David Barreras at *dbarreras@usccr.gov.*

Records generated from this meeting may be inspected and reproduced at the Regional Programs Unit Office, as they become available, both before and after the meeting. Records of the meeting will be available via *www.facadatabase.gov* under the Commission on Civil Rights, Kansas Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's website, *http://www.usccr.gov,* or may contact the Regional Programs Unit at the above email or street address.

Agenda

I. Welcome & Roll Call
II. Chair's Comments
IV. Committee Discussion
V. Next Steps
VI. Public Comment
VII. Adjournment

Dated: July 5, 2022.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2022–14621 Filed 7–8–22; 8:45 am]

BILLING CODE 6335–01–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Illinois Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of virtual business meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the

Federal Advisory Committee Act, that the Illinois Advisory Committee (Committee) to the U.S. Commission on Civil Rights will hold a virtual business meeting via Webex at 1:00 p.m. CT on Tuesday, September 27, 2022. The purpose of the meeting is to review a draft of the Committee's report on equal access to post-secondary education in Illinois.

DATES: The meeting will take place on Tuesday, September 27, 2022, from 1:00 p.m.–2:30 p.m. CT.

Link to Join (Audio/Visual): https://tinyurl.com/48cyvtru.

Telephone (Audio Only): Dial (800) 360–9505 USA Toll Free; Access code: 2764 821 2661.

FOR FURTHER INFORMATION CONTACT: Ana Fortes, Designated Federal Officer, at *afortes@usccr.gov* or (202) 519–2938.

SUPPLEMENTARY INFORMATION: Committee meetings are available to the public through the conference link above. Any interested member of the public may listen to the meeting. An open comment period will be provided to allow members of the public to make a statement as time allows. If joining via phone, callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Individuals who are deaf, deafblind, and hard of hearing may also follow the proceedings by first calling the Federal Relay Service at 1 (800) 877–8339 and providing the Service with the conference details found through registering at the web link above. To request additional accommodations, please email *afortes@usccr.gov* at least ten (10) days prior to the meeting.

Members of the public are also entitled to submit written comments; the comments must be received within 30 days following the meeting. Written comments may be emailed to Liliana Schiller at *lschiller@usccr.gov.* Persons who desire additional information may contact the Regional Programs Coordination Unit at (312) 353–8311.

Records generated from this meeting may be inspected and reproduced at the Regional Programs Coordination Unit Office, as they become available, both before and after the meeting. Records of the meeting will be available via *www.facadatabase.gov* under the Commission on Civil Rights, Illinois Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's website, *http://www.usccr.gov,* or may contact the Regional Programs Coordination Unit at the above phone number.

Agenda

I. Welcome & Roll Call
II. Approval of Minutes: August 25, 2022
III. Discussion
IV. Public Comment
V. Adjournment

Dated: July 5, 2022.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2022–14624 Filed 7–8–22; 8:45 am]

BILLING CODE 6335–01–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Illinois Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of virtual business meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act, that the Illinois Advisory Committee (Committee) to the U.S. Commission on Civil Rights will hold a virtual business meeting via Webex at 11:00 a.m. CT on Thursday, August 25, 2022. The purpose of the meeting is to review the first draft of the Committee's report on equal access to post-secondary education in Illinois.

DATES: The meeting will take place on Thursday, August 25, 2022, from 11:00 a.m.–12:30 p.m. CT.

Link to Join (Audio/Visual): https://tinyurl.com/443awkpe.

Telephone (Audio Only): Dial (800) 360–9505 USA Toll Free; Access code: 2763 611 1563.

FOR FURTHER INFORMATION CONTACT: Ana Fortes, Designated Federal Officer, at *afortes@usccr.gov* or (202) 519–2938.

SUPPLEMENTARY INFORMATION: Committee meetings are available to the public through the conference link above. Any interested member of the public may listen to the meeting. An open comment period will be provided to allow members of the public to make a statement as time allows. If joining via phone, callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Individuals who are deaf, deafblind, and hard of hearing may also follow the proceedings by first calling the Federal Relay Service at 1 (800) 877–8339 and providing the Service with the conference details found through registering at the web link above. To request additional accommodations, please email *afortes@usccr.gov* at least ten (10) days prior to the meeting.

Members of the public are also entitled to submit written comments; the comments must be received within 30 days following the meeting. Written comments may be emailed to Liliana Schiller at *lschiller@usccr.gov.* Persons who desire additional information may contact the Regional Programs Coordination Unit at (312) 353–8311.

Records generated from this meeting may be inspected and reproduced at the Regional Programs Coordination Unit Office, as they become available, both before and after the meeting. Records of the meeting will be available via *www.facadatabase.gov* under the Commission on Civil Rights, Illinois Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's website, *http://www.usccr.gov,* or may contact the Regional Programs Coordination Unit at the above phone number.

Agenda

I. Welcome & Roll Call
II. Approval of Minutes: June 23, 2022
III. Discussion
IV. Public Comment
V. Adjournment

Dated: July 5, 2022.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2022–14625 Filed 7–8–22; 8:45 am]

BILLING CODE 6335–01–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Illinois Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of virtual business meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act, that the Illinois Advisory Committee (Committee) to the U.S. Commission on Civil Rights will hold a virtual business meeting via Webex at 3:00 p.m. CT on Thursday, October 13, 2022. The purpose of the meeting is to review a draft of the Committee's report on equal access to post-secondary education in Illinois.

DATES: The meeting will take place on Thursday, October 13, 2022, from 3:00 p.m.–4:30 p.m. CT.

Link to Join (Audio/Visual): https://tinyurl.com/yer2z73m.

Telephone (Audio Only): Dial (800) 360–9505 USA Toll Free; Access code: 2764 293 5232.

FOR FURTHER INFORMATION CONTACT: Ana Fortes, Designated Federal Officer, at *afortes@usccr.gov* or (202) 519–2938.

SUPPLEMENTARY INFORMATION: Committee meetings are available to the public through the conference link above. Any interested member of the public may listen to the meeting. An open comment period will be provided to allow members of the public to make a statement as time allows. If joining via phone, callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Individuals who are deaf, deafblind, and hard of hearing may also follow the proceedings by first calling the Federal Relay Service at 1 (800) 877–8339 and providing the Service with the conference details found through registering at the web link above. To request additional accommodations, please email *afortes@usccr.gov* at least ten (10) days prior to the meeting.

Members of the public are also entitled to submit written comments; the comments must be received within 30 days following the meeting. Written comments may be emailed to Liliana Schiller at *lschiller@usccr.gov.* Persons who desire additional information may contact the Regional Programs Coordination Unit at (312) 353–8311.

Records generated from this meeting may be inspected and reproduced at the Regional Programs Coordination Unit Office, as they become available, both before and after the meeting. Records of the meeting will be available via *www.facadatabase.gov* under the Commission on Civil Rights, Illinois Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's website, *http://www.usccr.gov,* or may contact the Regional Programs Coordination Unit at the above phone number.

Agenda

I. Welcome & Roll Call
II. Approval of Minutes: September 27, 2022
III. Discussion
IV. Public Comment
V. Adjournment

Dated: July 5, 2022.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2022–14622 Filed 7–8–22; 8:45 am]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–469–818]

Notice of Commencement of a Compliance Proceeding Pursuant to Section 129 of the Uruguay Round Agreements Act

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

SUMMARY: The U.S. Department of Commerce (Commerce) is commencing a proceeding to gather information, analyze record evidence, and consider the determinations which would be necessary to bring its measures into conformity with the recommendations and rulings of the Dispute Settlement Body (DSB) of the World Trade Organization (WTO) in *United States—Antidumping and Countervailing Duties on Ripe Olives from Spain* (WTO/DS577). This dispute concerns the final determination issued in the countervailing duty (CVD) investigation of ripe olives from Spain.

DATES: Applicable July 11, 2022.

FOR FURTHER INFORMATION CONTACT: Mary Kolberg or Dusten Hom, AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1785 or (202) 482–5075, respectively.

SUPPLEMENTARY INFORMATION:

Background

On January 24, 2022, the United States informed the DSB that the United States intended to implement the DSB's recommendations and rulings in *WTO/DS577.* The CVD investigation at issue is:

Case No.	Full title	FR cite/publication date
C–469–818	Ripe Olives from Spain: Amended Final Affirmative Countervailing Duty Determination and Countervailing Duty Order.	83 FR 37469 (August 1, 2018).

Commencement of Section 129 Proceeding

In accordance with section 129(b)(1) of the Uruguay Round Agreements Act (URAA), 19 U.S.C. 3538, Commerce consulted with the Office of the United States Trade Representative, and on July 6, 2022, pursuant to those consultations, opened a segment in the CVD proceeding at issue to commence administrative action to comply with the DSB's recommendations and rulings. The segment will consist of a separate administrative record with its own administrative protective order. In accordance with 19 CFR 351.305(b), interested parties may request access to business proprietary information in this segment of the proceeding. For this Section 129 segment, we may request additional information and we may conduct verification of such information. Consistent with section 129(d) of the URAA, Commerce intends to make a preliminary determination in this Section 129 segment, intends to provide interested parties with an opportunity to provide written comments on the preliminary determination, and may hold a hearing.

Filing Requirements & Letter of Appearance

In accordance with Commerce's regulations, all submissions to Commerce must be filed electronically using Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* An electronically filed document must be received successfully in its entirety by the time and date it is due. Documents exempted from the electronic submission requirements must be filed manually (*i.e.,* in paper form) with Enforcement and Compliance's APO/Dockets Unit, Room 18002, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, and stamped with the date and time of receipt by the

applicable deadlines.[1] Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information until further notice.[2]

Pursuant to 19 CFR 351.103(d)(1), to be included on the public service list for the Section 129 segment of the aforementioned proceeding, all interested parties, including parties that were part of the public service list in the underlying investigation and any parties otherwise notified of Commerce's commencement of this Section 129 proceeding, must file a letter of appearance. The letter of appearance must be filed separately from any other document (with the exception of an application for administrative protective order (APO) access; parties applying for and granted APO access would automatically be on the public service list). Parties wishing to enter an appearance or submit information with regard to this proceeding must upload their filing(s) to the relevant case number. Additionally, for each submission made in ACCESS, parties must select ''S 129—SEC 129'' as the segment and enter ''DS577'' in the segment specific information field.

Submission of Factual Information

Except as requested or allowed by Commerce, the administrative record is closed for submitting new factual information. Specifically, Commerce will be seeking new factual information in addition to information already on the record of the investigation, and will provide interested parties an opportunity to submit factual information to rebut, clarify, or correct such factual information. Commerce will establish a timeline for the submission of this factual information at a later date.

Factual information is defined in 19 CFR 351.102(b)(21) as: (i) Evidence submitted in response to questionnaires; (ii) evidence submitted in support of allegations; (iii) publicly available information to value factors under 19 CFR 351.408(c) or to measure the adequacy of remuneration under 19 CFR 351.511(a)(2); (iv) evidence placed on the record by Commerce; and (v) evidence other than factual information described in (i)–(iv). The regulation requires any party, when submitting factual information, to specify under which subsection of 19 CFR 351.102(b)(21) the information is being submitted and, if the information is submitted to rebut, clarify, or correct factual information already on the record, to provide an explanation identifying the information already on the record that the factual information seeks to rebut, clarify, or correct.

Extension of Time Limits Regulation

Parties may request an extension of time limits before the expiration of a time limit. In general, an extension request will be considered untimely if it is filed after the expiration of the time limit.[3] For submissions that are due from multiple parties simultaneously, an extension request will be considered untimely if it is filed after 10:00 a.m. Eastern Time on the due date. Under certain circumstances, we may elect to specify a different time limit by which extension requests will be considered untimely for submissions which are due from multiple parties simultaneously. In such a case, we will inform parties in the letter or memorandum setting forth the deadline (including a specified time) by which extension requests must be filed to be considered timely. An extension request must be made in a separate, stand-alone submission; under limited circumstances we will grant untimely-field requests for an extension of time limits.[4]

Certification Requirements

Any party submitting factual information in an antidumping or CVD proceeding must certify to the accuracy and completeness of that information.[5] Parties must use the certification formats provided in 19 CFR 351.303(g).[6] Commerce intends to reject factual submissions if the submitting party does not comply with the applicable revised certification requirements.

Notification to Interested Parties

Interested parties may submit applications for disclosure under APO in accordance with 19 CFR 351.305. Parties wishing to participate in this proceeding should ensure that they meet the requirements of these procedures at 19 CFR 351.103(d) and enter their appearance. Representatives of interested parties may submit applications for disclosure under APO in accordance with 19 CFR 351.305.

This notice is published in accordance with section 129(b)(1) of the URAA.

Dated: July 6, 2022.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations.

[FR Doc. 2022–14705 Filed 7–8–22; 8:45 am]

BILLING CODE 3510–DS–P

[1] *See generally* 19 CFR 351.303 (for general filing requirements.).

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

[3] *See* 19 CFR 351.302(b).

[4] *See Extension of Time Limits; Final Rule,* 78 FR 57790 (September 20, 2013), available at *https://www.gpo.gov/fdsys/pkg/FR-2013-09-20/html/2013-22853.htm.*

[5] *See* section 782(b) of the Act.

[6] *See Certification of Factual Information to Import Administration During Antidumping and Countervailing Duty Proceedings,* 78 FR 42678 (July 17, 2013) (Final Rule); *see also* frequently asked questions regarding the Final Rule, available at *https://enforcement.trade.gov/tlei/notices/factual_info_final_rule_FAQ_07172013.pdf.*

DEPARTMENT OF COMMERCE

International Trade Administration

[A–423–812]

Initiation of Antidumping and Countervailing Duty Administrative Reviews; and Certain Carbon and Alloy Steel Cut-To-Length Plate From Belgium: Preliminary Results and Partial Rescission of Antidumping Duty Administrative Review; 2020–2021; Correction

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

ACTION: Notice; correction.

SUMMARY: The U.S. Department of Commerce (Commerce) published notices in the **Federal Register** of July 6, 2021, and June 6, 2022, respectively, in which Commerce announced the initiation and preliminary results and partial rescission of the 2020–2021 administrative review of the antidumping duty (AD) order on certain carbon and alloy steel cut-to-length plate (CTL Plate) from Belgium. In these notices, Commerce inadvertently misspelled the company name of NLMK Verona SpA, a company for which we initiated and subsequently rescinded an administrative review.

FOR FURTHER INFORMATION CONTACT: Alex Wood, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1959.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of July 6, 2021, in FR Doc 2021–14290, on page 35484, in the first column, and in the **Federal Register** of June 6, 2022, in FR Doc 2022–12086, on page 34246, in the third column, correct the name NLMK Verona SpP to NLMK Verona SpA.

Background

On July 6, 2021, and June 6, 2022, respectively, Commerce published in

the **Federal Register** an initiation of the 2020–2021 AD administrative review on CTL plate from Belgium and the preliminary results and partial rescission of the 2020–2021 AD administrative review on CTL Plate from Belgium.[1] In these notices, we incorrectly spelled the company name of NLMK Verona SpA, a company for which Commerce initiated and subsequently rescinded an administrative review.

Notification to Interested Parties

This notice is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Tariff Act of 1930, as amended, and 19 CFR 351.221(b)(4) and 19 CFR 351.221(c)(1)(i).

Dated: July 5, 2022.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations.

[FR Doc. 2022–14706 Filed 7–8–22; 8:45 am]

BILLING CODE 3510–DS–P

[1] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 86 FR 35481 (July 6, 2021); *see also Certain Carbon and Alloy Steel Cut-To-Length Plate From Belgium: Preliminary Results and Partial Rescission of Antidumping Duty Administrative Review; 2020–2021,* 87 FR 34244 (June 6, 2022).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–520–807]

Circular Welded Carbon-Quality Steel Pipe From the United Arab Emirates: Final Results of Antidumping Duty Administrative Review; 2019–2020

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

SUMMARY: The U.S. Department of Commerce (Commerce) determines that producers and/or exporters subject to this administrative review made sales of subject merchandise at prices less than normal value during the period of review (POR), December 1, 2019, through November 30, 2020.

DATES: Applicable July 11, 2022.

FOR FURTHER INFORMATION CONTACT: Benjamin A. Luberda or Steven Seifert, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2185 or (202) 482–3350, respectively.

SUPPLEMENTARY INFORMATION:

Background

This review covers five producers/exporters of the subject merchandise. Commerce selected two mandatory respondents for individual examination: Ajmal Steel Tubes & Pipes Ind. L.L.C./Ajmal Steel Tubes & Pipes Ind. L.L.C.-Branch-1 (collectively, Ajmal) [1] and Universal Tube and Plastic Industries, Ltd./THL Tube and Pipe Industries LLC/KHK Scaffolding and Formwork LLC (collectively, Universal).[2] The producers/exporters not selected for individual examination are Conares Metal Supply Limited, TSI Metal Industries L.L.C.,[3] and K.D. Industries Inc.

On January 7, 2022, Commerce published the *Preliminary Results.*[4] On April 25, 2022, we postponed the final results until July 1, 2022.[5] A summary of the events that occurred since Commerce published the *Preliminary Results,* as well as a full discussion of the issues raised by interested parties for these final results, may be found in the Issues and Decision Memorandum.[6] The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Commerce conducted this administrative review in accordance with section 751 of the Tariff Act of 1930, as amended (the Act).

Scope of the Order [7]

The merchandise subject to the order is welded carbon-quality steel pipes and tube, of circular cross-section, with an outside diameter not more than nominal 16 inches (406.4 mm), regardless of wall thickness, surface finish, end finish, or industry specification, and generally known as standard pipe, fence pipe and tube, sprinkler pipe, or structural pipe (although subject product may also be referred to as mechanical tubing). The products subject to this order are currently classifiable in Harmonized Tariff Schedule of the United States (HTSUS) statistical reporting numbers 7306.19.1010, 7306.19.1050, 7306.19.5110, 7306.19.5150, 7306.30.1000, 7306.30.5015, 7306.30.5020, 7306.30.5025, 7306.30.5032, 7306.30.5040, 7306.30.5055, 7306.30.5085, 7306.30.5090, 7306.50.1000,

[1] We collapsed Ajmal Steel Tubes & Pipes Ind. L.L.C. and Noble Steel Industries L.L.C. (Noble Steel) together in the final results of the 2016–2017 administrative review. *See Circular Welded Carbon-Quality Steel Pipe from the United Arab Emirates: Final Results of Antidumping Duty Administrative Review; 2016–2017,* 84 FR 44845 (August 27, 2019) (*CWP from the UAE 2016–2017 Final Results*). Because there is no information on the record of this administrative review that would lead us to revisit this determination, we are continuing to treat these companies as part of a single entity for the purposes of this administrative review. Moreover, in the *Preliminary Results,* we preliminarily found that Ajmal Steel Tubes & Pipes Ind., L.L.C.-Branch-1 (Ajmal Branch 1) is the successor-in-interest to Noble Steel. *See* Memorandum, ''Preliminary Successor-In-Interest Determination for Determination for Ajmal Steel Tubes & Pipes Ind. L.L.C.-Branch-1,'' dated December 30, 2021. No party has challenged this determination for the final results. Accordingly, we continue to find that Ajmal Branch 1 is the successor-in-interest to Noble Steel.

[2] Commerce previously determined that Universal is a single entity consisting of the following three producers/exporters of subject merchandise: Universal Tube and Plastic Industries, Ltd.; KHK Scaffolding and Framework LLC; and Universal Tube and Pipe Industries LLC (UTP). *See Circular Welded Carbon-Quality Steel Pipe from the United Arab Emirates: Affirmative Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination,* 81 FR 36882 (June 8, 2016), and accompanying Preliminary Decision Memorandum (PDM), unchanged in *Circular Welded Carbon-Quality Steel Pipe from the United Arab Emirates: Final Determination of Sales at Less Than Fair Value,* 81 FR 75030 (October 28, 2016), and accompanying Issues and Decision Memorandum. Because there is no information on the record of this administrative review that would lead us to revisit this determination, we are continuing to treat these companies as part of a single entity for the purposes of this administrative review. Additionally, we previously determined that THL Tube and Pipe Industries LLC is the successor-in-interest to UTP. *See CWP from the UAE 2016–2017 Final Results.*

[3] On December 30, 2021, we preliminarily found that TSI Metal Industries L.L.C. (TSI Metal) is the successor-in-interest to Tiger Steel Industries L.L.C. (Tiger Steel). *See* Memorandum, ''Preliminary Successor-In-Interest Determination for TSI Metal Industries L.L.C.,'' dated December 30, 2021. No party has challenged this determination for the final results. Thus, we continue to find that TSI Metal is the successor-in-interest to Tiger Steel. Accordingly, we will notify U.S. Customs and Border Protection (CBP) of this determination and assign Tiger Steel's company-specific case number and cash deposit rate to TSI Metal.

[4] *See Circular Welded Carbon-Quality Steel Pipe from the United Arab Emirates: Preliminary Results of Antidumping Duty Administrative Review; 2019–2020,* 87 FR 930 (January 7, 2022) (*Preliminary Results*), and accompanying PDM.

[5] *See* Memorandum, ''Circular Welded Carbon-Quality Steel Pipe from the United Arab Emirates: Extension of Deadline for Final Results of 2019–2020 Administrative Review,'' dated April 25, 2022.

[6] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the 2019–2020 Administrative Review of the Antidumping Duty Order on Circular Welded Carbon-Quality Steel Pipe from the United Arab Emirates,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[7] *See Circular Welded Carbon-Quality Steel Pipe from the Sultanate of Oman, Pakistan, and the United Arab Emirates: Amended Final Affirmative Antidumping Duty Determination and Antidumping Duty Orders,* 81 FR 91906 (December 19, 2016) (*Order*).

7306.50.5030, 7306.50.5050, and 7306.50.5070. Although the HTSUS numbers are provided for convenience and for customs purposes, the written product description remains dispositive.[8]

Analysis of Comments Received

All issues raised by interested parties to this administrative review are addressed in the Issues and Decision Memorandum. For a list of issues raised by parties, *see* the appendix to this notice.

Changes Since the Preliminary Results

Based on a review of the record and comments received from interested parties regarding the *Preliminary Results,* we made certain changes to the preliminary weighted-average margin calculations for Ajmal, Universal, and the non-examined companies.[9]

Rate for Non-Examined Companies

The Act and Commerce's regulations do not address the establishment of a weighted-average dumping margin 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 weighted-average dumping margin 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 rates that are zero, *de minimis* (*i.e.,* less than 0.5 percent), or determined entirely on the basis of facts available.

For the final results, Commerce calculated estimated weighted-average dumping margins for Ajmal and Universal that are not zero, *de minimis,* or based entirely on facts otherwise available. Accordingly, Commerce has continued to calculate the rate for companies not selected for individual examination using a weighted average of the margins calculated for Ajmal and Universal, weighted by each respondent's publicly-ranged total U.S. sales quantity.[10]

Final Results of the Review

We are assigning the following weighted-average dumping margins to the firms listed below for the period December 1, 2019, through November 30, 2020:

Exporter/producer	Weighted-average dumping margin (percent)
Ajmal Steel Tubes & Pipes Ind. L.L.C./Ajmal Steel Tubes & Pipes Ind. L.L.C.-Branch-1	2.27
Universal Tube and Plastic Industries, Ltd./THL Tube and Pipe Industries LLC/KHK Scaffolding and Formwork LLC	3.54
Conares Metal Supply Limited	2.77
TSI Metal Industries L.L.C	2.77
K.D. Industries Inc	2.77

Disclosure

We intend to disclose the calculations performed within five days of the date of publication of this notice to parties in this proceeding, in accordance with 19 CFR 351.224(b).

Assessment Rates

Pursuant to section 751(a)(2)(C) of the Act, and 19 CFR 351.212(b)(1), Commerce has determined, and CBP shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review.

Pursuant to 19 CFR 351.212(b)(1), because Ajmal and Universal reported the entered value of their U.S. sales, we calculated importer-specific *ad valorem* duty assessment rates based on the ratio of the total amount of dumping calculated for the examined sales to the total entered value of the sales for which entered value was reported.

For the companies that were not selected for individual review, we will assign an assessment rate based on the methodology descried in the ''Rate for Non-Examined Companies'' section, above.

Commerce's ''automatic assessment'' will apply to entries of subject merchandise during the POR produced by companies included in these final results of review for which the reviewed companies did not know that the merchandise they sold to the intermediary (*e.g.,* a reseller, trading company, or exporter) was destined for the United States. In such instances, we will instruct CBP to liquidate unreviewed entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction.[11]

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

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) the cash deposit rate for each specific company listed above will be that established in the final results of this review, except if the rate is less than 0.50 percent and, therefore, *de minimis* within the meaning of 19 CFR 351.106(c)(1), in which case the cash deposit rate will be zero; (2) for previously investigated companies not subject to this review, the cash deposit will continue to be the company-specific rate published for the most recently completed segment of this proceeding; (3) if the exporter is not a

[8] For a complete description of the scope of the order, *see* the Issues and Decision Memorandum.

[9] *See* the Issues and Decision Memorandum.

[10] When Commerce's individual examination of respondents is limited to two respondents, Commerce normally calculates: (A) a weighted average of the estimated weighted-average dumping margins calculated for the individually-examined respondents; (B) a simple average of the estimated weighted-average dumping margins calculated for the individually-examined respondents; and (C) a weighted average of the estimated weighted-average dumping margins calculated for the individually-examined respondents using each company's publicly-ranged U.S. sales quantities of subject merchandise. Commerce then compares then compares (B) and (C) to (A) and selects either the (B) or (C) rate based on the rate closest to (A) as the most appropriate rate for companies not selected for individual examination, as using the (A) rate would result in the disclosure of business proprietary information. *See, e.g., Ball Bearings and Parts Thereof from France, Germany, Italy, Japan, and the United Kingdom: Final Results of Antidumping Duty Administrative Reviews, Final Results of Changed-Circumstances Review, and Revocation of an Order in Part,* 75 FR 53661, 53663 (September 1, 2010). In this review, Commerce based the rate for companies not selected for individual examination on the publicly-ranged sales data of the mandatory respondents. For an analysis of the data, *see* Memorandum, ''Calculation of the All-Others Rate for the Final Results,'' dated concurrently with this notice.

[11] For a full discussion of this practice, *see Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

firm covered in this review, or a previous segment, but the manufacturer is, then the cash deposit rate will be the rate established for the most recent segment for the manufacturer of the merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will continue to be 5.95 percent, the all-others rate established in the LTFV investigation.[12] These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification Regarding Administrative Protective Order

This notice serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

We are issuing and publishing this notice in accordance with sections 751(a)(1) and 777(i) of the Act.

Dated: July 1, 2022.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations.

Appendix—List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the *Order*
IV. Final Successor-in-Interest Determination
V. Margin Calculations
VI. Discussion of the Issue
Comment: Selection of the Correct Universes of Sales for Ajmal for the Period of Review (POR)
VII. Recommendation

[FR Doc. 2022–14610 Filed 7–8–22; 8:45 am]

BILLING CODE 3510–DS–P

[12] *See Circular Welded Carbon-Quality Steel Pipe from the Sultanate of Oman, Pakistan, and the United Arab Emirates: Amended Final Affirmative Antidumping Duty Determination and Antidumping Duty Orders,* 81 FR 91906, 91908 (December 19, 2016).

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC160]

New England Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a public meeting of its Ecosystem-Based Fishery Management (EBFM) Committee to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This webinar will be held on Tuesday, July 26, 2022, at 9:30 a.m. Webinar registration URL information: *https://attendee.gotowebinar.com/register/609258508760430607.*

ADDRESSES:

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION:

Agenda

The EBFM Committee will meet receive updates on and discuss the following issues: (1) Preparation for public information workshops on Ecosystem-Based Fishery Management for Georges Bank, and (2) Prototype Management Strategy Evaluation of Georges Bank Ecosystem-Based Fishery management strategies. The Committee will discuss other business including discussions with NOAA Fisheries leadership about National Standard 1 concerns about stock complex catch limit management proposed in the example Fishery Ecosystem Plan. They may also discuss development of 2023 management priorities.

Although non-emergency issues not contained on the agenda may come before this Council for discussion, those issues may not be the subject of formal action during this meeting. Council action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency. The public also should be aware that the meeting will be recorded. Consistent with 16 U.S.C. 1852, a copy of the recording is available upon request.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Thomas A. Nies, Executive Director, at (978) 465–0492, at least 5 days prior to the meeting date.

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

Dated: July 6, 2022.

Tracey L. Thompson,

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

[FR Doc. 2022–14681 Filed 7–8–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC158]

Pacific Fishery Management Council; Public Meetings

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

ACTION: Notice of public meeting.

SUMMARY: The Pacific Fishery Management Council's (Pacific Council) Ad Hoc Marine Planning Committee (MPC) will hold a public meeting.

DATES: The meeting will be held Tuesday, July 26, 2022, from 10 a.m. to 4 p.m. Pacific Daylight Time or until business for the day has been completed.

ADDRESSES: This meeting will be held online. Specific meeting information, including directions on how to join the meeting and system requirements will be provided in the meeting announcement on the Pacific Council's website (see *www.pcouncil.org*). You may send an email to Mr. Kris Kleinschmidt (*kris.kleinschmidt@noaa.gov*) or contact him at (503) 820–2412 for technical assistance.

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220–1384.

FOR FURTHER INFORMATION CONTACT: Kerry Griffin, Staff Officer, Pacific Council; telephone: (503) 820–2409.

SUPPLEMENTARY INFORMATION: The primary purpose of this online meeting is for the MPC to discuss issues related to offshore wind energy development and NOAA Aquaculture Opportunity Areas. The MPC may discuss the Bureau of Ocean Energy Management's request for comment on its Draft Fisheries Mitigation Strategy and may develop a report to the Pacific Council for consideration at its September meeting. Other marine planning topics or emerging issues may be discussed as necessary. The meeting agenda will be available on the Pacific Council's website in advance of the meeting, and the meeting will be recorded for the benefit of interested parties who aren't able to attend the meeting at its scheduled time and date.

Although non-emergency issues not contained in the meeting agenda may be discussed, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this document and any issues arising after publication of this document that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

Requests for sign language interpretation or other auxiliary aids should be directed to Mr. Kris Kleinschmidt (*kris.kleinschmidt@noaa.gov;* (503) 820–2412) at least 10 days prior to the meeting date.

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

Dated: July 6, 2022.

Tracey L. Thompson,

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

[FR Doc. 2022–14684 Filed 7–8–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No. PTO–T–2022–0005]

Trademarks USPTO.gov Account ID Verification Program

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Notice.

SUMMARY: In late 2019, as part of the United States Patent and Trademark Office's (USPTO or Office) continuing efforts to protect the integrity of the U.S. trademark register, and to better protect its customers from scams and fraudulent activities related to the trademark register, the USPTO began requiring customers to create a *USPTO.gov* account to file electronic trademark forms. This enabled the Agency to monitor trademark filing behavior and aided in enforcing the existing USPTO Rules of Practice regarding submissions in trademark matters. On January 8, 2022, in anticipation of moving toward a mandatory identity (ID) verification process to further thwart fraud, the USPTO made ID verification available to *USPTO.gov* account holders on a voluntary basis. This allowed account holders to verify their identity in either paper or electronic form before ID verification became mandatory. On August 6, 2022, the USPTO will make it mandatory for existing and new account holders who occupy an appropriate user role to verify their identity as a condition for filing electronic trademark forms.

FOR FURTHER INFORMATION CONTACT: Robert Lavache, Office of the Deputy Commissioner for Trademark Examination Policy, at 571–272–5881. You can also send inquiries to *TMFRNotices@uspto.gov.*

SUPPLEMENTARY INFORMATION: Historically, trademark customers of the USPTO have only had to attest to the information in their applications and other submissions if the USPTO questioned the information. Thus, for example, if a third party had evidence that the identity of an applicant or registrant was false, that party would have to oppose the application or petition to cancel the registration before the USPTO's Trademark Trial and Appeal Board, a costly and time-consuming process.

In recent years, however, the Office has received an increasing number of trademark submissions containing false information, resulting in some bad actors obtaining trademark registrations to which they were not entitled. In some cases, these actors have filed tens of thousands of applications containing improper submissions that include false signatures, false addresses, false claims of use required to obtain and maintain a registration, and false or hijacked U.S. attorney credentials. They have also engaged in unauthorized practice of law and unauthorized representation of others before the USPTO. In other cases, bad actors have used the system to improperly file unauthorized submissions in a competitor's application and registration records. While the levels of misconduct and improper submissions are relatively low compared to the large annual volume of filings in trademark cases, the impact of these activities has become disproportionately significant, as evidenced by the growing number of internet-based scams that have been sanctioned and that have implicated thousands of applications featuring rule violations that the USPTO terminated. Additionally, these activities violate the USPTO rules of practice—including rules on signatures, certifications, and representation of others before the USPTO—and website terms of use, potentially calling into question the validity of any resulting registration.

In response, the USPTO has implemented measures, including a trademark administrative sanctions process that investigates suspicious applications and imposes sanctions on rule violators. *See* Trademarks Administrative Sanctions Process, 87 FR 431 (Jan. 5, 2022). The USPTO has also required those filing documents in trademark matters to have a *USPTO.gov* account. Moving forward, in an attempt to prevent the filing of applications and other submissions that are fraudulent or violate the USPTO's signature and representation rules, the USPTO will require *USPTO.gov* account holders to verify their identity in order to file electronic trademark forms.

I. USPTO.gov Login System

In 2019, as part of the USPTO's register protection initiatives, the USPTO established a three-phase login system intended to increase the accountability of those filing submissions. Phase 1, implemented in 2019, requires a user to create a *USPTO.gov* account in order to file electronic trademark forms. Once the account is created, the holder is subject to the terms of use. Account holders who violate the terms of use may have their accounts blocked to prevent continued abuse of the USPTO's electronic trademark systems. On January 8, 2022, the USPTO began implementing Phase 2 by making ID

verification available on a voluntary basis to existing *USPTO.gov* account holders. On August 6, 2022, the USPTO will make it mandatory for existing and new account holders who occupy an appropriate user role to verify their identity as a condition for filing electronic trademark forms. At that time, existing unverified *USPTO.gov* accounts will remain active, but will not be able to be used to access or submit trademark forms. Only verified account holders will be able to access and submit trademark forms. Phase 3 restricts access to electronic trademark records to only those authorized to make submissions related to those specific records. This will prevent unauthorized actors from filing submissions in application and registration records.

II. Phase 1 Account Login

When a user creates a *USPTO.gov* account, the USPTO can monitor filing behaviors and link improper submissions to a particular account, which it can then block. Currently, however, there is nothing to prevent a blocked account holder from using false information to create a new account in order to file trademark submissions. The USPTO must then investigate and pursue sanctions once it discovers that the blocked account holder has created a new account. There is also nothing to prevent someone who is engaging in the unauthorized practice of law and unauthorized representation of others before the USPTO from filing submissions that are contrary to the USPTO rules of practice, including rules on signatures, certifications, and representation of others before the USPTO. Again, the USPTO can only address rule violations after they are investigated and undergo an administrative sanctions process. These are resource-intensive. Lastly, there is nothing to prevent account holders from sharing accounts, which is a violation of the terms of use, unless or until the USPTO investigates and imposes sanctions. Phase 2 ID verification is designed to help address these three gaps.

III. Phase 2 ID Verification and Phase 3 Role-Based Access Controls

ID verification ensures that those making submissions to the USPTO to obtain or maintain a trademark registration are who they say they are and can be held accountable for misconduct, fraud, and/or abuse of the USPTO's systems. This will allow the USPTO to take down *USPTO.gov* accounts registered to bad actors and prevent them from creating new accounts or sharing accounts. Phase 2 of the USPTO's ID verification process also requires *USPTO.gov* account holders to identify their user role when verifying their identity. These user roles set the stage for the future implementation of Phase 3's role-based access controls. Phase 3 will enable the USPTO to limit submissions on a particular application or registration to a specific *USPTO.gov* account holder with the appropriate user role.

There are four authorized user roles: (1) trademark owner,[1] (2) U.S.-licensed attorney, (3) Canadian attorney or agent, and (4) sponsored attorney support staff. Under role-based access controls, owner accounts would have submission rights only for their own applications or registrations. For that reason, an owner account can only be established by the owner or by its authorized employees. Each employee who is authorized to file submissions on behalf of the owner may have a separate owner account. However, the owner account is limited to submissions related to the owner's applications and registrations. Only an attorney account or a sponsored staff account can be used to file submissions in multiple applications and registrations. An attorney account would have submission rights for only those applications or registrations in which the attorney is designated as an attorney of record. An attorney-sponsored support staff account would be similarly limited to applications or registrations in which a supervising attorney who sponsors the support staff account has access rights. Support staff who work with several attorneys must be sponsored by each attorney in order to have access rights to each attorney's applications or registrations. A reciprocally recognized Canadian trademark attorney or agent may prepare, sign, and file a new application and prepare and sign other application- and registration-related submissions on behalf of clients located in Canada, although a qualified U.S. attorney must file such submissions. ID verification, user roles, and access controls based on those user roles will provide more security for the trademark registration system, help prevent fraud in the system, and greatly aid in removing improper filings once discovered.

[1] A represented owner does not need a verified account because the owner's attorney will have a verified account and because the owner can electronically sign forms without verifying an account. If an owner becomes unrepresented after recognition of their attorney ends, by revocation or withdrawal, for example, an owner will have to establish and verify their own account in order to file an electronic form without representation.

IV. User Roles Limited to Owners and Attorneys

Section 1 of the Lanham Act provides that ''the owner of a trademark used in commerce may request registration of its trademark.'' Under USPTO rules, owners who are not represented by an attorney are authorized to file and make submissions regarding their trademarks. Also, USPTO rules allow submissions from attorneys who are authorized by the owner to represent them. Attorneys are subject to professional responsibility rules, ethical sanctions, potential malpractice remedies, and the loss of a law license for misrepresentation. These penalties are designed to ensure that the attorney representing the owner is acting on behalf of the owner.

Through investigations of suspicious filings, the USPTO has discovered that tens of thousands of trademark submissions have been made by actors who purport to act on behalf of the owner but are not adhering to USPTO rules that govern signatures, certifications, and representation of others before the USPTO. These rule violations jeopardize the validity of the submissions made as well as any resulting registration. The USPTO does not have assurances that these actors, typically non-attorney entities (*i.e.,* those engaging in unauthorized practice of law or unauthorized representation of others before the USPTO), are acting on behalf of the owner and with the owner's knowledge of the information contained in the submissions. Limiting access to electronic trademark forms through ID verification and user roles to only those whose submissions in trademark matters can be deemed an act of the owner will provide assurances to the USPTO and the public that filings are authorized by the owner, are made at their request, and are made with specific knowledge of the information contained in the submission.

V. No User Roles for Non-Attorney Entities

Under USPTO rules, non-attorney entities are not authorized to practice law or represent owners before the USPTO, and thus, there is no corresponding user role. A non-attorney entity such as a trademark preparation and/or filing company is one that: (1) does not have an attorney directly supervising the staff's interactions with clients or the USPTO, and (2) provides only law-related services to clients (*e.g.,* offers trademark information, not advice; acts as a mere scrivener when assisting in the preparation of trademark documents; or conducts trademark searches but does not offer opinions on

the registrability of a mark). When these entities provide legal advice, prepare trademark applications, or file submissions on behalf of others, they are likely engaging in unauthorized practice of law and unauthorized representation of others before the USPTO. Practice of law before the Office in trademark matters is described in 37 CFR 11.5(b)(2).

The USPTO has the authority to regulate the conduct of proceedings before the Office and the conduct of those who appear before the Office in proceedings, including practitioners and non-practitioners. *See* 5 U.S.C. 500(d)(2) (Federal agencies may sanction those ''individuals who appear in a representative capacity before the agency''); 35 U.S.C. 2(b)(2)(A) (the USPTO has the authority to establish regulations that ''shall govern the conduct of proceedings in the Office''); and 35 U.S.C. 3(b)(2)(A) (the Commissioner for Trademarks has the authority to manage and direct all aspects of trademark operations).

Some customers appear to rely on non-attorney entities for legal advice without realizing that the non-attorney entity cannot represent trademark applicants before the USPTO or that the entity's behavior could undermine the validity of their application or registration. Furthermore, these non-attorney entities are also routinely providing signatures on trademark submissions that violate the USPTO's rules. Under these rules, submissions must be personally signed, and therefore, signatures are non-delegable. 37 CFR 2.193(a), 11.18; Trademark Manual of Examining Procedure § 611.01(c). Authorizing someone who is not the signatory to sign a trademark submission jeopardizes the validity of the submission and may affect the validity of the entire application or registration.

The USPTO has imposed sanctions and terminated pending applications that contain violations of USPTO rules, without regard to whether the applicant was aware of the rule violations perpetrated by those making submissions on their behalf. These trademark applicants have been misled and defrauded by actors filing submissions at the USPTO, purportedly on their behalf but clearly against the owner's interest and, in most cases, without the owner's knowledge. To discourage reliance on non-attorney entities and to adhere to the Lanham Act and the USPTO rules more closely, the USPTO is limiting user roles through the ID verification process for a *USPTO.gov* account to those authorized under USPTO rules to make trademark submissions filings for the owner (*i.e.,* the owner and the owner's representative authorized to practice law before the USPTO in trademark matters).

Katherine K. Vidal,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 2022–14435 Filed 7–8–22; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Intent To Prepare an Environmental Impact Statement for O'Brien Road Access Modernization (ORAM), Within the Fort Meade Complex, Maryland

AGENCY: National Security Agency, Department of Defense (DoD).

ACTION: Notice of intent; notice of public scoping; request for comments.

SUMMARY: The DoD announces its intent to prepare an Environmental Impact Statement (EIS) to assess the potential effects associated with proposed access and infrastructure upgrades at the National Security Agency's (NSA) campus on Fort George G. Meade, Maryland (hereafter referred to as Fort Meade). The purpose of the proposed project is to increase efficiencies and capacity for required security processing of deliveries and traffic entering the NSA campus. Additionally, major construction projects have generated changes in Fort Meade traffic distribution, resulting in extensive delays for inspection and access. Publication of this notice begins a scoping process that identifies and determines the scope of environmental issues to be addressed in the EIS. This notice requests public participation in the scoping process and provides information on how to participate.

DATES: The public is invited to provide comments on the scope of the EIS during a 45-day public scoping period. Comments will be accepted until August 25, 2022.

In light of changing public health requirements, a narrated presentation will be made available in lieu of an in-person meeting. Information will be made available on the project website at *https://www.nab.usace.army.mil/oram*. For further information, see ''Scoping Process'' in the **SUPPLEMENTARY INFORMATION** section below).

ADDRESSES: Written comments regarding the scope of the EIS and comments on the scoping process may be submitted by any of the following methods:

Mail: ORAM EIS, c/o: HDR 2650, Park Tower Drive, Suite 400, Vienna, VA 22180;

Email: ORAM@hdrinc.com.

FOR FURTHER INFORMATION CONTACT: Mr. Jeffrey Williams, Sr. Environmental Engineer, *jdwill2@nsa.gov* 301–688–2970.

SUPPLEMENTARY INFORMATION:

Background: NSA is a tenant DoD agency on Fort Meade, occupying approximately 840 acres of the 5,107.7 acres of base property. Renovation and upgrade of inspection and access facilities for NSA is required to meet increased mission and security capacity. The existing Vehicle Control Inspection Facility (VCIF) and Vehicle Control Point 5 (VCP5) represent two significant entry points for access to the NSA campus. Both facilities require replacement due to process inefficiencies and insufficient capacity to meet current and future demand. Original sizing of the VCIF was to provide inspection facilities only for NSA deliveries and traffic. Post 9/11, a decision was made that NSA would inspect both Fort Meade and NSA deliveries. Additionally, major construction activities on Fort Meade have generated increases in traffic access and inspection throughout the installation. These conditions have resulted in extensive delays at the VCIF and traffic back-ups onto Maryland State Route 32. The design of VCP5 on O'Brien Road is also outdated and provides insufficient access capacity between the NSA campus and Fort Meade. Relocation of the Fort Meade Access Control Facility (ACF) on Mapes Road was included to facilitate the design and construction of the roadway system, as well as minimize environmental impacts.

Proposed Action and Alternatives: The proposed action would consist of: construction of a new VCIF with adjacent visitor control center; construction of a new Mail Screening Facility (MSF) adjacent to the VCIF; construction of a new VCP5; reconfiguration of the Mapes Road ACF; roadway improvements to provide enhanced routing and separation of traffic between NSA and Fort Meade; and associated infrastructure including sidewalks, inspection canopies, dog kennels, surface parking areas, stormwater management facilities, utilities, and related infrastructure.

It is anticipated that two build alternatives will be analyzed in detail through the EIS process that will involve distinct configurations of

project elements within the same general area on the NSA campus and Fort Meade. The No Action Alternative (not undertaking the proposed improvements) will also be analyzed in detail to provide a baseline for comparison with the action alternatives.

This notice of intent is required by 40 Code of Federal Regulations (CFR) 1501.9 and briefly describes the Proposed Action and possible alternatives and our proposed scoping process. The EIS will comply with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*), the Council on Environmental Quality regulations in 40 CFR parts 1500 through 1508, and DoD Instruction 4715.9 (Environmental Planning and Analysis).

Significant Issues: Environmental issues to be analyzed in the EIS will include potential effects on air quality, stream and wetland resources, forests, cultural resources, hazardous waste and materials, and transportation. Consultations to be incorporated into the preparation of the Draft EIS will include, but are not necessarily limited to, consultation under Section 7 of the Endangered Species Act and Section 106 of the National Historic Preservation Act.

Scoping Process: Public scoping is an early and open process for identifying and determining the scope of issues to be addressed in the EIS. Scoping begins with this notice and continues through the 45-day public comment period.

As part of the public scoping process, in lieu of a public scoping meeting, a narrated presentation about the project and how to provide scoping comments will be made available on August 3, 2022, for a two-day period. The presentation will be made available on the project website at *https://www.nab.usace.army.mil/oram.*

Upon completion of the scoping process, DoD will prepare a Draft EIS, and will publish a **Federal Register** notice announcing its public availability. The Draft EIS is anticipated to be available for public review by mid-2023. If you want the notice to be sent to you, please submit your request in writing (see **ADDRESSES** section in this notice). There will also be an opportunity to review and comment on the Draft EIS. Additionally, it is anticipated that a public meeting would be held after publication of the Draft EIS to present the Draft EIS and receive public comments regarding the document. NSA will consider all comments received and then prepare a Final EIS. As with the Draft EIS, NSA will announce the availability of the Final EIS and once again provide an opportunity for review and comment. The Final EIS and a Record of Decision on the Proposed Action are expected in late 2023.

Dated: June 30, 2022.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2022–14726 Filed 7–8–22; 8:45 am]

BILLING CODE 5001–06–P

ELECTION ASSISTANCE COMMISSION

Sunshine Act Meetings

AGENCY: U.S. Election Assistance Commission (EAC).

ACTION: Sunshine Act notice; notice of public roundtable agenda.

SUMMARY: U.S. Election Assistance Commission Roundtable Discussion: Disability and the Digital Divide in The Voting Process.

DATES: Tuesday, July 26, 2022, 11:00 a.m. Eastern.

ADDRESSES: Virtual via Zoom.

The roundtable discussion is open to the public and will be livestreamed on the U.S. Election Assistance Commission YouTube Channel: *https://www.youtube.com/channel/UCpN6i0g2rlF4ITWhwvBwwZw.*

FOR FURTHER INFORMATION CONTACT: Kristen Muthig, Telephone: (202) 897–9285, Email: *kmuthig@eac.gov.*

SUPPLEMENTARY INFORMATION:

Purpose: In accordance with the Government in the Sunshine Act (Sunshine Act), Public Law 94–409, as amended (5 U.S.C. 552b), the U.S. Election Assistance Commission (EAC) will conduct a virtual roundtable discussion on a new study analyzing the digital divide between citizens with and without disabilities during the 2020 through 2022 election period.

Agenda: The U.S. Election Assistance Commission (EAC) will hold a roundtable discussion on a new study released by the EAC and the Program for Disability Research at Rutgers University. The report highlights new data on computer and internet use, sources of information on the voting process used in 2020, accessibility of information sources, preferred ways of getting an answer to a question about the voting process, trust in information sources, sources of information on candidates and issues, expectations about voting and information sources in 2022, and knowledge of rights for accessible information.

The event will include presentations of the findings from professors Lisa Schur and Douglas Kruse from Rutgers University.

The full agenda will be posted in advance on the EAC website: *https://www.eac.gov.*

Background: In February 2021, the EAC released the ''Disability and Voting Accessibility in the 2020 Elections,'' a comprehensive national report identifying advancements and gaps in accessibility for voters with disabilities. The study focused on polling place access, mail and absentee voting accessibility, election administration challenges, COVID–19 obstacles, and community involvement. In July 2021, the EAC released ''The Fact Sheet: Disability and Voter Turnout in the 2020 Elections,'' a supplemental report with Rutgers University that used data from the federal government's Current Population Survey Voting and Registration Supplement for November 2020 to calculate disability turnout and identify trends.

Status: This roundtable discussion will be open to the public.

Amanda Joiner,

Acting General Counsel, U.S. Election Assistance Commission.

[FR Doc. 2022–14836 Filed 7–7–22; 4:15 pm]

BILLING CODE P

DEPARTMENT OF ENERGY

Nuclear Energy Advisory Committee

AGENCY: Office of Nuclear Energy, Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces an open meeting of the Nuclear Energy Advisory Committee. The Federal Advisory Committee Act requires that public notice of this meeting be announced in the **Federal Register**.

DATES: Tuesday, August 2, 2022; 9:00 a.m.–4:30 p.m.

ADDRESSES: Hilton Washington DC National Mall The Wharf, 480 L'Enfant Plaza SW, Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Luke Branscum, Designated Federal Officer, U.S. Department of Energy, 1000 Independence Ave. SW, Washington, DC 20585; (202) 586–4290; email: *Luke.Branscum@nuclear.energy.gov.*

SUPPLEMENTARY INFORMATION:

Purpose of the Committee: The Nuclear Energy Advisory Committee provides advice and recommendations to the Assistant Secretary for Nuclear Energy on national policy and scientific aspects of nuclear issues of concern to DOE.

Purpose of Meeting: The Nuclear Energy Advisory Committee will hold a meeting on August 2, 2022, to introduce the committee to the priorities of the Office of Nuclear Energy, to determine priorities for the Committee, and to discuss subcommittees to recommend for formation to the Assistant Secretary for Nuclear Energy.

Tentative Agenda

- Welcome and Opening Remarks
- Introductions of NEAC Members
- Office of Nuclear Energy Priorities
  - Nuclear Energy in a Global Context
  - Supporting the Exiting Nuclear Fleet
  - Developing and Deploying Advanced Reactor Technologies
  - Advanced Fuels/Fuel Cycle
  - Spent Fuel and HLW Management
- Priorities Q&A for NEAC Members & Discussion
- Discussion: NEAC Priorities
- Forming Subcommittees and Next Steps
- Public Comment Period and Closing Remarks
- Adjourn.

All attendees are requested to register in advance for the meeting at: *https://forms.office.com/g/wTUc0zcRzd* or by emailing *Luke.Branscum@nuclear.energy.gov.*

Public Participation: Written statements may be filed with the Committee either before or after the meeting. Individuals who wish to make oral statements pertaining to agenda items should contact Luke Branscum at the address or telephone listed above. Requests for an oral statement must be received at least five days prior to the meeting. Reasonable provision will be made to include requested oral statements in the agenda. The Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Individuals wishing to make public comments will be provided a maximum of five minutes to present their comments.

Minutes: Minutes will be available by contacting Luke Branscum at the address or phone number listed above. Minutes will also be available at the following website: *https://www.energy.gov/ne/nuclear-energy-advisory-committee.*

Signed in Washington, DC, on July 5, 2022.

LaTanya Butler,

Deputy Committee Management Officer.

[FR Doc. 2022–14675 Filed 7–8–22; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IN79–6–000]

FERC Form 580, Interrogatory on Fuel and Energy Purchase Practices; Notice of Request for Partial Waiver

Take notice that on July 1, 2022, pursuant to Rule 207(a)(5) of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure,[1] Pacific Gas and Electric Company submitted a request for a partial waiver of the requirement to respond to the 2022 FERC Form 580 Interrogatory on Fuel and Energy Purchase Practices, as more fully explained in the request.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

Comment Date: 5:00 p.m. Eastern time on July 22, 2022.

Dated: July 5, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–14721 Filed 7–8–22; 8:45 am]

BILLING CODE 6717–01–P

[1] 18 CFR 385.207 (2020).

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: EC22–84–000.
Applicants: Clearway Energy Group LLC.
Description: Joint Application for Authorization Under Section 203 of the Federal Power Act of Clearway Energy LLC.
Filed Date: 7/1/22.
Accession Number: 20220701–5436.
Comment Date: 5 p.m. ET 7/22/22.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–2606–015; ER17–815–004.
Applicants: Verso Escanaba LLC, Consolidated Water Power Company.
Description: Notice of Non-Material Change in Status of Consolidated Water Power Company, et al.
Filed Date: 7/5/22.
Accession Number: 20220705–5053.
Comment Date: 5 p.m. ET 7/26/22.

Docket Numbers: ER13–520–013; ER10–2605–017; ER10–2984–058; ER12–1626–014; ER13–521–013; ER13–1266–040; ER13–1267–013; ER13–1268–013; ER13–1269–013; ER13–1270–013; ER13–1271–013; ER13–1272–013; ER13–1273–013; ER13–1441–013; ER13–1442–013; ER15–2211–038; ER22–1385–001.
Applicants: BHER Market Operations, LLC., MidAmerican Energy Services, LLC, Solar Star California XX, LLC, Solar Star California XIX, LLC, Vulcan/BN Geothermal Power Company, Salton Sea Power L.L.C., Salton Sea Power Generation Company, Fish Lake Power LLC, Elmore Company, Del Ranch Company, CE Leathers Company,

CalEnergy, LLC, Pinyon Pines Wind II, LLC, Topaz Solar Farms LLC, Merrill Lynch Commodities, Inc., Yuma Cogeneration Associates, Pinyon Pines Wind I, LLC.

Description: Triennial Market Power Analysis for Southwest Region of Pinyon Pines Wind I, LLC, et al.

Filed Date: 6/29/22.

Accession Number: 20220629–5198.

Comment Date: 5 p.m. ET 8/29/22.

Docket Numbers: ER14–2666–006; ER15–1218–013; ER16–38–011; ER16–39–010; ER16–2501–007; ER16–2502–007; ER17–157–006; ER17–2341–008; ER17–2453–007; ER18–713–006; ER18–1775–005; ER20–2888–005.

Applicants: Townsite Solar, LLC,64KT 8me LLC, CA Flats Solar 150, LLC, Imperial Valley Solar 3, LLC, CA Flats Solar 130, LLC, Moapa Southern Paiute Solar, LLC, Tropico, LLC, Nicolis, LLC, Kingbird Solar B, LLC, Kingbird Solar A, LLC, Solar Star California XIII, LLC, Avalon Solar Partners, LLC.

Description: Triennial Market Power Analysis for Southwest Region of Avalon Solar Partners, LLC, et al.

Filed Date: 6/30/22.

Accession Number: 20220630–5362.

Comment Date: 5 p.m. ET 8/29/22.

Docket Numbers: ER20–2471–005.

Applicants: NedPower Mount Storm, LLC.

Description: Compliance filing: NedPower Mount Storm LLC submits tariff filing per 35: Informational Filing Regarding Transfer of Ownership to be effective N/A.

Filed Date: 7/5/22.

Accession Number: 20220705–5068.

Comment Date: 5 p.m. ET 7/26/22.

Docket Numbers: ER20–547–006; ER12–1911–005; ER12–1912–005; ER12–1913–005; ER12–1915–005; ER12–1916–005; ER12–1917–005; ER14–41–007; ER14–42–007; ER16–498–006; ER16–499–006; ER16–500–006; ER20–2448–002; ER21–133–002; ER21–736–003; ER21–1962–003; ER21–2634–001.

Applicants: Solar Star Lost Hills, LLC, Mulberry BESS LLC, RE Slate 1 LLC, HDSI, LLC, American Kings Solar, LLC, RE Mustang 4 LLC, RE Mustang 3 LLC, RE Mustang LLC, RE Rosamond Two LLC, RE Rosamond One LLC, RE McKenzie 6 LLC, RE McKenzie 5 LLC, RE McKenzie 4 LLC, RE McKenzie 3 LLC, RE McKenzie 2 LLC, RE McKenzie 1 LLC, Goldman Sachs Renewable Power Marketing LLC.

Description: Triennial Market Power Analysis for Southwest Region of Goldman Sachs Renewable Power Marketing LLC, et al.

Filed Date: 6/29/22.

Accession Number: 20220629–5197.

Comment Date: 5 p.m. ET 8/29/22.

Docket Numbers: ER22–507–001.

Applicants: Pinnacle Wind, LLC.

Description: Compliance filing: Informational Filing Regarding Upstream Change in Ownership to be effective N/A.

Filed Date: 7/5/22.

Accession Number: 20220705–5090.

Comment Date: 5 p.m. ET 7/26/22.

Docket Numbers: ER22–944–002.

Applicants: Black Rock Wind Force, LLC.

Description: Compliance filing: Informational Filing Regarding Upstream Change in Ownership to be effective N/A.

Filed Date: 7/5/22.

Accession Number: 20220705–5086.

Comment Date: 5 p.m. ET 7/26/22.

Docket Numbers: ER22–1991–001.

Applicants: New England Power Pool Participants Committee.

Description: Tariff Amendment: Correction Filing ER22–1991 to be effective 5/1/2022.

Filed Date: 7/5/22.

Accession Number: 20220705–5000.

Comment Date: 5 p.m. ET 7/26/22.

Docket Numbers: ER22–2281–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: 1148R32 American Electric Power NITSA and NOAs to be effective 6/1/2022.

Filed Date: 7/1/22.

Accession Number: 20220701–5389.

Comment Date: 5 p.m. ET 7/22/22.

Docket Numbers: ER22–2282–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: 1276R26 Evergy Metro NITSA NOA to be effective 7/1/2022.

Filed Date: 7/1/22.

Accession Number: 20220701–5401.

Comment Date: 5 p.m. ET 7/22/22.

Docket Numbers: ER22–2283–000.

Applicants: Black Bear Alabama Solar 1, LLC.

Description: Baseline eTariff Filing: Market-Based Rate Tariff Application with Expedited & Confidential Treatment to be effective 7/31/2022.

Filed Date: 7/5/22.

Accession Number: 20220705–5074.

Comment Date: 5 p.m. ET 7/26/22.

Docket Numbers: ER22–2284–000.

Applicants: Black Bear Alabama Solar Tenant, LLC.

Description: Baseline eTariff Filing: Market-Based Rate Tariff Application with Expedited & Confidential Treatment to be effective 7/31/2022.

Filed Date: 7/5/22.

Accession Number: 20220705–5077.

Comment Date: 5 p.m. ET 7/26/22.

Docket Numbers: ER22–2285–000.

Applicants: PJM Interconnection, L.L.C.

Description: Tariff Amendment: Notice of Cancellation of Original WMPA SA No. 5668; Queue No. AE2–079 to be effective 8/6/2022.

Filed Date: 7/5/22.

Accession Number: 20220705–5117.

Comment Date: 5 p.m. ET 7/26/22.

Docket Numbers: ER22–2286–000.

Applicants: PJM Interconnection, L.L.C.

Description: Tariff Amendment: Notice of Cancellation of Original WMPA SA No. 5667; Queue No. AE2–078 to be effective 8/6/2022.

Filed Date: 7/5/22.

Accession Number: 20220705–5132.

Comment Date: 5 p.m. ET 7/26/22.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES22–51–000.

Applicants: Ameren Illinois Company.

Description: Application Under Section 204 of the Federal Power Act for Authorization to Issue Securities of Ameren Services Company.

Filed Date: 6/30/22.

Accession Number: 20220630–5366.

Comment Date: 5 p.m. ET 7/21/22.

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: July 5, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–14690 Filed 7–8–22; 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: PR22–54–000.
Applicants: Duke Energy Ohio, Inc.
Description: § 284.123(g) Rate Filing: DEO-Revised Operating Statement to Reflect Change in State-Approved Rates to be effective 6/1/2022.
Filed Date: 6/30/22.
Accession Number: 20220630–5046.
Comment Date: 5 p.m. ET 7/21/22.
284.123(g) Protests Due: 5 p.m. ET 8/29/22.

Docket Numbers: RP22–1000–000.
Applicants: Transcontinental Gas Pipe Line Company, LLC.
Description: Compliance filing: Rate Schedule S–2 OFO Penalty Flow Through Refund Report to be effective N/A.
Filed Date: 6/30/22.
Accession Number: 20220630–5012.
Comment Date: 5 p.m. ET 7/12/22.

Docket Numbers: RP22–1001–000.
Applicants: Eastern Gas Transmission and Storage, Inc.
Description: Compliance filing: EGTS—Operational Gas Sales Report—2022 to be effective N/A.
Filed Date: 6/30/22.
Accession Number: 20220630–5019.
Comment Date: 5 p.m. ET 7/12/22.

Docket Numbers: RP22–1002–000.
Applicants: El Paso Natural Gas Company, L.L.C.
Description: § 4(d) Rate Filing: Permanent Capacity Release (WTG #617716 and 617729) to be effective 7/1/2022.
Filed Date: 6/30/22.
Accession Number: 20220630–5056.
Comment Date: 5 p.m. ET 7/12/22.

Docket Numbers: RP22–1003–000.
Applicants: Cove Point LNG, LP.
Description: § 4(d) Rate Filing: Cove Point—Modification of GT&C—Fuel Retainage to be effective 8/1/2022.
Filed Date: 6/30/22.
Accession Number: 20220630–5057.
Comment Date: 5 p.m. ET 7/12/22.

Docket Numbers: RP22–1004–000.
Applicants: Florida Gas Transmission Company, LLC.
Description: § 4(d) Rate Filing: FPL Exhibit B Update—New Contracts 128521 & 128522 to be effective 7/1/2022.
Filed Date: 6/30/22.
Accession Number: 20220630–5072.
Comment Date: 5 p.m. ET 7/12/22.

Docket Numbers: RP22–1005–000.
Applicants: Alliance Pipeline L.P.
Description: § 4(d) Rate Filing: Negotiated Rates—Various July 1 2022 Capacity Releases to be effective 7/1/2022.
Filed Date: 6/30/22.
Accession Number: 20220630–5073.
Comment Date: 5 p.m. ET 7/12/22.

Docket Numbers: RP22–1006–000.
Applicants: Florida Gas Transmission Company, LLC.
Description: § 4(d) Rate Filing: New Service Agreement—GRU to be effective 7/1/2022.
Filed Date: 6/30/22.
Accession Number: 20220630–5077.
Comment Date: 5 p.m. ET 7/12/22.

Docket Numbers: RP22–1007–000.
Applicants: El Paso Natural Gas Company, L.L.C.
Description: § 4(d) Rate Filing: Negotiated Rate Agreements (PDC Permian_Targa) to be effective 7/1/2022.
Filed Date: 6/30/22.
Accession Number: 20220630–5079.
Comment Date: 5 p.m. ET 7/12/22.

Docket Numbers: RP22–1008–000.
Applicants: Northern Natural Gas Company.
Description: § 4(d) Rate Filing: 20220630 Negotiated Rate to be effective 7/1/2022.
Filed Date: 6/30/22.
Accession Number: 20220630–5086.
Comment Date: 5 p.m. ET 7/12/22.

Docket Numbers: RP22–1009–000.
Applicants: Maritimes & Northeast Pipeline, L.L.C.
Description: § 4(d) Rate Filing: Negotiated Rates—Northern to Emera eff 7–1–22 to be effective 7/1/2022.
Filed Date: 6/30/22.
Accession Number: 20220630–5089.
Comment Date: 5 p.m. ET 7/12/22.

Docket Numbers: RP22–1010–000.
Applicants: El Paso Natural Gas Company, L.L.C.
Description: § 4(d) Rate Filing: Negotiated Rate Agreement Update (Conoco July 2022) to be effective 7/1/2022.
Filed Date: 6/30/22.
Accession Number: 20220630–5107.
Comment Date: 5 p.m. ET 7/12/22.

Docket Numbers: RP22–1011–000.
Applicants: El Paso Natural Gas Company, L.L.C.
Description: § 4(d) Rate Filing: Negotiated Rate Agreement (Devon) to be effective 8/1/2022.
Filed Date: 6/30/22.
Accession Number: 20220630–5110.
Comment Date: 5 p.m. ET 7/12/22.

Docket Numbers: RP22–1012–000.
Applicants: Rockies Express Pipeline LLC.
Description: § 4(d) Rate Filing: REX 2022–06–30 Negotiated Rate Agreement and Amendments to be effective 7/1/2022.
Filed Date: 6/30/22.
Accession Number: 20220630–5151.
Comment Date: 5 p.m. ET 7/12/22.

Docket Numbers: RP22–1013–000.
Applicants: MIGC LLC.
Description: MIGC LLC submits 2022 Annual Fuel Retention Percentage Tracker Filing.
Filed Date: 6/30/22.
Accession Number: 20220630–5165.
Comment Date: 5 p.m. ET 7/12/22.

Docket Numbers: RP22–1014–000.
Applicants: Algonquin Gas Transmission, LLC.
Description: § 4(d) Rate Filing: Negotiated Rates—Various Releases 7–1–22 to be effective 7/1/2022.
Filed Date: 6/30/22.
Accession Number: 20220630–5175.
Comment Date: 5 p.m. ET 7/12/22.

Docket Numbers: RP22–1015–000.
Applicants: Florida Gas Transmission Company, LLC.
Description: § 4(d) Rate Filing: Update Non-Conforming List and Negotiated Rate Record to be effective 7/1/2022.
Filed Date: 6/30/22.
Accession Number: 20220630–5186.
Comment Date: 5 p.m. ET 7/12/22.

Docket Numbers: RP22–1016–000.
Applicants: Texas Eastern Transmission, LP.
Description: § 4(d) Rate Filing: TETLP EPC AUG 2022 FILING to be effective 8/1/2022.
Filed Date: 6/30/22.
Accession Number: 20220630–5203.
Comment Date: 5 p.m. ET 7/12/22.

Docket Numbers: RP22–1017–000.
Applicants: LA Storage, LLC.
Description: § 4(d) Rate Filing: Filing of Negotiated Rate, Conforming IW Agreements 6.30.22 to be effective 7/1/2022.
Filed Date: 6/30/22.
Accession Number: 20220630–5213.
Comment Date: 5 p.m. ET 7/12/22.

Docket Numbers: RP22–1018–000.
Applicants: Transcontinental Gas Pipe Line Company, LLC.
Description: § 4(d) Rate Filing: Negotiated Rates—Cherokee AGL—Replacement Shippers—Jul 2022 to be effective 7/1/2022.
Filed Date: 6/30/22.
Accession Number: 20220630–5231.
Comment Date: 5 p.m. ET 7/12/22.

Docket Numbers: RP22–1019–000.
Applicants: Gulf Shore Energy Partners, LP.
Description: § 4(d) Rate Filing: Change in Executed Service Agreement to be effective 7/1/2022.

Filed Date: 6/30/22.
Accession Number: 20220630–5236.
Comment Date: 5 p.m. ET 7/12/22.

Docket Numbers: RP22–1020–000.
Applicants: Double E Pipeline, LLC.
Description: § 4(d) Rate Filing: Negotiated Rate & Non-Conforming Agreements—MRC Permian Company to be effective 7/1/2022.
Filed Date: 6/30/22.
Accession Number: 20220630–5249.
Comment Date: 5 p.m. ET 7/12/22.

Docket Numbers: RP22–1021–000.
Applicants: Trailblazer Pipeline Company LLC.
Description: § 4(d) Rate Filing: TPC 2022–06–30 Negotiated Rate Agreement Amendment to be effective 7/1/2022.
Filed Date: 6/30/22.
Accession Number: 20220630–5267.
Comment Date: 5 p.m. ET 7/12/22.

Docket Numbers: RP22–1022–000.
Applicants: Texas Eastern Transmission, LP.
Description: § 4(d) Rate Filing: Negotiated Rates—UGI to DTE eff 7–1–22 to be effective 7/1/2022.
Filed Date: 7/1/22.
Accession Number: 20220701–5001.
Comment Date: 5 p.m. ET 7/13/22.

Docket Numbers: RP22–1023–000.
Applicants: Cheyenne Plains Gas Pipeline Company, L.L.C.
Description: § 4(d) Rate Filing: Firm Variable Quantity Transportation to be effective 8/1/2022.
Filed Date: 7/1/22.
Accession Number: 20220701–5006.
Comment Date: 5 p.m. ET 7/13/22.

Docket Numbers: RP22–1024–000.
Applicants: Alliance Pipeline L.P.
Description: § 4(d) Rate Filing: Conversion to Section-Based Tariff to be effective 8/1/2022.
Filed Date: 7/1/22.
Accession Number: 20220701–5027.
Comment Date: 5 p.m. ET 7/13/22.

Docket Numbers: RP22–1025–000.
Applicants: Alliance Pipeline L.P.
Description: Tariff Amendment: Alliance Cancellation of Sheet-Based Tariff to be effective 8/1/2022.
Filed Date: 7/1/22.
Accession Number: 20220701–5033.
Comment Date: 5 p.m. ET 7/13/22.

Docket Numbers: RP22–1026–000.
Applicants: Eastern Gas Transmission and Storage, Inc.
Description: Compliance filing: EGTS—2022 Overrun and Penalty Revenue Distribution to be effective N/A.
Filed Date: 7/1/22.
Accession Number: 20220701–5038.
Comment Date: 5 p.m. ET 7/13/22.

Docket Numbers: RP22–1027–000.
Applicants: Equitrans, L.P.
Description: § 4(d) Rate Filing: Negotiated Rate Capacity Release Agreements—7/1/2022 to be effective 7/1/2022.
Filed Date: 7/1/22.
Accession Number: 20220701–5063.
Comment Date: 5 p.m. ET 7/13/22.

Docket Numbers: RP22–1028–000.
Applicants: Texas Gas Transmission, LLC.
Description: § 4(d) Rate Filing: Cap Rel Neg Rate Agmt (Jay-Bee 34447 to MacQuarie 53677) to be effective 7/1/2022.
Filed Date: 7/1/22.
Accession Number: 20220701–5088.
Comment Date: 5 p.m. ET 7/13/22.

Docket Numbers: RP22–1029–000.
Applicants: Gulf South Pipeline Company, LLC.
Description: § 4(d) Rate Filing: Amendment to NC Service Agmt (Brewton 45719) to be effective 7/1/2022.
Filed Date: 7/1/22.
Accession Number: 20220701–5089.
Comment Date: 5 p.m. ET 7/13/22.

Docket Numbers: RP22–1030–000.
Applicants: Cove Point LNG, LP.
Description: Compliance filing: Cove Point—2022 Penalty Revenue Distribution to be effective N/A.
Filed Date: 7/1/22.
Accession Number: 20220701–5090.
Comment Date: 5 p.m. ET 7/13/22.

Docket Numbers: RP22–1031–000.
Applicants: Transwestern Pipeline Company, LLC.
Description: § 4(d) Rate Filing: Rate Case Filing to be effective 8/1/2022.
Filed Date: 7/1/22.
Accession Number: 20220701–5099.
Comment Date: 5 p.m. ET 7/13/22.

Docket Numbers: RP22–1032–000.
Applicants: Rover Pipeline LLC.
Description: § 4(d) Rate Filing: Summary of Negotiated Rate Capacity Release Agreements on 7–1–22 to be effective 7/1/2022.
Filed Date: 7/1/22.
Accession Number: 20220701–5120.
Comment Date: 5 p.m. ET 7/13/22.

Docket Numbers: RP22–1033–000.
Applicants: Northern Natural Gas Company.
Description: § 4(d) Rate Filing: 20220701 Section 4 Rate Case Part 1 of 3 to be effective 8/1/2022.
Filed Date: 7/1/22.
Accession Number: 20220701–5131.
Comment Date: 5 p.m. ET 7/13/22.

Docket Numbers: RP22–1034–000.
Applicants: WTG Hugoton, LP.
Description: § 4(d) Rate Filing: Annual Fuel Retention Percentage Filing 2022–2023 to be effective 6/30/2022.
Filed Date: 7/1/22.
Accession Number: 20220701–5135.
Comment Date: 5 p.m. ET 7/13/22.

Docket Numbers: RP22–1035–000.
Applicants: West Texas Gas Utility, LLC.
Description: Annual Purchased Gas Cost Reconciliation Report of West Texas Gas Utility, LLC.
Filed Date: 7/1/22.
Accession Number: 20220701–5139.
Comment Date: 5 p.m. ET 7/13/22.

Docket Numbers: RP22–1036–000.
Applicants: Millennium Pipeline Company, LLC.
Description: § 4(d) Rate Filing: MMGS to Mitsui Name Change—Agmt 142019 to be effective 7/1/2022.
Filed Date: 7/1/22.
Accession Number: 20220701–5157.
Comment Date: 5 p.m. ET 7/13/22.

Docket Numbers: RP22–1037–000.
Applicants: Gulf South Pipeline Company, LLC.
Description: § 4(d) Rate Filing: Cap Rel Neg Rate Agmt (Osaka 46429 to ConocoPhillips 55428) to be effective 7/1/2022.
Filed Date: 7/1/22.
Accession Number: 20220701–5182.
Comment Date: 5 p.m. ET 7/13/22.

Docket Numbers: RP22–1038–000.
Applicants: Gulf South Pipeline Company, LLC.
Description: § 4(d) Rate Filing: Amendment to NC Neg Rate Agmt (Uniper 46406) to be effective 7/1/2022.
Filed Date: 7/1/22.
Accession Number: 20220701–5184.
Comment Date: 5 p.m. ET 7/13/22.

Docket Numbers: RP22–1039–000.
Applicants: Millennium Pipeline Company, LLC.
Description: § 4(d) Rate Filing: Narragansett dba National Grid to dba Rhode Island Name Change—Agmt 210165 to be effective 7/1/2022.
Filed Date: 7/1/22.
Accession Number: 20220701–5197.
Comment Date: 5 p.m. ET 7/13/22.

Docket Numbers: RP22–1040–000.
Applicants: Gulf South Pipeline Company, LLC.
Description: § 4(d) Rate Filing: Superseding Neg Rate Agmt Southern 49811 and Neg Rate Agmt FPL 55411 to be effective 7/1/2022.
Filed Date: 7/1/22.
Accession Number: 20220701–5227.
Comment Date: 5 p.m. ET 7/13/22.

Docket Numbers: RP22–1041–000.
Applicants: Crossroads Pipeline Company.
Description: § 4(d) Rate Filing: Non-Conforming Agreement Housekeeping to be effective 8/1/2022.
Filed Date: 7/1/22.
Accession Number: 20220701–5277.

Comment Date: 5 p.m. ET 7/13/22.

Docket Numbers: RP22–1042–000.

Applicants: Portland Natural Gas Transmission System.

Description: § 4(d) Rate Filing: Narragansett name change to dba Rhode Island Energy—NR/Non-Con Amendment to be effective 7/1/2022.

Filed Date: 7/1/22.

Accession Number: 20220701–5354.

Comment Date: 5 p.m. ET 7/13/22.

Docket Numbers: RP22–1043–000.

Applicants: Equitrans, L.P.

Description: § 4(d) Rate Filing: Remove Terminated Agreement—7/31/2022 to be effective 8/5/2022.

Filed Date: 7/5/22.

Accession Number: 20220705–5045.

Comment Date: 5 p.m. ET 7/18/22.

Docket Numbers: RP22–472–000.

Applicants: Interstate Gas Supply, Inc., Dominion Energy Solutions, Inc.

Description: Interstate Gas Supply, Inc. and Dominion Energy Solutions, Inc. submit Second Status Report.

Filed Date: 6/30/22.

Accession Number: 20220630–5291.

Comment Date: 5 p.m. ET 7/12/22.

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: RP17–346–004.

Applicants: Northwest Pipeline LLC.

Description: Compliance filing: Northwest Pipeline: Unopposed Petition to Amend Settlement Agreement to Extend to be effective N/A.

Filed Date: 6/30/22.

Accession Number: 20220630–5229.

Comment Date: 5 p.m. ET 7/12/22.

Any person desiring to protest in any 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: July 5, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–14689 Filed 7–8–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER22–2246–000]

BCE Los Alamitos, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of BCE Los Alamitos, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is July 25, 2022

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: July 5, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–14688 Filed 7–8–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP22–478–000]

Florida Gas Transmission Company, LLC; Notice of Request Under Blanket Authorization and Establishing Intervention and Protest Deadline

Take notice that on June 24, 2022, Florida Gas Transmission Company, LLC (Florida Gas), 1300 Main Street, Houston, Texas 77002, filed in the above referenced docket a prior notice request pursuant to sections 157.205, 157.208, 157.210, and 157.211 of the Commission's regulations under the Natural Gas Act (NGA), and Florida Gas' blanket certificate issued in Docket No. CP82–533–000, for authorization to increase mainline capacity by approximately 29,850 million British Thermal Units per day, and make auxiliary facility modifications under section 2.55(a) on compressor units at the existing Compressor Station (CS) 15 in Taylor County, CS 16 in Bradford County, CS 17 in Marion County, and CS 18 in Orange County, all in Florida (Orange County Project). The Orange County Project will enable Florida Gas to transport interstate natural gas from three existing receipt points in George County, Mississippi, and Mobile County, Alabama, to two existing delivery points in Orange County, Florida for the Orlando Utilities Commission, an existing customer of Florida Gas. The estimated cost for the project is $1,364,655 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 TYY, (202) 502–8659.

Any questions concerning this prior notice request should be directed to Blair Lichtenwalter, Senior Director of Certificates, Florida Gas Transmission Company, LLC, 1300 Main Street, Houston, Texas 77002, by phone (713) 989–2605, or fax (713) 989–1205, or via email at *Blair.Lichtenwalter@energytransfer.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 September 3, 2022. How to file protests, motions to intervene, and comments is explained below.

Protests

Pursuant to section 157.205 of the Commission's regulations under the NGA,[1] any person [2] 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,[3] and must be submitted by the protest deadline, which is September 3, 2022. 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 Procedure [4] and the regulations under the NGA [5] by the intervention deadline for the project, which is September 3, 2022. 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 September 3, 2022. 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 CP22–478–000 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''; or [6]

(2) You can file a paper copy of your submission by mailing it to the address below.[7] Your submission must reference the Project docket number CP22–478–000.

Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

The Commission encourages electronic filing of submissions (option 1 above) and has eFiling staff available to assist you at (202) 502–8258 or *FercOnlineSupport@ferc.gov.*

Protests and motions to intervene must be served on the applicant either by mail or email (with a link to the document) at: 1300 Main Street, P.O. Box 4967, Houston, Texas 77210, or *Blair.Lichtenwalter@energytransfer.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.

[1] 18 CFR 157.205.

[2] Persons include individuals, organizations, businesses, municipalities, and other entities. 18 CFR 385.102(d).

[3] 18 CFR 157.205(e).

[4] 18 CFR 385.214.

[5] 18 CFR 157.10.

[6] Additionally, you may file your comments electronically by using the eComment feature, which is located on the Commission's website at *www.ferc.gov* under the link to Documents and Filings. Using eComment is an easy method for interested persons to submit brief, text-only comments on a project.

[7] Hand-delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

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: July 5, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–14719 Filed 7–8–22; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OW–2015–0641; FRL–9984–01–OW]

Proposed Information Collection Request; Comment Request; BEACH Act Grant Program (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is planning to submit an information collection request (ICR), ''Beaches Environmental Assessment and Coastal Health (BEACH) Act Grant Program'' (EPA ICR No. 2048.07, OMB Control No. 2040–0244) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (PRA). Before doing so, EPA is soliciting public comments on specific aspects of the proposed information collection as described below. This is a proposed extension of the ICR, which is currently approved through April 30, 2023. 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.

DATES: Comments must be submitted on or before September 9, 2022.

ADDRESSES: Submit your comments, referencing Docket ID No. EPA–HQ–OW–2015–0641 online using *www.regulations.gov* (our preferred method), by email to *OW-Docket@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Lisa Larimer, Office of Water, Office of Science and Technology, Standards and Health Protection Division (4305T), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 566–1017; fax number: (202) 566–0409; email address: *larimer.lisa@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents which explain in detail the information that EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Pursuant to section 3506(c)(2)(A) of the PRA (44 United States Code (U.S.C.) 3501 *et seq*), EPA is soliciting comments and information to enable it to: (i) evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (ii) evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (iii) enhance the quality, utility, and clarity of the information to be collected; and (iv) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval. At that time, EPA will issue another **Federal Register** notice to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB.

Abstract: The Beaches Environmental Assessment and Coastal Health (BEACH) Act amends the Clean Water Act (CWA) in part and authorizes the U.S. Environmental Protection Agency (EPA) to award BEACH Act grants to coastal and Great Lakes states, tribes, and territories (collectively referred to as jurisdictions) to develop and implement beach monitoring and notification programs. The grants assist those jurisdictions to develop and implement a consistent approach to monitor recreational water quality; assess, manage, and communicate health risks from waterborne microbial contamination; notify the public of pollution occurrences; and post beach advisories and closures to prevent public exposure to microbial pathogens.

Per CWA section 406, 33 U.S.C. 1346, to qualify for a BEACH Act grant, a jurisdiction must submit information to EPA documenting that its beach monitoring and notification program is consistent with performance criteria outlined in the *National Beach Guidance and Required Performance Criteria for Grants, 2014 Edition.* In addition, recipients of BEACH Act grants must submit water quality monitoring data and information on public notification actions to EPA. All beach program information will be collected by the EPA's Office of Science and Technology, stored in the Beach Advisory and Closing On-line Notification (BEACON) system, and accessible via EPA's Beaches website for use by the public; state, tribal, territorial, and local environmental and public health agencies; and EPA.

This ICR renews the BEACH Act Grant Program ICR, OMB Control Number 2040–0244, which is approved through April 30, 2023. This ICR renewal describes the estimated burden associated with the information collection of water quality monitoring data and public notification actions from recipients of BEACH Act grants.

Form Numbers: None.

Respondents/affected entities: Potential respondents to this ICR are recipients of BEACH Act grants, including 29 coastal and Great Lakes states, 4 tribes, 5 U.S. territories, and Erie County, Pennsylvania.

Respondent's obligation to respond: Required to obtain or retain a benefit (Section 406 of the Clean Water Act, 33 U.S.C. 1346).

Estimated number of respondents: 40 (total).

Frequency of response: Annual; however, the Agency encourages more frequent reporting to provide more up-to-date information to the public.

Total estimated burden: 254,634 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $17,663,581 (per year), includes $7,222,280 annualized capital or operation & maintenance (O&M) costs.

Changes in Estimates: There is an increase of 162,750 hours in the total estimated respondent burden compared with the ICR currently approved by OMB. This increase is in response to feedback to better account for labor costs and to structure the ICR to better align with the burden associated with the present program. Specifically, the increase is due to three main reasons: (1) the existing ICR did not fully capture the respondent labor associated with collecting water quality samples, (2) the restructuring of actions into developmental and annual grant activities and subsequent recalculation of the associated burden, and (3) the anticipated addition of one tribal respondent. The total respondent cost increased by $2.1M, due to the changes described, an increase in the cost to analyze water samples, and slight increases in the salary rates. However, this increase is offset by a $4.3M decrease in respondent O&M cost resulting from using actual respondent sampling frequency data rather than previous estimates that overcounted sampling. Agency burden and cost increased by 117 hours because the existing ICR did not capture some of the labor associated with the administration of beach grants or the Agency O&M cost for contractor assistance to jurisdictions with data submission and maintaining the statutorily required database.

Deborah Nagle,

Director, Office of Science and Technology, Office of Water.

[FR Doc. 2022–14678 Filed 7–8–22; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL ELECTION COMMISSION

Sunshine Act Meeting

TIME AND DATE: Thursday, July 14, 2022 at 10:00 a.m.

PLACE: Hybrid Meeting: 1050 First Street NE, Washington, DC (12th Floor) and virtual.

Note: For those attending the meeting in person, current COVID–19 safety protocols for visitors, which are based on the CDC COVID–19 community level in Washington, DC, will be updated on the commission's contact page by the Monday before the meeting. See the contact page at *https://www.fec.gov/contact/.* If you would like to virtually access the meeting, see the instructions below.

STATUS: This meeting will be open to the public, subject to the above-referenced guidance regarding the COVID–19 community level and corresponding health and safety procedures. To access the meeting virtually, 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 2022–06: Hispanic Leadership Trust

Draft Advisory Opinion 2022–09: Democratic Party of Wisconsin Federal

Draft Advisory Opinion 2022–07: Congressman Eric Swalwell and Swalwell for Congress

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.

Individuals who plan to attend in person and who require special assistance, such as sign language interpretation or other reasonable accommodations, should contact Laura E. Sinram, Acting Secretary and Clerk, at (202) 694–1040, at least 72 hours prior to the meeting date.

Vicktoria J. Allen,

Acting Deputy Secretary of the Commission.

[FR Doc. 2022–14831 Filed 7–7–22; 4:15 pm]

BILLING CODE 6715–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The 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 the BHC Act (12 U.S.C. 1842(c)).

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 Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than August 10, 2022.

A. Federal Reserve Bank of Atlanta (Erien O. Terry, Assistant Vice President) 1000 Peachtree Street NE, Atlanta, Georgia 30309, or electronically to *Applications.Comments@atl.frb.org:*

1. *CommerceOne Financial Corporation, Birmingham, Alabama;* to become a bank holding company by acquiring CommerceOne Bank, Birmingham, Alabama.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2022–14717 Filed 7–8–22; 8:45 am]

BILLING CODE 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 Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than July 26, 2022.

A. Federal Reserve Bank of Atlanta (Erien O. Terry, Assistant Vice President) 1000 Peachtree Street NE, Atlanta, Georgia 30309, or electronically to *Applications.Comments@atl.frb.org:*

1. *The George J. White Revocable Trust, Robert D. White, as trustee, the Marilyn M. White Revocable Trust, Marilyn M. White, as trustee, Robert D. White, and Amy D. White, all of Mount Dora, Florida; George J. White III, Decatur, Georgia; Anna C. White, Asheville, North Carolina; and Amelia M. White, Athens, Georgia;* a group acting in concert to retain voting shares of FNBMD Bancshares, Inc., and thereby indirectly retain voting shares of The First National Bank of Mount Dora, both of Mount Dora, Florida.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2022–14718 Filed 7–8–22; 8:45 am]

BILLING CODE 6210–01–P

GENERAL SERVICES ADMINISTRATION

[Notice–MA–2022–08; Docket No. 2022–0002; Sequence No.15]

Relocation Allowances—Extended Waiver of Certain Federal Travel Regulation (FTR) Provisions During the COVID–19 Pandemic

AGENCY: Office of Government-wide Policy (OGP), General Services Administration (GSA).

ACTION: Notice of GSA Bulletin FTR 22–07, Extended waiver of certain Federal Travel Regulation (FTR) provisions during the Coronavirus Disease 2019 (COVID–19) pandemic.

SUMMARY: This GSA Bulletin FTR 22–07 informs agencies that certain provisions of the FTR governing official relocation travel and renewal agreement travel (RAT) may continue to be temporarily waived for the period of time stated in the bulletin. This bulletin also rescinds an expiring GSA bulletin pertaining to relocation allowances during the pandemic and re-establishes information therein via this new bulletin.

DATES: *Applicability Date:* This notice is retroactively effective for official relocation travel performed after March 13, 2019, one year prior to the date of the Presidential national emergency proclamation concerning COVID–19.

FOR FURTHER INFORMATION CONTACT: Mr. Rick Miller, Senior Policy Analyst, Office of Government-wide Policy, Office of Asset and Transportation Management, at 202–501–3822, or *travelpolicy@gsa.gov.* Please cite Notice of GSA Bulletin FTR 22–07.

SUPPLEMENTARY INFORMATION:

Background: Federal agencies authorize relocation entitlements to those individuals listed at FTR § 302–1.1 and those assigned under the Government Employees Training Act (GETA) (5 U.S.C. chapter 41). Since the Presidential national emergency proclamation issued March 13, 2020 concerning COVID–19, the pandemic has resulted in various travel-related disruptions to relocating employees. Accordingly, GSA issued Bulletin 22–04 (86 FR 73279 December 27, 2021) to rescind FTR 21–04 (86 FR 14326 March 15, 2021) (which rescinded and replaced related GSA Bulletins FTR 20–06 (85 FR 23029 April 24, 2020) and FTR 21–02 (85 FR 59311 September 21, 2020)), to allow agencies to determine whether to implement waivers of time limits established by the FTR for completion of all aspects of relocation, temporary storage of household goods (HHG) shipments, house hunting trips (HHT), and time remaining in a second tour of duty upon return from renewal agreement travel (RAT). GSA Bulletin FTR 22–04 and the waiver provisions therein, is set to expire on June 30, 2022.

As COVID–19 has continued to produce uncertainty and create difficulties for relocating individuals, GSA is extending certain FTR waivers by rescinding GSA Bulletin FTR 22–04 and re-establishing the information therein by issuance of this new GSA Bulletin FTR 22–07 with a later expiration date. GSA Bulletin FTR 20–06, FTR 21–02 and FTR 21–04 remain rescinded. The new GSA Bulletin FTR 22–07 can be viewed at *https://www.gsa.gov/ftrbulletins.*

Dated: June 30, 2022.

Krystal J. Brumfield,

Associate Administrator, Office of Government-wide Policy.

[FR Doc. 2022–14716 Filed 7–8–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project ''Medical Expenditure Panel Survey (MEPS) COVID–19 Changes.''

DATES: Comments on this notice must be received by September 9, 2022.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by email at *doris.lefkowitz@AHRQ.hhs.gov.*

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by email at *doris.lefkowitz@AHRQ.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Proposed Project

''Medical Expenditure Panel Survey (MEPS) COVID–19 Changes''

The Medical Expenditure Panel Survey (MEPS) consists of the following three components and has been conducted annually since 1996:

- *Household Component (MEPS–HC):* A sample of households participating in the National Health Interview Survey (NHIS) in the prior calendar year are interviewed 5 times over a 2 and one-half (2.5) year period. These 5 interviews yield 2 years of information on use of, and expenditures for, health care, sources of payment for that health care, insurance status, employment, health status and health care quality.
- *Medical Provider Component (MEPS–MPC):* The MEPS–MPC collects information from medical and financial records maintained by hospitals, physicians, pharmacies and home health agencies named as sources of care by household respondents.
- *Insurance Component (MEPS–IC):* The MEPS–IC collects information on establishment characteristics, insurance offerings and premiums from

employers. The MEPS–IC is conducted by the Census Bureau for AHRQ and is cleared separately.

This request is for the MEPS–HC only. The OMB Control Number for the MEPS–HC and MEPS–MPC is 0935–0118, which was last approved by OMB on November 18, 2020, and will expire on November 30, 2023.

The purpose of this request is to update questions related to COVID–19 in MEPS. New round 1 questions on COVID–19 capture information on whether household members have ever had COVID–19 and when they most recently had COVID–19. Follow-up questions in later rounds determine if household members have had COVID–19 in the interview reference period.

This study is being conducted by AHRQ through its contractors, Westat and RTI International, pursuant to AHRQ's statutory authority to conduct and support research on healthcare and on systems for the delivery of such care, including activities with respect to the cost and use of health care services and with respect to health statistics and surveys. 42 U.S.C. 299a(a)(3) and (8); 42 U.S.C. 299b–2.

Method of Collection

The questions will be asked of all MEPS sample members with a single household respondent reporting for the household. The first two questions serve as gate questions and only respondents who report having a COVID–19 diagnosis in the relevant time period will receive follow-up questions about the timing of their most recent infection. These questions will be administered in the existing Priority Conditions Enumeration section of MEPS, which includes a similar series of questions about whether household members have ever been diagnosed with certain medical conditions.

Historically, MEPS has been conducted using Computer Assisted Personal Interviewing (CAPI) where field interviews conduct interviews with household respondents in person. However, MEPS is currently being conducted via multiple modes, including face-to-face, phone, and virtual interviewing, due to the ongoing COVID–19 pandemic.

The information collected on COVID–19 diagnoses will undergo editing and be reviewed for data quality, including consistency with publicly available sources of data on COVID–19 infections. Additionally, the resulting variables will be included on the annual MEPS full-year consolidated public use data files after being assessed for any potential disclosure concerns.

The new CAPI questions collecting information about COVID–19 will be folded into the regular processing stream of MEPS data to produce estimates of health care utilization and expenditures. The information collected on COVID–19 diagnoses will be used to compare healthcare utilization and expenditures between those who have had confirmed COVID–19 and those who have not. Additionally, the information collected on the timing of recent infections can be used to either include or exclude recent infections from calendar year or round-specific estimates of healthcare utilization and expenditures. This allows researchers to examine both shorter-term and longer-term impacts of a COVID–19 diagnosis on healthcare utilization and expenditures.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for respondents' time to participate in this research. The addition of several questions related to COVID–19 adds minimal burden in hours and costs to the core CAPI interview, estimated to add 1 minute per interview and a total of 222 burden hours.

Exhibit 2 shows the estimated annualized cost burden associated with respondents' time to participate in this research. The total cost burden is estimated to be $6,218 annually.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Activity	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
COVID–19 questions included in the MEPS questionnaire	13,338 *	1	1/60	222

* While the expected number of responding units for the annual estimates is 12,804, it is necessary to adjust for survey attrition of initial respondents by a factor of 0.96 (13.338 = 12/804/0.96).

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Activity	Number of respondents	Total burden hours	Average hourly wage rate *	Total cost burden
COVID–19 questions included in the MEPS questionnaire	13,338	222	$28.01	$6,218

* Based upon mean hourly wage, ''May 2021 National Occupational Employment and Wage Estimates United States,'' U.S. Department of Labor, Bureau of Labor Statistics, retrieved at *https://www.bls.gov/oes/current/oes_nat.htm#00-0000.*

Request for Comments

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3520, comments on AHRQ's information collection are requested with regard to any of the following: (a) whether the proposed collection of information is necessary for the proper performance of AHRQ's health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: July 5, 2022.

Mamatha Pancholi,

Acting Chief of Staff, Chief Data Officer.

[FR Doc. 2022–14637 Filed 7–8–22; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee on Breast Cancer in Young Women (ACBCYW)

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, the CDC announces the following meeting for the Advisory Committee on Breast Cancer in Young Women (ACBCYW). This meeting is open to the public, limited only by the number of audio and web conference lines (100 audio and web conference lines are available). Online registration is required.

DATES: The meeting will be held on August 23, 2022, from 11:00 a.m. to 4:00 p.m., EDT.

ADDRESSES: All meeting participants must register online for the meeting at least 2 business days in advance at *https://www.cdc.gov/cancer/breast/what_cdc_is_doing/meetings.htm.* Please complete all the required fields and submit your registration no later than August 19, 2022. Registered participants will receive the audio and web conference access instructions before the meeting.

FOR FURTHER INFORMATION CONTACT: Kimberly E. Smith, MBA, MHA, Designated Federal Officer, National Center for Chronic Disease Prevention and Health Promotion, CDC, 4770 Buford Highway NE, Mailstop S107–4, Atlanta, Georgia 30341; Telephone (404) 498–0073; Fax (770) 488–4760; Email: *acbcyw@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Purpose: The committee provides advice and guidance to the Secretary, HHS; the Assistant Secretary for Health; and the Director, CDC, regarding the formative research, development, implementation, and evaluation of evidence-based activities designed to prevent breast cancer (particularly among those at heightened risk) and promote the early detection and support of young women who develop the disease. The advice provided by the Committee will assist in ensuring scientific quality, timeliness, utility, and dissemination of credible appropriate messages and resource materials.

Matters to be Considered: The agenda will include discussions on current topics related to breast cancer in young women. These will include Mental/Behavioral Health, Sexual Health, Genetics and Genomics, and Provider Engagement. Agenda items are subject to change as priorities dictate.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2022–14712 Filed 7–8–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2022–0062]

Advisory Committee on Immunization Practices (ACIP); Amended Notice of Meeting

AGENCY: Centers for Disease Control and Prevention, Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, the Centers for Disease Control and Prevention (CDC) announces the following meeting of the Advisory Committee on Immunization Practices (ACIP). This meeting is open to the public. Time will be available for public comment.

DATES: The meeting will be held on June 22, 2022, from 10:00 a.m. to 5:10 p.m., EDT, and June 23, 2022, from 10:00 a.m. to 5:00 p.m., EDT (times subject to change). The docket is currently open to receive written comments. Written comments must be received on or before June 23, 2022.

SUPPLEMENTARY INFORMATION: Notice is hereby given of a change in the meeting of the Advisory Committee on Immunization Practices (ACIP); June 22, 2022, from 10:00 a.m. to 5:00 p.m., EDT, and June 23, 2022, from 10:00 a.m. to 2:00 p.m., EDT (times subject to change), in the original **Federal Register** notice.

The virtual meeting was published in the **Federal Register** on Tuesday, May 10, 2022, Volume 87, Number 90, pages 28013–28014.

The virtual meeting is being amended to change the times to June 22, 2022, from 10:00 a.m. to 5:10 p.m., EDT, and June 23, 2022, from 10:00 a.m. to 5:00 p.m., EDT (times subject to change), and to update the matters to be considered, which should read as follows:

Matters To Be Considered: The agenda will include discussions on influenza vaccine; pneumococcal vaccines; measles, mumps, rubella (MMR) vaccine; COVID–19 vaccines; meningococcal vaccines; respiratory syncytial virus vaccine; Chikungunya vaccines; and human papillomavirus vaccine. Recommendation votes on influenza vaccine, pneumococcal vaccine, MMR vaccine, and the use of Moderna COVID–19 vaccine in children ages 6 through 17 years are scheduled. A Vaccines for Children vote(s) is scheduled on pneumococcal vaccine and is possible on MMR vaccine. Agenda items are subject to change as priorities dictate. For more information on the meeting agenda, visit *https://www.cdc.gov/vaccines/acip/meetings/index.html.* The meeting will be webcast live via the World Wide Web; for more information on ACIP, visit the ACIP website: *https://www.cdc.gov/vaccines/acip/index.html.*

FOR FURTHER INFORMATION CONTACT: Stephanie Thomas, ACIP Committee Management Specialist, Centers for Disease Control and Prevention, National Center for Immunization and Respiratory Diseases, 1600 Clifton Road NE, Mailstop H24–8, Atlanta, Georgia 30329–4027; Telephone: 404–639–8367; Email: *ACIP@cdc.gov.*

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2022–14713 Filed 7–8–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Health and Nutrition Examination Survey (NHANES) Stored DNA Specimens; Proposed Cost Schedule and Guidelines for Proposal To Use DNA Specimens

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS), announces the availability of stored DNA specimens obtained from participants in the National Health and Nutrition Examination Survey (NHANES) and the proposal parameters and fee schedule for use. NHANES is one of a series of health-related surveys conducted by CDC's National Center for Health Statistics (NCHS).

DATES: The stored NHANES DNA specimens are available July 11, 2022. The fee structure for these specimens is effective July 11, 2022.

FOR FURTHER INFORMATION CONTACT: Jody McLean, Division of Health and Nutrition Examination Surveys, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Hyattsville, MD 20782, Telephone: (301) 458–4683; Email: *NHANESgenetics@cdc.gov.*

Authority: Sections 301,306 and 308 of the Public Health Service Act (42 U.S.C. 241, 242k, and 242m).

SUPPLEMENTARY INFORMATION:

Background: NHANES is a program of periodic surveys conducted by NCHS. NHANES has provided national estimates of the health and nutritional status of the U.S. civilian non-institutionalized population since the 1960s. The goals of NHANES are: (1) to estimate the number and percentage of people in the U.S. population and designated subgroups with selected diseases and risk factors for those diseases; (2) to monitor trends in the prevalence, awareness, treatment, and control of selected diseases; (3) to monitor trends in risk behaviors and environmental exposures; (4) to analyze risk factors for selected diseases; (5) to study the relation among diet, nutrition and health; (6) to explore emerging public health issues and new technologies; and (7) to establish and maintain a national probability sample of baseline information on health and nutritional status.

DNA Specimens, Availability, and Resulting Data

The availability of the NHANES III Phase 2 DNA specimens was first announced in 2002. NHANES III Phase 2 DNA specimens (1991–1994) are from participants ages 12 or older (see: *https://wwwn.cdc.gov/nchs/nhanes/nhanes3/default.aspx* for more information on NHANES III).

NHANES III Phase 2 DNA specimens are crude DNA lysates extracted from cell lines; therefore, DNA concentrations vary and are estimated to range from 7.5–65.0 ng/μL with an average of approximately four micrograms in 100 μL. DNA specimens are available from 7,159 NHANES III Phase 2 participants. Forty microliters of each DNA specimen will be distributed in 82 plates, including four plates of quality control specimens. NHANES III DNA specimens are in limited supply and thus are not available as a partial set (which is a request for less than the total number of participants available). Due to the extraction method, NHANES III DNA specimens are not appropriate for all projects and assays. For background information on all DNA specimens, see the NHANES Biospecimen Program report at *https://www.cdc.gov/nchs/data/series/sr_02/sr02_170.pdf.*

In 1999, NHANES became a continuous survey, with data released every two years (see *https://wwwn.cdc.gov/nchs/nhanes/continuousnhanes/default.aspx* for more information on continuous NHANES). The availability of DNA specimens from the continuous NHANES was first announced in 2007.

Continuous NHANES DNA specimens are available as collections from NHANES 1999–2002 (NHANES 1999–2000 and 2001–2002 specimens are available as one collection) and NHANES two-year cycles 2007–08, 2009–10, and 2011–12. In continuous NHANES, DNA was purified from whole blood; aliquots of DNA were normalized to concentrations of approximately 50 ng/μl, and 40 μl of each DNA specimen will be distributed. There are purified DNA specimens from 7,830 NHANES 1999–2002 participants. These specimens will be distributed into 90 plates, including four plates of quality control specimens. There are purified DNA specimens available from 4,612 NHANES 2007–2008 participants. These will be distributed into approximately 54 plates, including three plates of quality control specimens. There are purified DNA specimens available from 4,893 NHANES 2009–2010 participants. These will be distributed into 58 plates, including three additional plates of quality control specimens. There are purified DNA specimens available from 4,147 NHANES 2011–12 participants. These will be distributed into 49 plates, including three additional plates of quality control specimens.

DNA specimens will be available for testing only from participants who consented to future research.

The resulting data from DNA specimen testing will be linkable to variables (public use and restricted) and available for analyses through the NCHS Research Data Center (RDC; *https://www.cdc.gov/rdc/index.htm*) for approved proposals unless otherwise determined by the NHANES Project Officer. Access to these data at the NCHS RDC is only through an approved proposal process mechanism to assure confidentiality (see ''APPROVED PROPOSALS: Post-Testing Procedures'' section).

Parameters for DNA Specimen Use and Resulting Data

1. Investigators must justify why they need a specimen from a national probability sample of the U.S. population for their study.

2. Investigators must specify which NHANES cycles they are requesting DNA specimens from and the specific laboratory tests to be conducted on those specified DNA specimens.

3. Only those proposals for which the laboratory testing will result in findings determined not to have clinical significance for participants will be approved. The consent document for DNA storage and future research use of DNA specimens states that individual results will not be provided to participants. Therefore, no proposals involving tests with clinical significance will be approved. DHANES/NCHS will use the most recent American College of Medical Genetics and Genomics (ACMG) recommendations for reporting secondary findings [1] to assess the proposed tests and their potential for yielding clinically significant findings. Investigators must verify that the proposed tests do not produce variants (*e.g.,* single-nucleotide polymorphisms,

[1] See ''*Guidelines for Returning Individual Results from Genome Research Using Population-Based Banked Specimens*'' (*https://nap.nationalacademies.org/catalog/18829/issues-in-returning-individual-results-from-genome-research-using-population-based-banked-specimens-with-a-focus-on-the-national-health-and-nutrition-examination-survey),* convened by the National Academies of Science Committee on National Statistics in 2014 at the request of NCHS's Board of Scientific Counselors.

translocation and inversions, copy number variations) on specific genes listed by the most recent ACMG recommendations as reportable secondary findings and describe how potential secondary findings results will be handled.

4. Upon receipt of the specimen and after conducting the approved testing, investigators must provide a copy of the resulting data obtained from DNA testing to the Division of Health and Nutrition Examination Survey (DHANES)/NCHS for quality control assessment.

5. After DHANES/NCHS has completed the initial quality control assessment of submitted data, investigators will be given up to six months to conduct a comprehensive quality assurance review. At this review's completion, the resulting data's availability will be publicly announced on the NHANES website Genetic Variant Search: *http://www.nhgeneticvariant.com/*. The resulting data can be linked to other NCHS variables (public use and restricted) for secondary data analysis. Analysis and linkage of the resulting data are conducted in the NCHS RDC via a separate proposal unless otherwise determined by the NHANES Project Officer (see ''APPROVED PROPOSALS: Post-Testing Procedures'' section).

Proposals Testing DNA Specimens Already Obtained From Previous Solicitations

Investigators who have obtained NHANES DNA specimens from previous solicitations and have sufficient DNA left may request to do additional tests on the remaining DNA. These proposals must be submitted and approved as further provided herein. The investigator must pay an additional cost (see ''COST SCHEDULE'' section) per each additional proposal).

Proposal Evaluation

All proposals for the use of NHANES DNA specimens will be evaluated by the NHANES Project Officer, a Technical Panel, the NCHS Confidentiality Officer, the NCHS Human Subjects Contact, and the NCHS Ethics Review Board (ERB). Applications will have a Scientific Review by the NHANES Project Officer and the Technical Panel. The Technical Panel comprises two members with subject matter expertise: one from CDC staff and one external to CDC, *i.e.,* from other federal agencies, academia, or industry. Only technical panel members with no conflict of interest and no previous knowledge of the research project will be asked to review the proposal. The members review each proposal for scientific and technical merit and ensure that the proposed project does not go beyond the general purpose of collecting the blood specimens for DNA in NHANES (see ''PROCEDURES FOR PROPOSALS'' section).

After the proposal is approved by the NHANES Project Officer and the Technical Panel, it will be submitted for Institutional Review. All proposals will undergo Institutional Review by the NCHS Human Subjects Contact and the NCHS ERB for any potential human subjects concerns to ensure appropriate human subjects protections are provided in compliance with 45 CFR 46 and by the NCHS Confidentiality Officer for disclosure risk. The NCHS ERB will review the proposal even if the investigators have received approval from their institutional review panel. The proposal, if approved, will become an amendment to the current NHANES ERB Protocol (*i.e.,* the NHANES ERB Protocol that is in effect at the time of the investigator's proposal approval).

If a proposal is approved, the author's title, specific aims, name, and phone number will be maintained by NCHS and released if requested by the public. NCHS will not maintain unapproved proposals.

Procedures for Proposals

All investigators (including CDC investigators) must submit a proposal for the use of NHANES DNA specimens and follow the instructions as set forth herein, including following the outline set out below. Proposals should be a maximum of 20 1.5-spaced typed pages, excluding figures and tables, using at least size 10 font. The cover of the proposal (which is not included in the 20-page limit) should include the title of the proposal, the name, address, phone number, and email address of the principal investigator (PI), and the name of the institution where the laboratory analysis will be done. The name, address, phone number, and email address of all additional investigators should also be included on the cover. Office of Human Research Protections assurance numbers for the institutions in the proposed project should be included. CDC investigators must include the expiration date of their Collaborative Institutional Training Initiative (CITI) training. All proposals should be submitted via email to *NHANESgenetics@cdc.gov*. Note: If the investigator would like to propose a subsample of the complete set, please contact the NHANES Project Officer to discuss feasibility.

The following criteria will be used for technical evaluation of proposals:

(1) *Abstract:* Please limit the abstract to 300 words.

(2) *Specific Aims:* List the broad objectives; describe concisely and realistically what the proposed project is intended to accomplish and state the specific hypotheses to be tested.

(3) *Background and Public Health Significance:*

(A) Describe the public health significance of the proposed study.

(B) Discuss how the results will be used. Analyses should be consistent with the NHANES mission to assess the health of the nation. The Scientific Review will ensure that the proposed project does not go beyond the general purpose of collecting the blood specimens for DNA in the survey or the specific stated goals of the proposal.

(4) *Design, Method, and Analytic Plan:* The appropriateness and adequacy of the methodology proposed to reach the specific aims and the appropriateness of using the NHANES (a complex, multistage probability sample of the national population) to address the goals of the proposal will be assessed.

(A) *Study Design and Methods:* Include a detailed description of the laboratory methods. The characteristics of the laboratory assay, such as reliability, and validity, should be included with appropriate references. The laboratory must demonstrate expertise in the proposed test, including the capability to handle the workload requested in the proposal. The potential difficulties and limitations of the proposed procedures should also be discussed. Address methods to ensure adequate handling and storage of DNA specimens. Proposals *must* specify variants or the commercial assay(s) used to test the proposed research hypotheses and include a statement of why the specific standard assay(s) is/are necessary to test the proposed hypotheses. Note: A standard assay is a commercially available assay for a curated set of variants or biological markers. Investigators who submit successful proposals will be provided with quality control specimens at no additional cost. Approved projects must run these quality control specimens and submit these results along with the results from the NHANES DNA specimens unless the NHANES Project Officer has approved an alternative quality control review plan. The proposal should address any additional quality control procedures the laboratory will use to assure the validity of the test results and address methods to ensure adequate handling and storage of specimens.

(B) *Analytic Plan:* Describe the data analysis and statistical methods to be employed. Include power calculations. Resulting data from DNA specimens are restricted access data and must be analyzed in the NCHS RDC. The proposal should state that the data analysis will be conducted in the RDC unless DHANES/NCHS determines otherwise.

(5) *Additional information for NHANES:*

(A) *Clinical Significance of Results:* The consent document for DNA specimen storage and future studies states that individual results will not be provided to participants; therefore, no tests that need to be reported back to the participant can be proposed. DHANES/NCHS will use the most recent American College of Medical Genetics and Genomics (ACMG) recommendations for reporting secondary findings to review the proposed tests and the potential secondary findings. Investigators must verify that the proposed tests do not produce variants on specific genes listed by the most recent ACMG recommendations as reportable secondary findings and describe how potential secondary test results will be handled. The 2021 statement, ''ACMG SF v3.0 list for reporting of secondary findings in clinical exome and genome sequencing: a policy statement of the American College of Medical Genetics and Genomics (ACMG),'' lists 73 genes where specific variants on these genes are pathogenic for 34 conditions.

(B) *Data Transfer:* Specify the secure method to transfer the resulting data to NCHS. Investigators must use a device that meets federal information processing standards (FIPS 140–2 and FIPS 197).

(C) *Period of Performance:* Specify the proposed project period. Substantial progress must be made in the first year that specimens have been obtained, and the project should be completed within a reasonable period of time. Please discuss the approximate time the investigator expects this project will take to complete. The NHANES Project Officer must be consulted about the disposition of the specimens. At the end of the project period, any unused specimens must be returned to the NHANES DNA Specimen Repository or destroyed by the investigator.

(D) *Funding:* Include the source and status of the funding to perform the requested laboratory analysis. Investigators will be responsible for the cost of processing and shipping the specimens (see COST SCHEDULE FOR PROVIDING NHANES DNA SPECIMENS and *Cost Schedule for NHANES DNA Specimens* for details).

(6) *Resumes/CV:* Please include a two-page CV for each member of the study team in the proposal (not as attachments; CVs do not count towards page maximum).

Submission of Proposals

Proposals must be submitted in MS Word format by email to *NHANESgenetics@cdc.gov.*

Proposal Timeframes

- Submission of Proposals: Can be submitted on an ongoing basis
- Scientific Review: Completed approximately two months after proposal submission
- Institutional Review: Completed approximately six weeks after completion of scientific review
- Notification of Approval: Approximately 30 days after completion of Institutional Review
- Anticipated Distribution of Specimens: Approximately 60 days after the following is completed: notification of proposal approval, agreements signed (as described below), and payments received (as described below)

Note: Timeframes may vary depending on the nature of the proposal and the results of each level of review. Unforeseen circumstances could result in a change to this schedule.

Approved Proposals

Investigators must transfer payment to DHANES/NCHS and sign terms and conditions agreements for the use of the DNA specimens with CDC/NCHS before releasing the NHANES DNA specimens. Investigator(s) must agree to: (a) use the specimens only for the approved tests; (b) use the test results only for purposes as stated in the approved proposal; (c) not link the results of the proposed project to any other data; (d) not use the DNA specimens for commercial purposes, as set forth in a legally binding Materials Transfer Agreement (MTA; if non-government investigators) or Interagency Agreement (IAA; if government investigators); and (e) sign and abide by a Designated Agent Agreement (DAA) with CDC/NCHS in accordance with NCHS' confidentiality legislation.

Agency Agreements

A formal signed agreement, embodied in the form of an MTA or an IAA, and a DAA with investigators who have projects approved, must be completed before the release of the specimens to the investigator. For the MTA or IAA, this agreement will contain the conditions for use of the specimens as stated in this **Federal Register** notice and as agreed upon by the investigators and CDC. The DAA is the mechanism by which CDC/NCHS may authorize the designation of agents to exclusively perform activities needed to produce approved data using the Confidential Information Protection and Statistical Efficiency Act (CIPSEA; Title V of the E-Government Act of 2002 [Pub. L. 107–347])-protected NHANES DNA specimens. The DAA must be signed by the investigator taking custody of DNA specimens and producing resulting data.

Continuations

A brief progress report must be submitted annually to NHANES. This report should describe the work completed and the timeline to project completion. When five years have elapsed since the initial approval of the proposal by the NCHS ERB, the investigator must provide an updated project timeline to complete the study for approval by NHANES. If a new investigator(s) is added at any time during the project, or the Principal Investigator has changed, the NHANES Project Officer must be notified.

Approved Proposals: Post-Testing Procedures

After DNA specimens are received and testing is complete, the investigators must send the resulting data back for DHANES/NCHS quality control assessment. While DHANES/NCHS quality control assessment is underway, the investigator can submit an NCHS RDC proposal (*http://www.cdc.gov/rdc*) to conduct an additional quality assurance review. The vast majority of resulting data from DNA specimens is restricted; therefore, the data are available only in the NCHS RDC. Once the investigators' quality assurance review is complete and the results are returned to DHANES/NCHS, investigators will be given up to six months to conduct a comprehensive quality assurance review in the NCHS RDC. The quality assurance review timeframe will be negotiated between the investigators and the NHANES Project Officer and will depend on the type, number, and characteristics of the tests submitted. The results of the quality assurance review will be provided to DHANES/NCHS, and appropriate aspects will become part of the data set documentation. The public announcement, informing that test results are available for secondary data analyses after submission and acceptance of proposals, will occur once the quality assurance review timeframe has ended. For a list of currently

available variant data, see: *http://www.nhgeneticvariant.com/.*

A minority of resulting data from DNA specimens are not restricted. In these cases, the resulting data will undergo disclosure review by the NCHS Confidentiality Officer and NCHS Disclosure Review Board or designee before the linked data are sent to the investigators for quality control review. Once approved by disclosure review and after the investigators have signed the Data Sharing Agreement, the linked data file will be sent to the investigators for use pursuant to the terms of the relevant agreement. The quality control review must take place within 60 days or a negotiated length of time, and the return of the data to NCHS within the next 30 days so these data may be released to the public.

Disposition of Specimens

The provided DNA specimens cannot be used for any purpose other than the specifically requested purpose outlined in the proposal and approved through the Scientific and Institutional Review. No DNA specimens can be shared with others, including other investigators, unless specified in the proposal and so approved. Specimens must be returned upon completion of the approved project or destroyed. Both options require written approval from the NHANES Project Officer.

Cost Schedule for Providing NHANES DNA Specimens

There is a nominal processing fee of $17.17 for each DNA specimen received from an NHANES DNA Repository. The costs include collecting, processing, storing, and retrieving the DNA specimens, reviewing proposals, and preparing the data files. The costs listed are for the recurring laboratory materials to dispense and prepare the DNA specimens during collection and shipping. The NHANES DNA Specimen repository costs include long-term storage (including inventory management and materials and equipment) and accessioning of specimens and specimen retrieval for shipment to the investigator. Labor costs are based on a proposal administrator to manage the proposal process and computer programmers at NCHS who prepare the data files for the release of the data along with documentation on the NHANES web page. If the investigators request to use the DNA specimens for another proposed project after the completion of the initial project, the additional cost will be 5 percent of the specimen set cost to handle the processing of the data and management of the subsequent proposal process. A new proposal must be submitted and go through the approval process before any additional use of the DNA specimens.

COST SCHEDULE FOR NHANES DNA SPECIMENS

Total costs	1999–2002, 2007–2008, 2009–2010, 2011–2012 complete sets	1999–2002, 2007–2008, 2009–2010, 2011–2012 partial set	NHANES III complete set
Materials and equipment—contractor: plates, reagents, assays, aliquoting and packaging specimens; use of equipment	$1.72	$5.15	$0.85
Labor—contractor: processing, handling, and shipping; NCHS: data quality control	5.66	28.31	2.83
Proposal review and administrative expenses—contractor: inventory management and reporting; NCHS: management of proposal process non-NCHS: technical panel fees	3.43	6.87	1.72
Space—contractor: freezer use and maintenance	6.36	6.36	3.17
Cost per specimen	17.17	46.69	8.58
Cost per new proposal:			
1999–2002	134,430.92	*	
2007–2008	79,181.82	*	
2009–2010	84,006.11	*	
2011–2012	71,181.89	*	
III			61,454.85
Cost per additional proposal: **			
1999–2002	6,721.94	***	
2007–2008	4,130.72	***	
2009–2010	4,200.08	***	
2011–2012	3,559.95	***	
III			3,072.17

* Cost calculated upon request.
** Additional research using DNA specimens already obtained from previous solicitations.
*** This charge will be 5 percent of the original cost.
Note: Applicable CDC overhead and NCHS management and oversight charges will be added to these rates for proposals coming from federal agencies.

Angela K. Oliver,

Executive Secretary, Centers for Disease Control and Prevention.

[FR Doc. 2022–14702 Filed 7–8–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Solicitation of Nominations for Appointment to the Board of Scientific Counselors, National Center for Injury Prevention and Control (BSC, NCIPC)

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC) is seeking nominations for membership on the BSC, NCIPC. The BSC, NCIPC consists of 18 experts in fields associated with surveillance; basic epidemiologic research; intervention research; and implementation, dissemination, and evaluation of promising and evidence-based strategies for the prevention of injury, violence, and drug abuse. Nominations are being sought for

individuals who have expertise and qualifications necessary to contribute to the accomplishments of the Committee's objectives. Nominees will be selected based on expertise in the fields of pertinent disciplines involved in injury, violence, and drug overdose prevention, including, but not limited to, epidemiology, statistics, trauma surgery, rehabilitation medicine, behavioral science/psychology, health economics, program evaluation, political science, law, criminology, informatics, and other aspects of injury management. Federal employees will not be considered for membership. Members may be invited to serve for up to four-year terms. Selection of members is based on candidates' qualifications to contribute to the accomplishment of BSC, NCIPC objectives (*https://www.cdc.gov/injury/bsc/*).

DATES: Nominations for membership on the BSC, NCIPC must be received no later than September 1, 2022. Packages received after this time will not be considered for the current membership cycle.

ADDRESSES: All nominations should be emailed to *ncipcbsc@cdc.gov*.

FOR FURTHER INFORMATION CONTACT: Arlene Greenspan, DrPH, MPH, PT, Associate Director for Science, NCIPC, CDC, 4770 Buford Highway NE, Mailstop S–1069, Atlanta, Georgia 30341; Telephone: (770) 488–1279; Email: *ncipcbsc@cdc.gov*.

SUPPLEMENTARY INFORMATION: The U.S. Department of Health and Human Services policy stipulates that committee membership be balanced in terms of points of view represented and the Committee's function. Appointments shall be made without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, gender identity, HIV status, disability, and cultural, religious, or socioeconomic status. Nominees must be U.S. citizens and cannot be full-time employees of the U.S. Government. Current participation on federal workgroups or prior experience serving on a federal advisory committee does not disqualify a candidate; however, HHS policy is to avoid excessive individual service on advisory committees and multiple committee memberships. Committee members are Special Government Employees, requiring the filing of financial disclosure reports at the beginning and annually during their terms. CDC reviews potential candidates for BSC, NCIPC membership each year and provides a slate of nominees for consideration to the Secretary of HHS for final selection. HHS notifies selected candidates of their appointment near the start of the term in September, or as soon as the HHS selection process is completed. Note that the need for different expertise varies from year to year and a candidate who is not selected in one year may be reconsidered in a subsequent year. Candidates should submit the following items:

- Cover letter stating area of expertise.
- Current curriculum vitae, including complete contact information (telephone numbers, mailing address, email address).
- At least one letter of recommendation from person(s) not employed by the U.S. Department of Health and Human Services. Candidates may submit letter(s) from current HHS employees if they wish, but at least one letter must be submitted by a person not employed by an HHS agency (*i.e.,* CDC, NIH, FDA, SAMHSA, etc.).

Nominations may be submitted by the candidate himself or herself or by the person/organization recommending the candidate.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2022–14714 Filed 7–8–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2020–E–2120 and FDA–2020–E–2121]

Determination of Regulatory Review Period for Purposes of Patent Extension; TABRECTA

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 TABRECTA 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 September 9, 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 January 9, 2023. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before September 9, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 9, 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–2120 and FDA–2020–E–2121 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; TABRECTA.'' 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, TABRECTA (capmatinib). TABRECTA is indicated for the treatment of adult patients with metastatic non-small cell lung cancer whose tumors have a mutation that leads to mesenchymal-epithelial transition exon 14 skipping as detected by an FDA approved test. This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s). Subsequent to this approval, the USPTO received patent term restoration applications for TABRECTA (U.S. Patent Nos. 7,767,675; 8,420,645) from Incyte Corp. and Incyte Holdings Corp., and the USPTO requested FDA's assistance in determining the patents' 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 TABRECTA 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 TABRECTA is 4,164 days. Of this time, 4,015 days occurred during the testing phase of the regulatory review period, while 149 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:* December 13, 2008. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on December 13, 2008.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* December 10, 2019. FDA has verified the applicant's claim that the new drug application (NDA) for TABRECTA (NDA 213591) was initially submitted on December 10, 2019.

3. *The date the application was approved:* May 6, 2020. FDA has verified the applicant's claim that NDA 213591 was approved on May 6, 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 applications for patent extension, this applicant seeks 5 years of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: July 1, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–14674 Filed 7–8–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–1385]

Patient-Focused Drug Development: Selecting, Developing, or Modifying Fit-for-Purpose Clinical Outcome Assessments; Draft Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders; Availability; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice entitled ''Patient-Focused Drug Development: Selecting, Developing, or Modifying Fit-for-Purpose Clinical Outcome Assessments; Draft Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders; Availability'' that appeared in the **Federal Register** of June 30, 2022. The document announced the publication of a draft guidance, the third in a series of four methodological patient-focused drug development guidance documents that describe how stakeholders (patients, researchers, medical product developers, and others) can collect and submit patient experience data and other relevant information from patients and caregivers to be used for medical product development and regulatory decision-making. The document was published with the incorrect docket number. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Lisa Granger, Office of Policy, Planning, Legislation and International Affairs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3330, Silver Spring, MD 20993–0002, 301–796–9115, email: *Lisa.Granger@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Friday, June 30, 2022 (87 FR 39101), in FR Doc. 2022–13952, the following corrections are made:

1. On page 39101, in the third column in the header of the document, ''Docket No. FDA–2018–N–2455'' is corrected to read ''Docket No. FDA–2022–D–1385.''
2. On page 39102, in first column in ''Instructions,'' ''Docket No. FDA–2018–N–2455'' is corrected to read ''Docket No. FDA–2022–D–1385.''

Dated: July 5, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–14677 Filed 7–8–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–2143]

Xellia Pharmaceuticals USA, LLC; Withdrawal of Approval of an Abbreviated New Drug Application for Bacitracin for Injection

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA or Agency) Center for Drug Evaluation and Research (CDER) is withdrawing the approval of an abbreviated new drug application (ANDA) for bacitracin for injection, 50,000 units/vial (ANDA 203177), held by Xellia Pharmaceuticals USA, LLC (Xellia). Xellia has requested withdrawal of approval of this application and has waived its opportunity for a hearing.

DATES: Approval is withdrawn as of July 11, 2022.

FOR FURTHER INFORMATION CONTACT: Sungjoon Chi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6216, Silver Spring, MD 20993–0002, 301–402–9674, *Sungjoon.Chi@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On January 31, 2020, FDA requested that all application holders of bacitracin for injection voluntarily request withdrawal of approval of their applications under § 314.150(d) (21 CFR 314.150(d)). Bacitracin for injection is an antibiotic for intramuscular administration, the use of which is limited to the treatment of infants with pneumonia and empyema caused by staphylococci shown to be susceptible to the drug. Bacitracin for injection poses serious risks, including nephrotoxicity and anaphylactic reactions. Health care professionals generally no longer use bacitracin for injection to treat infants with pneumonia and empyema because other effective FDA-approved treatments are available that do not have these risks.

In April 2019, FDA's Antimicrobial Drugs Advisory Committee met and discussed the safety and effectiveness of bacitracin for injection. The advisory committee voted almost unanimously, with one abstention, that the benefits of bacitracin for intramuscular injection do not outweigh its risks, including nephrotoxicity and anaphylactic reactions, for the drug's only approved indication. Based on FDA's review of currently available data and information, the Agency believes that the potential problems associated with bacitracin for injection are sufficiently serious that the drug should be removed from the market.

In a letter dated June 14, 2021, Xellia requested that FDA withdraw approval of ANDA 203177 under § 314.150(d) and waived its opportunity for a hearing. Therefore, for the reasons discussed above, which the applicant does not dispute in its letter requesting withdrawal of approval under § 314.150(d), FDA's approval of ANDA 203177 and all amendments and supplements thereto, is withdrawn (see **DATES**). Distribution of Xellia's bacitracin for injection (50,000 units/vial) into interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the Federal Food,

Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d))).

Dated: July 5, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–14680 Filed 7–8–22; 8:45 am]

BILLING CODE 4164–01–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: November 3, 2022.

Time: 11:00 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Video Assisted Meeting.

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: July 6, 2022.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–14686 Filed 7–8–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Infectious Diseases Research.

Date: August 3, 2022.

Time: 2:00 p.m. to 7:00 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: Shiv A Prasad, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5220, MSC 7852, Bethesda, MD 20892, 301–443–5779, *prasads@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: July 6, 2022.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–14685 Filed 7–8–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Investigator Initiated Program Project Applications (P01 Clinical Trial Not Allowed).

Date: August 4, 2022.

Time: 11:00 a.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G31, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Cynthia L. De La Fuente, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G31, Rockville, MD 20852, 240–669–2740, *delafuentecl@niaid.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: July 5, 2022.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–14651 Filed 7–8–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; New Technologies for the In Vivo Delivery of Gene Therapeutics for an HIV Cure (R01 Clinical Trial Not Allowed).

Date: August 4–5, 2022.

Time: 11:00 a.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3E71, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Lee G. Klinkenberg, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3E71, Rockville, MD 20852, 301–761–7749, *lee.klinkenberg@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: July 5, 2022.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–14650 Filed 7–8–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2022–0397]

Information Collection Request to Office of Management and Budget; OMB Control Number: 1625–0077

AGENCY: Coast Guard, DHS.

ACTION: Sixty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the following collection of information: 1625–0077, Security Plans for Ports, Vessels, Facilities, and Outer Continental Shelf Facilities and Other Security-Related Requirements; without change. Our ICR describes the information we seek to collect from the public. Before submitting this ICR to OIRA, the Coast Guard is inviting comments as described below.

DATES: Comments must reach the Coast Guard on or before September 9, 2022.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG–2022–0397] to the Coast Guard using the Federal eRulemaking Portal at *https://www.regulations.gov.* See the ''Public participation and request for comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

A copy of the ICR is available through the docket on the internet at *https://www.regulations.gov.* Additionally, copies are available from: COMMANDANT (CG–6P), ATTN: PAPERWORK REDUCTION ACT MANAGER, U.S. COAST GUARD, 2703 MARTIN LUTHER KING JR. AVE. SE, STOP 7710, WASHINGTON, DC 20593–7710.

FOR FURTHER INFORMATION CONTACT: A.L. Craig, Office of Privacy Management, telephone 202–475–3528, or fax 202–372–8405, for questions on these documents.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. 3501 *et seq.,* chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) the practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology.

In response to your comments, we may revise this ICR or decide not to seek an extension of approval for the Collection. We will consider all comments and material received during the comment period.

We encourage you to respond to this request by submitting comments and related materials. Comments must contain the OMB Control Number of the ICR and the docket number of this request, [USCG–2022–0397], and must be received by September 9, 2022.

Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at *https://www.regulations.gov* and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

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

Information Collection Request

Title: Security Plans for Ports, Vessels, Facilities, and Outer Continental Shelf Facilities and Other Security-Related Requirements.

OMB Control Number: 1625–0077.

Summary: This information collection is associated with the maritime security requirements mandated by the Maritime Transportation Security Act (MTSA) of 2002, 46 U.S.C. 70103 (formerly 33 U.S.C. 1226(c)), 46 U.S.C. 70034 (formerly 33 U.S.C. 1231), 46 U.S.C. chapter 701, 46 U.S.C. 70051 and 70052 (formerly 50 U.S.C. 191 & 192). Security assessments, security plans and other security-related requirements are in Title 33 CFR parts 101 through 106.

Need: This information is needed to determine if vessels and facilities are in compliance with certain security standards.

Forms:

- CG–6025, Facility Vulnerability and Security Measures Summary
- CG–6025A, Vulnerability and Security Measures Addendum

Respondents: Vessel and facility owners and operators.

Frequency: On occasion.

Hour Burden Estimate: The estimated burden has decreased from 1,198,530 hours to 1,070,430 hours a year, due to a decrease in the estimated annual number of responses.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended.

Dated: June 30, 2022.

Kathleen Claffie,

Chief, Office of Privacy Management, U.S. Coast Guard.

[FR Doc. 2022–14697 Filed 7–8–22; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2022–0208]

Information Collection Request to Office of Management and Budget; OMB Control Number: 1625–0048

AGENCY: Coast Guard, DHS.

ACTION: Sixty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the following collection of information: 1625–0048, Vessel Reporting Requirements; without change. Our ICR describes the information we seek to collect from the public. Before submitting this ICR to OIRA, the Coast Guard is inviting comments as described below.

DATES: Comments must reach the Coast Guard on or before September 9, 2022.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG–2022–0208] to the Coast Guard using the Federal eRulemaking Portal at *https://www.regulations.gov.* See the ''Public participation and request for comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

A copy of the ICR is available through the docket on the internet at *https://www.regulations.gov.* Additionally, copies are available from: Commandant (CG–6P), Attn: Paperwork Reduction Act Manager, U.S. Coast Guard, 2703 Martin Luther King Jr. Ave. SE, STOP 7710, Washington, DC 20593–7710.

FOR FURTHER INFORMATION CONTACT: A.L. Craig, Office of Privacy Management, telephone 202–475–3528, or fax 202–372–8405, for questions on these documents.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. 3501 *et seq.,* chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) the practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology.

In response to your comments, we may revise this ICR or decide not to seek an extension of approval for the Collection. We will consider all comments and material received during the comment period.

We encourage you to respond to this request by submitting comments and related materials. Comments must contain the OMB Control Number of the ICR and the docket number of this request, [USCG–2022–0208], and must be received by September 9, 2022.

Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at *https://www.regulations.gov* and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

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

Information Collection Request

Title: Vessel Reporting Requirements.

OMB Control Number: 1625–0048.

Summary: Owners, Charterers, Managing Operators, or Agents of U.S. vessels must immediately notify the Coast Guard if they believe the vessel may be lost or in danger. The Coast Guard uses this information to investigate the situation and, when necessary, plan appropriate search and rescue operations.

Need: Section 2306(a) of 46 U.S.C. requires the owner, charterer, managing operator, or a agent of vessel of the United States to immediately notify the Coast Guard if: (1) There is reason to believe that the vessel may have been lost or imperiled, or (2) more than 48 hours have passed since last receiving communication from the vessel. These reports must be followed by written confirmation submitted to the Coast Guard within 24 hours. The implementing regulations are contained in 46 CFR part 4.

Forms: None.

Respondents: Businesses or other for profit organizations.

Frequency: On occasion.

Hour Burden Estimate: The estimated burden remains 138 hours a year. There is no proposed change to the reporting requirements of this collection. The reporting requirements and methodology for calculating burden, remains unchanged.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended.

Dated: June 30, 2022.

Kathleen Claffie,

Chief, Office of Privacy Management, U.S. Coast Guard.

[FR Doc. 2022–14699 Filed 7–8–22; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2022–0395]

Information Collection Request to Office of Management and Budget; OMB Control Number: 1625–0063

AGENCY: Coast Guard, DHS.

ACTION: Sixty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the following collection of information: 1625–0063, Marine Occupational Health and Safety Standards for Benzene; without change. Our ICR describes the information we seek to collect from the public. Before submitting this ICR to OIRA, the Coast Guard is inviting comments as described below.

DATES: Comments must reach the Coast Guard on or before September 9, 2022.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG–2022–0395] to the Coast Guard using the Federal eRulemaking Portal at *https://www.regulations.gov.* See the ''Public participation and request for comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

A copy of the ICR is available through the docket on the internet at *https://www.regulations.gov.* Additionally, copies are available from: Commandant (CG–6P), Attn: Paperwork Reduction Act Manager, U.S. Coast Guard, 2703 Martin Luther King Jr. Ave. Se, Stop 7710, Washington, DC 20593–7710.

FOR FURTHER INFORMATION CONTACT: A.L. Craig, Office of Privacy Management, telephone 202–475–3528, or fax 202–372–8405, for questions on these documents.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. 3501 *et seq.,* chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) the practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology.

In response to your comments, we may revise this ICR or decide not to seek an extension of approval for the Collection. We will consider all comments and material received during the comment period.

We encourage you to respond to this request by submitting comments and related materials. Comments must contain the OMB Control Number of the ICR and the docket number of this request, [USCG–2022–0395], and must be received by September 9, 2022.

Submitting comments

We encourage you to submit comments through the Federal eRulemaking Portal at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at *https://www.regulations.gov* and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

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

Information Collection Request

Title: Marine Occupational Health and Safety Standards for Benzene—46 CFR 197 subpart C.

OMB Control Number: 1625–0063.

Summary: To protect marine workers from exposure to toxic Benzene vapor, the Coast Guard implemented Title 46 CFR 197 subpart C.

Need: This information collection is vital to verifying compliance.

Forms: None.

Respondents: Owners and operators of vessels.

Frequency: On occasion.

Hour Burden Estimate: The estimated burden remains 38,165 hours a year.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended.

Dated: June 30, 2022.

Kathleen Claffie,

Chief, Office of Privacy Management, U.S. Coast Guard.

[FR Doc. 2022–14720 Filed 7–8–22; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2022–0394]

Information Collection Request to Office of Management and Budget; OMB Control Number: 1625–0037

AGENCY: Coast Guard, DHS.

ACTION: Sixty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the following collection of information: 1625–0037, Certificates of Compliance, Boiler/Pressure Vessel Repairs, Cargo Gear Records, Shipping Papers, and National Fire Protection Association (NFPA) 10 Certification; without change. Our ICR describes the information we seek to collect from the public. Before submitting this ICR to OIRA, the Coast Guard is inviting comments as described below.

DATES: Comments must reach the Coast Guard on or before September 9, 2022.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG–2022–0394] to the Coast Guard using the Federal eRulemaking Portal at *https://www.regulations.gov.* See the ''Public participation and request for comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

A copy of the ICR is available through the docket on the internet at *https://www.regulations.gov.* Additionally, copies are available from: Commandant (CG–6P), Attn: Paperwork Reduction Act Manager, U.S. Coast Guard, 2703 Martin Luther King Jr. Ave. SE, Stop 7710, Washington, DC 20593–7710.

FOR FURTHER INFORMATION CONTACT: A.L. Craig, Office of Privacy Management,

telephone 202–475–3528, or fax 202–372–8405, for questions on these documents.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. 3501 *et seq.,* chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) the practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology.

In response to your comments, we may revise this ICR or decide not to seek an extension of approval for the Collection. We will consider all comments and material received during the comment period.

We encourage you to respond to this request by submitting comments and related materials. Comments must contain the OMB Control Number of the ICR and the docket number of this request, [USCG–2022–0394], and must be received by September 9, 2022.

Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at *https://www.regulations.gov* and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

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

Information Collection Request

Title: Certificates of Compliance, Boiler/Pressure Vessel Repairs, Cargo Gear Records, Shipping Papers, and NFPA 10 Certification.

OMB Control Number: 1625–0037.

Summary: 46 U.S.C. 3301, 3305, 3306, 3702, 3703, 3711, 3714, 4302, and 4502 authorize the Coast Guard to establish marine safety regulations to protect life, property, and the environment. These regulations are prescribed in Title 46 Code of Federal Regulations.

Need: 46 U.S.C. 3301, 3305, 3306, 3702, 3703, 3711, 3714, 4302, and 4502 authorize the Coast Guard to establish marine safety regulations to protect life, property, and the environment. These regulations are prescribed in Title 46 Code of Federal Regulations.

Forms:

- CG–3585, Certificate of Compliance.
- CG–5437A, Port State Control Report of Inspection—Form A.
- CG–5437B, Port State Control Report of Inspection—Form B.

Respondents: Owners and operators of vessels.

Frequency: On occasion.

Hour Burden Estimate: The estimated burden has decreased from 18,703 hours to 15,703 a year, due to a change in the methodology for calculating the Shipping Papers burden.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended.

Dated: June 30, 2022.

Kathleen Claffie,

Chief, Office of Privacy Management, U.S. Coast Guard.

[FR Doc. 2022–14700 Filed 7–8–22; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2022–0396]

Information Collection Request to Office of Management and Budget; OMB Control Number: 1625–0065

AGENCY: Coast Guard, DHS.

ACTION: Sixty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the following collection of information: 1625–0065, Offshore Supply Vessels; without change. Our ICR describes the information we seek to collect from the public. Before submitting this ICR to OIRA, the Coast Guard is inviting comments as described below.

DATES: Comments must reach the Coast Guard on or before September 9, 2022.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG–2022–0396] to the Coast Guard using the Federal eRulemaking Portal at *https://www.regulations.gov.* See the ''Public participation and request for comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

A copy of the ICR is available through the docket on the internet at *https://www.regulations.gov.* Additionally, copies are available from: Commandant (CG–6P), Attn: Paperwork Reduction Act Manager, U.S. Coast Guard, 2703 Martin Luther King Jr. Ave. SE, Stop 7710, Washington, DC 20593–7710.

FOR FURTHER INFORMATION CONTACT: A.L. Craig, Office of Privacy Management, telephone 202–475–3528, or fax 202–372–8405, for questions on these documents.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. 3501 *et seq.,* chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) the practical

utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology.

In response to your comments, we may revise this ICR or decide not to seek an extension of approval for the Collection. We will consider all comments and material received during the comment period.

We encourage you to respond to this request by submitting comments and related materials. Comments must contain the OMB Control Number of the ICR and the docket number of this request, [USCG–2022–0396], and must be received by September 9, 2022.

Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at *https://www.regulations.gov*. If your material cannot be submitted using *https://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at *https://www.regulations.gov* and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

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

Information Collection Request

Title: Offshore Supply Vessels—Title 46 CFR Subchapter L.

OMB Control Number: 1625–0065.

Summary: 46 U.S.C. 3301, 3305, 3306, 3306, 3307, and 3308 authorize the Coast Guard to prescribe safety regulations. 46 CFR part 126 promulgates marine safety regulations for offshore supply vessels (OSV).

Need: The OSV posting/marking requirements are needed to provide instructions to those onboard of actions to be taken in the event of an emergency.

The reporting/recordkeeping requirements verify compliance with regulations without Coast Guard presence to witness routine matters, including OSVs based overseas as an alternative to Coast Guard inspection.

Forms: None.

Respondents: Owners and operators of vessels.

Frequency: On occasion.

Hour Burden Estimate: The estimated burden has decreased from 1,230 hours to 718 hours a year, due to a decrease in the estimated annual number of respondents.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended.

Dated: June 30, 2022.

Kathleen Claffie,

Chief, Office of Privacy Management, U.S. Coast Guard.

[FR Doc. 2022–14698 Filed 7–8–22; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. FEMA–2022–0005]

Privacy Act of 1974; System of Records

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Notice of a modified system of records.

SUMMARY: In accordance with the Privacy Act of 1974, the Department of Homeland Security (DHS) proposes to modify and reissue a current DHS system of records titled ''Department of Homeland Security/Federal Emergency Management Agency (FEMA)-004 Non-Disaster Grant Management Information Files System Records.'' This system of records allows DHS/FEMA to collect and maintain records from points of contact for state, local, tribal, territorial, and other entities applying for FEMA grant programs that are not disaster related. FEMA collects grant management information to determine eligibility for DHS grant awards for non-disaster grants and for the issuance of awarded funds. DHS/FEMA is updating this system of records to revise and add routine uses, as well as update the retention schedule. This updated system will be included in DHS's inventory of record systems.

DATES: Submit comments on or before August 10, 2022. This modified system will be effective upon publication. New or modified routine uses will be effective August 10, 2022.

ADDRESSES: You may submit comments, identified by docket number FEMA–2022–0005 by one of the following methods:

- *Federal e-Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–343–4010.
- *Mail:* Lynn Parker Dupree, Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528–0655.

Instructions: All submissions received must include the agency name and docket number FEMA–2022–0005. 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.*

FOR FURTHER INFORMATION CONTACT: For general questions please contact: Tammi Hines, (202) 212–5100, *FEMA-Privacy@fema.dhs.gov,* Senior Director for Information Management Directorate, Federal Emergency Management Agency, Washington, DC 20472. For privacy issues please contact: Lynn Parker Dupree, (202) 343–1717, *Privacy@hq.dhs.gov,* Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528–0655.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with the Privacy Act of 1974, DHS/FEMA proposes to modify an existing DHS system of records titled, ''DHS/FEMA–004 Non-Disaster Grant Management Information Files System of Records''. The goal of FEMA's non-disaster related grant programs is to provide funding to enhance the capacity of state, local, tribal, and territorial emergency responders to prevent, respond to, and recover from a weapon of mass destruction terrorism incident involving chemical, biological, radiological, nuclear, explosive devices, and cyber-attacks. FEMA's non-disaster grant programs currently provide funds to all 50 states, the District of Columbia, the Commonwealth of Puerto Rico, American Samoa, the Commonwealth of Northern Mariana Islands, Guam, the U.S. Virgin Islands, certain types of non-profit organizations, and some private entities. FEMA non-disaster related grant programs are directed at a broad spectrum of state and local emergency responders, including firefighters, emergency medical services, emergency management agencies, law enforcement, and public officials. The source of the

information collected by FEMA generally comes from state, local, tribal, and territorial governments; port authorities; transit authorities; non-profit organizations; and private companies seeking grant funding. The nature of data collected by FEMA includes basic public information about the agency or organization, the organization's financial information, and the organization's demonstrated need for the non-disaster grant funds.

Many of FEMA's non-disaster related grant programs implement objectives addressed in the Robert T. Stafford Disaster Relief and Emergency Assistance Act; a series of post-9/11 laws as outlined in the Authorities Section; the post-Katrina Emergency Management Reform Act (PKEMPRA) of 2006; and Homeland Security Presidential Directives (HSPD).

FEMA is updating this System of Records Notice to reflect the following changes: Routine Use E is being modified, and Routine Use F is being added to conform to Office of Management and Budget Memorandum M–17–12 regarding breach notification and investigation. FEMA is also updating this System of Records Notice to clarify the updated retention schedule. The National Archives and Records Administration (NARA) General Records Schedule (GRS) has been updated since this notice was last published. These records now follow General Records Schedule 1.2, Item 10 and Item 21. Furthermore, this notice includes non-substantive changes to simplify the formatting and text of the previously published notice.

Consistent with DHS's information-sharing mission, information stored in the DHS/FEMA–004 Non-Disaster Grant Management Information Files System of Records may be shared with other DHS components that have a need to know the information to carry out their national security, law enforcement, immigration, intelligence, or other homeland security functions. In addition, information may be shared with appropriate federal, state, local, tribal, territorial, foreign, or international government agencies consistent with the routine uses set forth in this system of records notice.

This updated system will be included in DHS's inventory of record systems.

II. Privacy Act

The Privacy Act codifies fair information practice principles in a statutory framework governing the means by which Federal Government agencies collect, maintain, use, and disseminate individuals' records. The Privacy Act applies to information that is 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. In the Privacy Act, an individual is defined to encompass U.S. citizens and lawful permanent residents. Additionally, the Judicial Redress Act (JRA) provides covered persons with a statutory right to make requests for access and amendment to covered records, as defined by the Judicial Redress Act, along with judicial review for denials of such requests. In addition, the Judicial Redress Act prohibits disclosures of covered records, except as otherwise permitted by the Privacy Act.

Below is the description of the DHS/FEMA–004 Non-Disaster Grant Management Information Files System of Records.

In accordance with 5 U.S.C. 552a(r), DHS has provided a report of this system of records to the Office of Management and Budget and to Congress.

SYSTEM NAME AND NUMBER:

Department of Homeland Security (DHS)/Federal Emergency Management Agency (FEMA)-004 Non-Disaster Grant Management Information Files.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

DHS/FEMA maintains records at DHS/FEMA Headquarters in Washington, DC, and DHS/FEMA regional field offices. Additionally, DHS/FEMA maintains records in FEMA information technology systems such as the FEMA Non-Disaster (ND) Grants and Assistance to Firefighters Grants (AFG) systems.

SYSTEM MANAGER(S):

Deputy Assistant Administrator, Grant Program Directorate, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Section 614 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5196c), as amended by Section 202, Title II of the Implementing Recommendations of the 9/11 Commission Act of 2007 (Pub. L. 110–053); Section 1809 of the Homeland Security Act of 2002 (6 U.S.C. 571 *et seq.*), as amended by Section 301(a) Title III of the Implementing Recommendations of the 9/11 Commission Act of 2007 (Pub. L. 110–053); Section 2003(a) of the Homeland Security Act of 2002 (6 U.S.C. 101 *et seq.*), as amended by Section 101, Title I of the Implementing Recommendations of the 9/11 Commission Act of 2007, (Pub. L. 110–053); Section 2004(a) of the Homeland Security Act of 2002 (6 U.S.C. 101 *et seq.*), as amended by Section 101, Title I of the Implementing Recommendations of the 9/11 Commission Act of 2007, (Pub. L. 110–053); Section 2004 of the Homeland Security Act of 2002 (6 U.S.C. 605 *et seq.*), as amended by Section 101, Title I of the Implementing Recommendations of the 9/11 Commission Act of 2007, (Pub. L. 110–53); Section 2005 of the Homeland Security Act of 2002 (6 U.S.C. 606 *et seq.*), as amended by Section 101, Title I of the Implementing Recommendations of the 9/11 Commission Act of 2007, (Pub. L. 110–53); the Post-Katrina Emergency Management Reform Act of 2006 (6 U.S.C. 723); Title III of Division D of the Consolidated Security, Disaster Assistance, and Continuing Appropriations Act, 2009 (Pub. L. 110–329); Title III of Division E of the Consolidated Appropriations Act, 2008 (Pub. L. 110–161); Section 1406, Title XIV of the Implementing Recommendations of the 9/11 Commission Act of 2007 (Pub. L. 110–053); Section 1513, Title XV of the Implementing Recommendations of the 9/11 Commission Act of 2007 (Pub. L. 110–053); Section 1532(a), Title XV of the Implementing Recommendations of the 9/11 Commission Act of 2007 (Pub. L. 110–053); 46 U.S.C. 70107; the Federal Financial Assistance Management Improvement Act of 1999 (Pub. L. 160–107); and National Historic Preservation Act of 1966, as amended, Public Law 89–665, Sec. 102, 16 U.S.C. 470.

PURPOSE(S) OF THE SYSTEM:

The purpose of this system is to assist in determining eligibility of awards for non-disaster related grants and for the issuance of awarded funds. The system also allows DHS to contact individuals to ensure completeness and accuracy of grants and applications.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Categories of individuals covered by this system include the respective points of contact (POC) for grant applications and awardees of grant funds. Awardees of grant funds include state, local, tribal, and territorial governments; port authorities; transit authorities; non-profit organizations;

and private companies (in rare instances).

CATEGORIES OF RECORDS IN THE SYSTEM:

Categories of records in this system include:

- Name of Organization's Designated Point of Contact;
- Point of Contact Title;
- Grant applicant organization Point of Contact's office mailing address;
- Grant applicant organization Point of Contact's office phone number;
- Grant applicant organization Point of Contact's office cellphone number;
- Grant applicant organization Point of Contact's office fax number;
- Grant applicant organization Point of Contact's work email address;
- Organization Name;
- Organization's Federal Employer Identification Number (EIN);
- Organization's Dun & Bradstreet (B&D) Data Universal Numbering System (DUNS) Number (a unique nine-digit numeric identifier assigned to each organization's location);
- Organization's Bank Routing Number; and
- Organization's Bank Account Number.

RECORD SOURCE CATEGORIES:

DHS/FEMA obtains records from grantees, applicants for award, grant applicants' points of contact, and grant program monitors.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND 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 DHS 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 United States 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. DHS or any component thereof;
2. Any employee or former employee of DHS in his/her official capacity;
3. Any employee or former employee of DHS in his/her individual capacity when the department of Justice or DHS has agreed to represent the employee; or
4. The United States or any agency thereof.

B. To a congressional office from the record of an individual in response to an inquiry from that congressional office made at the request of the individual to whom the record pertains.

C. To the National Archives and Records Administration (NARA) or General Services Administration pursuant to records management inspections being conducted under the authority of 44 U.S.C. 2904 and 2906.

D. To an agency or organization for the purpose of performing audit or oversight operations as authorized by law, but only such information as is necessary and relevant to such audit or oversight function.

E. To appropriate agencies, entities, and persons when (1) DHS suspects or has confirmed that there has been a breach of the system of records; (2) DHS has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, DHS (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 DHS's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

F. To another federal agency or federal entity, when DHS 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.

G. To an appropriate federal, state, tribal, local, international, or foreign law enforcement agency or other appropriate authority charged with investigating or prosecuting a violation or enforcing or implementing a law, rule, regulation, or order, when a record, either on its face or in conjunction with other information, indicates a violation or potential violation of law, which includes criminal, civil, or regulatory violations and such disclosure is proper and consistent with the official duties of the person making the disclosure.

H. To contractors and their agents, grantees, experts, consultants, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for DHS, when necessary to and accomplish an agency function related to this system of records. Individuals provided information under this routine use are subject to the same Privacy Act requirements and limitations on disclosure as are applicable to DHS officers and employees.

I. To an individual's employer or affiliated organization to the extent necessary to verify employment or membership status.

J. To the news media and the public, with the approval of the Chief Privacy Officer in consultation with counsel, when there exists a legitimate public interest in the disclosure of the information or when disclosure is necessary to preserve confidence in the integrity of DHS or is necessary to demonstrate the accountability of DHS's officers, employees, or individuals covered by the system, 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.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

DHS/FEMA stores records in this system electronically or on paper in secure facilities in a locked drawer behind a locked door. The records may be stored on magnetic disc, tape, and digital media.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

DHS/FEMA may retrieve records by the Point of Contact of an organization or the name of organization itself.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

DHS/FEMA retains grant application information for audit, oversight operations, and appeal purposes. In accordance with General Records Schedule (GRS) 1.2, Item 10, FEMA destroys grant administrative records and hard copies of unsuccessful grant application files after three years after final action is taken on the file. In accordance with General Records Schedule 1.2, Item 21, FEMA deletes electronically received and processed copies of unsuccessful grant application files after three years from the date final action is taken on the file.

In accordance with NARA Authority N1–311–95–001, Item 1, FEMA maintains grant project records for three years after the end of the fiscal year that the grant or agreement is finalized or when no longer needed, whichever is sooner.

In accordance with NARA Authority N1–311–95–001, Item 3, FEMA retires grant final reports to the Federal Records Center three years after cutoff and transfers them to NARA 20 years after cutoff. In accordance with NARA

Authority N1–311–95–001, Item 2; N1–311–01–008, Item 1; and N1–311–04–001, Item 1, FEMA stores all other grant records for six years and three months from the date of closeout (when closeout is the date FEMA closes the grant in its financial system) and final audit and appeals are resolved and then deleted.

The customer service assessment forms that have been filled out and returned by disaster assistance applicants are temporary records that are destroyed upon transmission of the final report, per NARA Authority N1–311–00–001, Item 1.

The statistical and analytical reports resulting from these assessments are temporary records that are retired three years after the final report cutoff and destroyed 20 years after the report cutoff per NARA Authority N1–311–00–001, Item 2. The assessment results database are temporary records that are destroyed when no longer needed for analysis purposes, per NARA Authority N1–311–00–001, Item 3.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

DHS/FEMA safeguards records in this system in accordance with applicable rules and policies, including all applicable DHS automated systems security and access policies. DHS/FEMA imposes strict controls to minimize the risk of compromising the information that is being stored. DHS/FEMA limits access to the computer system containing the records in this system to those individuals who have a need-to-know the information for the performance of their official duties and who have appropriate clearances or permissions.

RECORD ACCESS PROCEDURES:

Individuals seeking access to and notification of any record contained in this system of records, or seeking to contest its content, may submit a request in writing to the Chief Privacy Officer and FEMA's Freedom of Information Act (FOIA) Officer whose contact information can be found at *https://www.dhs.gov/foia-contact-information.* If an individual believes more than one component maintains Privacy Act records concerning him or her, the individual may submit the request to the Chief Privacy Officer and Chief Freedom of Information Act Officer, Department of Homeland Security, Washington, DC 20528–0655, or electronically at *https://www.dhs.gov/dhs-foia-privacy-act-request-submission-form.* Even if neither the Privacy Act nor the Judicial Redress Act provide a right of access, certain records about you may be available under the Freedom of Information Act.

When an individual is seeking records about himself or herself from this system of records or any other Departmental system of records, the individual's request must conform with the Privacy Act regulations set forth in 6 CFR part 5. The individual must first verify his/her identity, meaning that the individual must provide his/her full name, current address, and date and place of birth. The individual must sign the request, and the individual's signature must either be notarized or submitted under 28 U.S.C. 1746, a law that permits statements to be made under penalty of perjury as a substitute for notarization. An individual may obtain more information about this process at *http://www.dhs.gov/foia.* In addition, the individual should:

- Explain why he or she believes the Department would have information being requested;
- Identify which component(s) of the Department he or she believes may have the information;
- Specify when the individual believes the records would have been created; and
- Provide any other information that will help the FOIA staff determine which DHS component agency may have responsive records.

If the request is seeking records pertaining to another living individual, the request must include an authorization from the individual whose record is being requested, authorizing the release to the requester.

Without the above information, the component(s) may not be able to conduct an effective search, and the individual's request may be denied due to lack of specificity or lack of compliance with applicable regulations.

CONTESTING RECORD PROCEDURES:

For records covered by the Privacy Act or covered Judicial Redress Act records, individuals may make a request for amendment or correction of a record of the Department about the individual by writing directly to the Department component that maintains the record, unless the record is not subject to amendment or correction. The request should identify each particular record in question, state the amendment or correction desired, and state why the individual believes that the record is not accurate, relevant, timely, or complete. The individual may submit any documentation that would be helpful. If the individual believes that the same record is in more than one system of records, the request should state that and be addressed to each component that maintains a system of records containing the record.

NOTIFICATION PROCEDURES:

See ''Record Access Procedures'' above.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

80 FR 13404 (March 13, 2015); and FR 39705 (August 7, 2009).

* * * * *

Lynn P. Dupree,

Chief Privacy Officer, Department of Homeland Security.

[FR Doc. 2022–14673 Filed 7–8–22; 8:45 am]

BILLING CODE 4410–10–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–670 and 731–TA–1570 (Final)]

Freight Rail Coupler Systems and Components From China

Determinations

On the basis of the record [1] developed in the subject investigations, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930 (''the Act''), that an industry in the United States is not materially injured or threatened with material injury by reason of imports of freight rail coupler systems and components from China, provided for in subheading 8607.30.10 [2] of the Harmonized Tariff Schedule of the United States, that have been found by the U.S. Department of Commerce (''Commerce'') to be sold in the United States at less than fair value (''LTFV''), and to be subsidized by the government of China.[3]

Background

The Commission instituted these investigations effective September 29, 2021, following receipt of petitions filed with the Commission and Commerce by the Coalition of Freight Coupler Producers consisting of McConway & Torley LLC (''M&T''), Pittsburgh, PA,

[1] The record is defined in § 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

[2] Unfinished subject merchandise may also be imported under subheading 7326.90.86. Subject merchandise attached to finished rail cars may also be imported under subheadings 8606.10.00, 8606.30.00, 8606.91.00, 8606.92.00, 8606.99.01 or under subheading 9803.00.50 if imported as an Instrument of International Traffic.

[3] 87 FR 30869 (May 20, 2022) and 87 FR 32121 (May 27, 2022).

and the United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union, AFLCIO, CLC (''USW'').[4] The final phase of the investigations was scheduled by the Commission following notification of preliminary determinations by Commerce that imports of freight rail coupler systems and components from China were subsidized within the meaning of section 703(b) of the Act (19 U.S.C. 1671b(b)) and sold at LTFV within the meaning of 733(b) of the Act (19 U.S.C. 1673b(b)). Notice of the scheduling of the final phase of the Commission's investigations and of a public hearing to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** on March 8, 2022 (87 FR 14037). The Commission conducted its hearing on May 12, 2022. All persons who requested the opportunity were permitted to participate.

The Commission made these determinations pursuant to §§ 705(b) and 735(b) of the Act (19 U.S.C. 1671d(b) and 19 U.S.C. 1673d(b)). It completed and filed its determinations in these investigations on July 5, 2022. The views of the Commission are contained in USITC Publication 5331 (July 2022), entitled *Freight Rail Coupler Systems and Components from China: Investigation Nos. 701–TA–670 and 731–TA–1570 (Final).*

By order of the Commission.

Issued: July 5, 2022.

William Bishop,

Supervisory Hearing and Information Officer.

[FR Doc. 2022–14639 Filed 7–8–22; 8:45 am]

BILLING CODE 7020–02–P

[4] Initially, Petitioner was M&T and another domestic producer. However, the other domestic producer withdrew, and USW was added to the petitions.

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1005 (Rescission)]

Certain L-Tryptophan, L-Tryptophan Products, and Their Methods of Production; Notice of Commission Determination To Institute a Rescission Proceeding; Rescission of the Remedial Orders; Termination of 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 grant a joint petition to rescind the limited exclusion order (''LEO'') and cease and desist order (''CDO'') (collectively, ''the remedial orders'') 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.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on June 14, 2016, based on a complaint filed by complainants Ajinomoto Co., Inc. of Tokyo, Japan and Ajinomoto Heartland Inc. of Chicago, Illinois (collectively, ''Ajinomoto''). *See* 81 FR 38735–36 (June 14, 2016). The complaint, as supplemented, alleged violations of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337) (''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 L-tryptophan, L-tryptophan products, and their methods of production by reason of infringement of certain claims of U.S. Patent No. 7,666,655 (''the '655 patent'') and U.S. Patent No. 6,180,373 (''the '373 patent''). *See id.* The notice of investigation named CJ CheilJedang Corp. of Seoul, Republic of Korea, CJ America, Inc. of Downers Grove, Illinois, and PT CheilJedang Indonesia of Jakarta, Indonesia (collectively, ''CJ'') as respondents in this investigation. *See id.* The Office of Unfair Import Investigations was not a party to the investigation.

On December 18, 2017, the Commission issued a final determination finding a violation of section 337 with respect to certain tryptophan-producing bacteria strains (''the later strains''), but no violation of section 337 with respect to other strains (''the earlier strains''). The Commission issued the remedial orders, *i.e.,* an LEO against the infringing articles and a CDO against CJ America.

On February 16, 2018, Ajinomoto filed an appeal with the United States Court of Appeals for the Federal Circuit (''Federal Circuit'') from the Commission's final determination finding no violation of section 337 with respect to the earlier strains. On February 27, 2018, CJ also filed an appeal with the Federal Circuit from the Commission's final determination finding a violation of section 337 with respect to the later strains.

On May 25, 2018, CJ filed a motion for partial dismissal of the appeal with respect to the '373 patent based on expiration of that patent. On June 27, 2018, the Federal Circuit issued an order dismissing the appeal with respect to the '373 patent. On August 6, 2019, the Federal Circuit affirmed the Commission's final determination with respect to the remaining '655 patent.

On June 3, 2022, Ajinomoto and CJ filed a joint petition to rescind the remedial orders based on settlement. The petition includes a confidential and public version of the settlement agreement and indicates that there are no other agreements, written or oral, express or implied between the parties concerning the subject matter of the investigation. No response to the petition was filed.

Having reviewed the petition and the settlement agreement between Ajinomoto and CJ provided therewith, the Commission finds that the conditions which led to the issuance of the remedial orders no longer exist, and therefore, granting the joint petition to rescind is warranted under section 337(k) (19 U.S.C. 1337(k)). The Commission also finds that the requirements of Commission Rule 210.76(a) (19 CFR 210.76(a)) are satisfied. Accordingly, the Commission has determined to institute a rescission proceeding and to grant the joint petition to rescind the remedial orders. The rescission proceeding is terminated.

The Commission vote for this determination took place on July 5, 2022.

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: July 5, 2022.

William Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2022–14627 Filed 7–8–22; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Application for Self-Insurance Under the Black Lung Benefits Act

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Office of Workers' Compensation Programs (OWCP)-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 the agency receives on or before August 10, 2022.

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) 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; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) 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: Nicole Bouchet by telephone at 202–693–0213, or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: This information collection is essential to the mission of OWCP's Division of Coal Mine Workers' Compensation, which administers the Black Lung Benefits Act (BLBA). The statute grants the Department authority to authorize and regulate coal mine operators who wish to self-insure their BLBA liabilities. This information collection would provide OWCP with sufficient information to determine whether a coal mine operator should be (or continue to be) authorized to self-insure. The information would also allow OWCP to determine the security amount a coal mine operator must deposit to guarantee that it will be able to meet its BLBA liabilities. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on May 2, 2022 (87 FR 11738).

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–OWCP.

Title of Collection: Application for Self-Insurance Under the Black Lung Benefits Act.

OMB Control Number: 1240–0057.

Affected Public: Private Sector—Businesses or other for-profits.

Total Estimated Number of Respondents: 49.

Total Estimated Number of Responses: 294.

Total Estimated Annual Time Burden: 261 hours.

Total Estimated Annual Other Costs Burden: $34,080.

(Authority: 44 U.S.C. 3507(a)(1)(D))

Nicole Bouchet,

Senior PRA Analyst.

[FR Doc. 2022–14664 Filed 7–8–22; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF LABOR

Wage and Hour Division

Agency Information Collection Activities; Comment Request; Information Collections: Labor Standards for Federal Service Contracts Regulations

AGENCY: Wage and Hour Division, Department of Labor.

ACTION: Notice.

SUMMARY: The Department of Labor (Department) is soliciting comments concerning a proposed extension of the information collection request (ICR) titled, ''Labor Standards for Federal Service Contracts Regulations.'' This comment request is part of continuing Departmental efforts to reduce paperwork and respondent burden in accordance with the Paperwork Reduction Act of 1995. The Department proposes to extend its information collection without change to existing requirements. 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 can be properly assessed. A copy of the proposed information request can be obtained by contacting the office listed below in the **FOR FURTHER INFORMATION CONTACT** section of this Notice.

DATES: Written comments must be submitted to the office listed in the **ADDRESSES** section below on or before September 9, 2022.

ADDRESSES: You may submit comments identified by Control Number 1235–0007 by either one of the following methods: *Email: WHDPRAComments@dol.gov; Mail, Hand Delivery, Courier:* Division of Regulations, Legislation, and Interpretation, Wage and Hour, U.S. Department of Labor, Room S–3502, 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 Control Number identified above for this information collection. Because we continue to experience delays in receiving mail in the Washington, DC area, commenters are strongly encouraged to transmit their comments electronically via email or to submit them by mail early. Comments, including any personal information provided, become a matter of public record. They will also be summarized and/or included in the request for Office

of Management and Budget (OMB) approval of the information collection request.

FOR FURTHER INFORMATION CONTACT: Amy DeBisschop, Division of Regulations, Legislation, and Interpretation, Wage and Hour Division, U.S. Department of Labor, Room S–3502, 200 Constitution Avenue NW, Washington, DC 20210; telephone: (202) 693–0406 (this is not a toll-free number). Alternative formats are available upon request by calling 1–866–487–9243. If you are deaf, hard of hearing, or have a speech disability, please dial 7–1–1 to access telecommunications relay services.

SUPPLEMENTARY INFORMATION:

I. Background

The Department's Wage and Hour Division (WHD) administers the McNamara-O'Hara Service Contract Act (SCA or Act), 41 U.S.C. 351 *et seq.* The SCA applies to every contract entered into by the United States or the District of Columbia, the principal purpose of which is to furnish services to the United States through the use of service employees. The SCA requires contractors and subcontractors performing services on covered federal or District of Columbia contracts in excess of $2,500 to pay service employees in various classes no less than the monetary wage rates and fringe benefits found prevailing in the locality, or the rates (including prospective increases) contained in a predecessor contractor's collective bargaining agreement. Safety and health standards also apply to such contracts. WHD enforces the compensation requirements of the SCA.

A. Vacation Benefit Seniority List

Section 2(a) of the SCA provides that every contract subject to the Act must contain a provision specifying the minimum monetary wages and fringe benefits to be paid to the various classes of service employees performing work on the contract. Many wage determinations issued for recurring services performed at the same federal facility provide for certain vested fringe benefits (*e.g.,* vacations), which are based on the employee's total length of service with a contractor or any predecessor contractor. *See* 29 CFR 4.162. When found to prevail, such fringe benefits are incorporated in wage determinations and are usually stated as ''one-week paid vacation after one year's service with a contractor or successor, two weeks after two years,'' etc. These provisions ensure that employees receive the vacation benefit payments that they have earned and accrued by requiring that such payments be made by successor contractors who hire the same employees who have worked over the years at the same facility in the same locality for predecessor contractors.

B. Conformance Record

Section 2(a) of the SCA provides that every contract subject to the Act must contain a provision specifying the minimum monetary wage and fringe benefits to be paid the various classes of service employees employed on the contract work. *See* 41 U.S.C. 351, *et seq.* Problems sometimes arise (1) when employees are working on service contracts in job classifications that the Department was not previously informed about and (2) when there are job classifications for which no wage data are available.

Section 4.6(b)(2) of 29 CFR part 4 provides a process for ''conforming'' (*i.e.,* adding) classifications and wage rates to the wage determinations for classes of service employees not previously listed on a wage determination but where employees are actually working on an SCA covered contract. This process ensures that the requirements of section 2(a) of the Act are fulfilled and that a formal record exists as part of the contract which documents the wage rate and fringe benefits to be paid for a conformed classification while a service employee(s) is employed on the contract.

The contracting officer is required to review each contractor-proposed conformance to determine if the unlisted classes have been properly classified by the contractor so as to provide a reasonable relationship (*i.e.,* appropriate level of skill comparison) between such unlisted classifications and the classifications (and wages) listed in the wage determination. *See* 29 CFR 4.6(b)(2). Moreover, the contracting agency is required to forward the conformance action to WHD for review and approval. *Id.*

C. Indexing

In any case where a contract succeeds a contract under which a class was previously conformed, the contractor may use an optional procedure known as indexing (*i.e.,* adjusting) to determine a new wage rate for a previously conformed class. *See* 29 CFR 4.6(b)(2)(iv)(B). This procedure does not require the Department's approval, but it requires the contractor to notify the contracting agency in writing that a previously conformed class has been indexed and to include information describing how the new rate was computed. *Id.*

D. Submission of Collective Bargaining Agreement (CBA)

Sections 2(a) and 4(c) of the SCA provide that any contractor that *succeeds* a contract subject to the Act and under which substantially the same services are furnished shall pay any service workers employed on the contract no less than the wages and fringe benefits to which such workers would have been entitled if employed under the *predecessor* contract. *See* 29 CFR 4.163(a).

29 CFR 4.6(l)(1) requires a predecessor contractor to provide to the contracting officer a copy of any CBA governing the wages and fringe benefits paid service employees performing work on the contract during the contract period. The contracting agency submits these CBAs to WHD where they are used in issuing wage determinations for successor contracts subject to sections 2(a) and 4(c) of the SCA. *See* 29 CFR 4.4(c).

WHD uses this information to determine whether covered employers have complied with various legal requirements of the laws administered by the agency. The Department seeks approval to extend this information collection related to labor standards for federal service contracts.

II. Review Focus

The Department of Labor is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Enhance the quality, utility, and clarity of the information to be collected;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; or
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

III. Current Actions

The Department of Labor seeks an approval for the extension of this information collection that requires

employers to make, maintain, and preserve records in accordance with statutory and regulatory requirements.

Type of Review: Extension.

Agency: Wage and Hour Division.

Title: Labor Standards for Federal Service Contracts Regulations.

OMB Control Number: 1235–0007.

Affected Public: Business or other for-profit, Not-for-profit institutions.

Total Respondents: 137,394.

Total Annual Responses: 137,394.

Estimated Total Burden Hours: 136,462.

Estimated Time per Response: Vacation Benefit Seniority List: 1 hour. Conformance Record: 30 minutes. Conformance Indexing: 2 hours. Collective Bargaining Agreement: 5 minutes.

Frequency: On occasion.

Total Burden Cost (Capital/Startup): $0.

Total Burden Costs (Operation/Maintenance): $0.

Dated: July 1, 2022.

Amy DeBisschop,

Director, Division of Regulations, Legislation, and Interpretation.

[FR Doc. 2022–14663 Filed 7–8–22; 8:45 am]

BILLING CODE 4510–27–P

NATIONAL SCIENCE FOUNDATION

Sunshine Act Meetings

The National Science Board's (NSB) 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, July 11, 2022, from 12:30–1:30 p.m. EDT.

PLACE: This meeting will be held by video conference through the National Science Foundation.

STATUS: Open.

MATTERS TO BE CONSIDERED: The agenda of the teleconference is: Committee Chair's Opening Remarks; Approval of Executive Committee Minutes of April 5, 2022; and Discuss issues and topics for an agenda of the NSB meeting scheduled for August 3–4, 2022.

CONTACT PERSON FOR MORE INFORMATION: Point of contact for this meeting is: Nirmala Kannankutty, (*nkannank@nsf.gov*), 703/292–8000. Members of the public can observe this meeting through a You Tube livestream. Access the livestream at: *https://www.youtube.com/?v=gicfB6iPjpU.*

Chris Blair,

Executive Assistant to the National Science Board Office.

[FR Doc. 2022–14752 Filed 7–7–22; 11:15 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2022–0001]

Sunshine Act Meetings

TIME AND DATE: Weeks of July 11, 18, 25, August 1, 8, 15, 2022. The schedule for Commission meetings is subject to change on short notice. The NRC Commission Meeting Schedule can be found on the internet at: *https://www.nrc.gov/public-involve/public-meetings/schedule.html.*

PLACE: The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings or need this meeting notice or the transcript or other information from the public meetings in another format (*e.g.,* braille, large print), please notify Anne Silk, NRC Disability Program Specialist, at 301–287–0745, by videophone at 240–428–3217, or by email at *Anne.Silk@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

STATUS: Public.

Members of the public may request to receive the information in these notices electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555, at 301–415–1969, or by email at *Wendy.Moore@nrc.gov* or *Betty.Thweatt@nrc.gov.*

MATTERS TO BE CONSIDERED:

Week of July 11, 2022

There are no meetings scheduled for the week of July 11, 2022.

Week of July 18, 2022—Tentative

Thursday, July 21, 2022

9:00 a.m. Update on 10 CFR part 53 Licensing and Regulation of Advanced Nuclear Reactors; (Contact: Greg Oberson: 301–415–2183)

Additional Information: The meeting will be held in the Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland. The public is invited to attend the Commission's meeting in person or watch live via webcast at the Web address—*https://video.nrc.gov/.*

Week of July 25, 2022—Tentative

There are no meetings scheduled for the week of July 25, 2022.

Week of August 1, 2022—Tentative

There are no meetings scheduled for the week of August 1, 2022.

Week of August 8, 2022—Tentative

There are no meetings scheduled for the week of August 8, 2022.

Week of August 15, 2022—Tentative

There are no meetings scheduled for the week of August 15, 2022.

CONTACT PERSON FOR MORE INFORMATION: For more information or to verify the status of meetings, contact Wesley Held at 301–287–3591 or via email at *Wesley.Held@nrc.gov.*

The NRC is holding the meetings under the authority of the Government in the Sunshine Act, 5 U.S.C. 552b.

Dated: July 7, 2022.

For the Nuclear Regulatory Commission.

Wesley W. Held,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2022–14845 Filed 7–7–22; 4:15 pm]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2022–78 and CP2022–84]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* July 13, 2022.

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).:* MC2022–78 and CP2022–84; *Filing Title:* USPS Request to Add Priority Mail Contract 752 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* July 5, 2022; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Katalin Clendenin; *Comments Due:* July 13, 2022.

This Notice will be published in the **Federal Register**.

Erica A. Barker,

Secretary.

[FR Doc. 2022–14672 Filed 7–8–22; 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).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95200; File No. SR–ICC–2022–008]

Self-Regulatory Organizations; ICE Clear Credit LLC; Notice of Filing of Proposed Rule Change Relating to the Stress Testing Framework and the Liquidity Risk Management Framework

July 5, 2022.

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 June 23, 2022, ICE Clear Credit LLC (''ICC'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared primarily by ICC. The Commission is publishing this notice to solicit comments on the proposed rule change, security-based swap submission, or advance notice from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

The principal purpose of the proposed rule change is to revise the ICC Stress Testing Framework (''STF'') and the ICC Liquidity Risk Management Framework (''LRMF''). These revisions do not require any changes to the ICC Clearing Rules (''Rules'').

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, ICC included statements concerning the purpose of and basis for the proposed rule change, security-based swap submission, or advance notice and discussed any comments it received on the proposed rule change, security-based swap submission, or advance notice. The text of these statements may be examined at the places specified in Item IV below. ICC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of these statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

(a) Purpose

ICC proposes revising the STF and LRMF to introduce new stress scenarios, clarify existing stress scenarios, and make other minor edits. ICC believes the proposed changes will facilitate the prompt and accurate clearance and settlement of securities transactions and derivative agreements, contracts, and transactions for which it is responsible. ICC proposes to move forward with implementation of these changes following Commission approval of the proposed rule change. The proposed rule change is described in detail as follows.

I. STF

The proposed amendments to the STF introduce new stress scenarios related to the Coronavirus pandemic and oil price war (the ''COVID–19/Oil Crisis''), clarify existing stress scenarios related to credit default index swaptions (''index options''), and make other minor edits.

The proposed changes amend Section 5.1 containing the historically observed extreme but plausible market scenarios. ICC proposes a minor edit to abbreviate a term. ICC proposes to introduce additional stress scenarios related to the COVID–19/Oil Crisis. ICC previously introduced price-based stress scenarios related to the COVID–19/Oil Crisis in the STF, which replicate observed instrument price changes during this period.[3] ICC proposes to incorporate complementing spread-based stress scenarios related to the COVID–19/Oil Crisis, which reflect observed relative spread increases and decreases during this period (the ''COVID–19/Oil Crisis Spread Scenarios''). Additionally, the stress scenarios related to index options (*i.e.,* the stress options-implied Mean Absolute Deviation (''MAD'') scenarios) would be moved into a separate section and corresponding references throughout the STF would accordingly refer to this new Section 9.

ICC proposes additional clarifications in Section 5 and throughout the STF. To distinguish from the COVID–19/Oil Crisis Spread Scenarios, ICC would refer to the price-based stress scenarios as the COVID–19/Oil Crisis Price Scenarios in Section 5.2 and throughout the STF. ICC also proposes to incorporate the COVID–19/Oil Crisis Spread Scenarios

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] See SR–ICC–2020–009 for additional information on the introduction of the COVID–19/Oil Crisis price-based stress scenarios.

in the other categories of scenarios, namely in Section 5.3 (hypothetically constructed (forward looking) extreme but plausible market scenarios) and Section 5.4 (extreme model response test scenarios), as well as in Section 14 (interpretation of results).

ICC proposes further details to describe how the existing stress scenarios for index option positions are integrated within the current set of stress scenarios for CDS index and single name instruments. Currently, the stress options-implied MAD scenarios are generated for index option positions. Such scenarios are not applied to portfolios independently but rather directly incorporated into the CDS stress scenarios. As such, the proposed changes clarify that the stress options-implied MAD scenarios complement the underlying stress scenarios (in Section 6) and reference proposed Section 9 for more detail on the stress options-implied MAD approach (in Section 8).

Moreover, proposed Section 9 memorializes the stress options-implied MAD scenarios and approach more clearly. Information from Section 5.1 on these scenarios would reside in Section 9 with certain amendments. The proposed amendments do not change the stress testing methodology and instead add detail and update terminology to be clearer. Proposed language explains that when index options are present in a portfolio, the underlying market stress test scenarios incorporate the stress options-implied MAD scenarios. Terminology changes specify that the scenarios consider an increase/decrease in the options-implied MAD upon spread widening/tightening and clarification changes detail the incorporation of the options-implied MAD in the scenarios. The proposed changes more clearly set forth the creation of the stress options-implied MAD, including how the necessary components are derived. No changes are proposed with respect to what the final scenario prices of the index option instruments reflect. The following sections are renumbered accordingly throughout the STF, including in Table 1 in Section 14. Finally, proposed Section 17 adds a revision history to track changes.

II. LRMF

ICC proposes corresponding changes to the LRMF to introduce new stress scenarios related to the COVID–19/Oil Crisis, clarify existing stress scenarios related to index options, and make other minor edits.

ICC proposes to revise Section 2.3 regarding liquidity requirements for client-related accounts. The amended language specifies that Clearing Participants deposit 100% of their Euro denominated client gross margin in any acceptable collateral to match Schedule 401 in the ICC Rules. This is intended to be a clean-up change to remove an outdated provision to ensure consistency across the LRMF and ICC Rules and would not change current requirements.

ICC proposes updates to Section 3.3.2 regarding the historically observed extreme but plausible market scenarios. The proposed changes define extreme market events to include COVID–19 and the simultaneous occurrence of the oil price war and make grammatical edits to change a term to its plural form. ICC also previously introduced the COVID–19/Oil Crisis price-based stress scenarios in the LRMF [4] and proposes to incorporate the complementing COVID–19/Oil Crisis Spread Scenarios, which are also referred to as the COVID19OCSS, in the LRMF. The price-based stress scenarios would be referred to as the COVID–19/Oil Crisis Price Scenarios or COVID19OCPS throughout the document.

Revisions to the existing stress options-implied MAD scenarios are proposed in Section 3.3.2. To ensure consistency with the STF, ICC proposes the inclusion of similar language and changes in subsection (b). The proposed changes memorialize the stress options-implied MAD scenarios and approach more clearly in the LRMF, including how the scenarios for index option positions are integrated within the current set of stress scenarios for CDS index and single name instruments. The proposed amendments do not change the methodology and instead add detail and update terminology to be clearer. Terminology changes specify that the scenarios consider an increase/decrease in the options-implied MAD and clarification changes detail the incorporation of the options-implied MAD in the scenarios. The proposed changes more clearly set forth the creation of the stress options-implied MAD, including how the necessary components are derived. No changes are proposed with respect to what the final scenario prices of the index option instruments reflect. A typographical fix is made in the footnotes to refer to the correct reference document. In addition, ICC proposes to amend subsection (d) to add a section symbol and to set out how the stress options-implied MAD scenarios that complement the extreme model response test scenarios are derived to match language currently in the STF.

[4] *Id.*

ICC proposes additional minor updates to Section 3.3. ICC would incorporate the COVID–19/Oil Crisis Spread Scenarios in Section 3.3.3 in Table 1 containing the liquidity stress testing scenarios and in Section 3.3.4 related to the interpretation of results. ICC also proposes a minor edit to the extreme market scenarios in Table 1 to specify that the COVID19OCPS are extreme.

(b) Statutory Basis

ICC believes that the proposed rule change is consistent with the requirements of Section 17A of the Act [5] and the regulations thereunder applicable to it, including the applicable standards under Rule 17Ad–22.[6] In particular, Section 17A(b)(3)(F) of the Act [7] requires that the rule change be consistent with the prompt and accurate clearance and settlement of securities transactions and derivative agreements, contracts and transactions cleared by ICC, the safeguarding of securities and funds in the custody or control of ICC or for which it is responsible, and the protection of investors and the public interest.

As discussed herein, the proposed amendments introduce new stress scenarios, clarify existing stress scenarios, and make other minor edits. Such changes strengthen the STF and LRMF by introducing spread-based COVID–19/Oil Crisis scenarios that complement the current scenarios and by memorializing the stress options-implied MAD scenarios more clearly to ensure transparency and that responsible parties effectively carry out their assigned duties. The additional clarification and clean-up changes further ensure readability and clarity, including by adding a revision history to track changes, updating terminology, ensuring that references are accurate, and ensuring consistency between the LRMF and the ICC Rules regarding client-related liquidity requirements to avoid potential confusion. ICC believes that having policies and procedures that clearly and accurately document its risk management practices, including stress testing and liquidity stress testing, are an important component to the effectiveness of ICC's risk management system and support ICC's ability to maintain adequate financial resources and sufficient liquid resources. Accordingly, in ICC's view, the proposed rule change is consistent with the prompt and accurate clearance and settlement of securities transactions,

[5] 15 U.S.C. 78q–1.

[6] 17 CFR 240.17Ad–22.

[7] 15 U.S.C. 78q–1(b)(3)(F).

derivatives agreements, contracts, and transactions, the safeguarding of securities and funds in the custody or control of ICC or for which it is responsible, and the protection of investors and the public interest, within the meaning of Section 17A(b)(3)(F) of the Act.[8]

The amendments would also satisfy relevant requirements of Rule 17Ad–22.[9] Rule 17Ad–22(e)(4)(ii)[10] requires ICC to establish, implement, maintain, and enforce written policies and procedures reasonably designed to effectively identify, measure, monitor, and manage its credit exposures to participants and those arising from its payment, clearing, and settlement processes, including by maintaining additional financial resources at the minimum to enable it to cover a wide range of foreseeable stress scenarios that include, but are not limited to, the default of the two participant families that would potentially cause the largest aggregate credit exposure for ICC in extreme but plausible market conditions. The introduction of the COVID–19/Oil Crisis Spread Scenarios would complement the current scenarios and add additional insight into potential weaknesses in the ICC risk management methodology, thereby supporting ICC's ability to manage its financial resources. Additional proposed changes ensure consistency across the STF and LRMF and more clearly describe the stress options-implied MAD scenarios, including how the scenarios for index option positions are integrated within the current set of stress scenarios for CDS index and single name instruments. The proposed amendments add detail and update terminology to be clearer, which would ensure transparency and strengthen the documentation, thereby supporting the effectiveness of ICC's risk management system. The proposed clarification and clean-up changes further enhance the readability of the STF and LRMF and ensure that it remains up-to-date, clear, and transparent. As such, the proposed amendments would strengthen ICC's ability to maintain its financial resources and withstand the pressures of defaults, consistent with the requirements of Rule 17Ad–22(e)(4)(ii).[11]

Rule 17Ad–22(e)(4)(vi)[12] requires ICC to establish, implement, maintain, and enforce written policies and procedures reasonably designed to effectively identify, measure, monitor, and manage its credit exposures to participants and those arising from its payment, clearing, and settlement processes, including by testing the sufficiency of its total financial resources available to meet the minimum financial resource requirements, including by conducting stress testing of its total financial resources once each day using standard predetermined parameters and assumptions; conducting a comprehensive analysis on at least a monthly basis of the existing stress testing scenarios, models, and underlying parameters and assumptions; and reporting the results of its analyses to appropriate decision makers at ICC. The proposed rule change continues to ensure that ICC's policies and procedures provide a clear framework for ICC to conduct stress testing and analysis and report the results to appropriate decision makers at ICC, in compliance with this requirement. As such, ICC believes the proposed rule change is consistent with the requirements of Rule 17Ad–22(e)(4)(vi).[13]

Rule 17Ad–22(e)(7)(i)[14] requires ICC to establish, implement, maintain, and enforce written policies and procedures reasonably designed to effectively measure, monitor, and manage the liquidity risk that arises in or is borne by it, including measuring, monitoring, and managing its settlement and funding flows on an ongoing and timely basis, and its use of intraday liquidity by maintaining sufficient liquid resources at the minimum in all relevant currencies to effect same-day and, where appropriate, intraday and multiday settlement of payment obligations with a high degree of confidence under a wide range of foreseeable stress scenarios that includes, but is not limited to, the default of the participant family that would generate the largest aggregate payment obligation for ICC in extreme but plausible market conditions. The introduction of the COVID–19/Oil Crisis Spread Scenarios would complement the current scenarios and add additional insight into potential weaknesses in the ICC liquidity risk management methodology, thereby supporting ICC's ability to ensure that it maintains sufficient liquidity resources. The proposed clarification and clean-up changes provide further clarity and transparency regarding ICC's liquidity risk management practices in the LRMF, including by promoting uniformity with the STF, ensuring consistency between the LRMF and the ICC Rules regarding the client-related liquidity requirements, and ensuring that information and references are current, including in Table 1 which sets out the liquidity stress testing scenarios. As such, the proposed amendments would promote ICC's ability to ensure that it maintains sufficient liquid resources in accordance with the requirements of Rule 17Ad–22(e)(7)(i).[15]

(B) Clearing Agency's Statement on Burden on Competition

ICC does not believe the proposed rule change would have any impact, or impose any burden, on competition. The proposed changes introduce complementing COVID–19/Oil Crisis Spread Scenarios, add clarification on the existing stress scenarios related to index options, and make other minor edits, which ICC believes are appropriate in furtherance of the risk management of the clearing house. The changes to the STF and LRMF will apply uniformly across all market participants. ICC does not believe these amendments would affect the costs of clearing or the ability of market participants to access clearing. Therefore, ICC does not believe the proposed rule change would impose any burden on competition that is inappropriate in furtherance of the purposes of the Act.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments relating to the proposed rule change have not been solicited or received. ICC will notify the Commission of any written comments received by ICC.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) by order approve or disapprove such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

[8] *Id.*

[9] 17 CFR 240.17Ad–22.

[10] 17 CFR 240.17Ad–22(e)(4)(ii).

[11] *Id.*

[12] 17 CFR 240.17Ad–22(e)(4)(vi).

[13] *Id.*

[14] 17 CFR 240.17Ad–22(e)(7)(i).

[15] *Id.*

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–ICC–2022–008 on the subject line.

Paper Comments

Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

All submissions should refer to File Number SR–ICC–2022–008. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filings will also be available for inspection and copying at the principal office of ICE Clear Credit and on ICE Clear Credit's website at *https://www.theice.com/clear-credit/regulation.*

All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–ICC–2022–008 and should be submitted on or before August 1, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–14634 Filed 7–8–22; 8:45 am]

BILLING CODE 8011–01–P

[16] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–649; OMB Control No. 3235–0701]

Proposed Collection; Comment Request; Extension: Rule 18a–1

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (''PRA'') (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the existing collection of information provided for in Rule 18a–1 (17 CFR 240.18a–1), under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*) (''Exchange Act''). The Commission plans to submit this existing collection of information to the Office of Management and Budget (''OMB'') for extension and approval.

Rule 18a–1 establishes net capital requirements for nonbank security-based swap dealers that are not also broker-dealers registered with the Commission (''stand-alone SBSDs''). First, under paragraphs (a)(2) and (d) of Rule 18a–1, a stand-alone SBSD may apply to the Commission to be authorized to use internal value-at-risk (''VaR) models to compute net capital, and a stand-alone SBSD authorized to use internal models must review and update the models it uses to compute market and credit risk, as well as back-test the models. Second, under paragraph (f) of Rule 18a–1, a stand-alone SBSD is required to comply with certain requirements of Exchange Act Rule 15c3–4 (17 CFR 240.15c3–4). Rule 15c3–4 requires OTC derivatives dealers and firms subject to its provisions to establish, document, and maintain a system of internal risk management controls to assist the firm in managing the risks associated with business activities, including market, credit, leverage, liquidity, legal, and operational risks. Third, for purposes of calculating ''haircuts'' on credit default swaps, paragraph (c)(1)(vi)(B)(1)(*iii*) of Rule 18a–1 requires stand-alone SBSDs that are not using internal models to use an industry sector classification system that is documented and reasonable in terms of grouping types of companies with similar business activities and risk characteristics. Fourth, under paragraph (h) of Rule 18a–1, stand-alone SBSDs are required to provide the Commission with certain written notices with respect to equity withdrawals. Fifth, under paragraph (c)(5) of Appendix D to Rule 18a–1 (17 CFR 240.18a–1d), stand-alone SBSDs are required to file with the Commission two copies of any proposed subordinated loan agreement (including nonconforming subordinated loan agreements) at least 30 days prior to the proposed execution date of the agreement. Finally, under paragraph (c)(1)(ix)(C) of Rule 18a–1, a nonbank SBSD may treat collateral held by a third-party custodian to meet an initial margin requirement of a security-based swap or swap customer as being held by the nonbank SBSD for purposes of the capital in lieu of margin charge provisions of the rule if certain conditions are met. In particular, the SBSD must execute an account control agreement and must maintain written documentation of its analysis that in the event of a legal challenge the account control agreement would be held to be legal, valid, binding, and enforceable under the applicable law.

The aggregate annual burden for all respondents is estimated to be 21,024 hours. The aggregate annual cost burden for all respondents is estimated to be $2,598,500.

Written comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's estimates of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted by September 9, 2022.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

Please direct your written comments to: David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington,

DC 20549, or send an email to: *PRA_Mailbox@sec.gov.*

Dated: July 5, 2022.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–14635 Filed 7–8–22; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95196; File Nos. SR–NYSE–2021–67, SR–NYSEAMER–2021–43, SR–NYSEArca–2021–97, SR–NYSECHX–2021–17, SR–NYSENAT–2021–23]

Self-Regulatory Organizations; New York Stock Exchange LLC, NYSE American LLC, NYSE Arca, Inc., NYSE Chicago, Inc., and NYSE National, Inc.; Notice of Withdrawal of Proposed Rule Changes To Amend Their Respective Fee Schedules To Offer Colocation Users Wireless Connectivity to CME Group Data and Establish Associated Fees

July 5, 2022.

On November 3, 2021, New York Stock Exchange LLC (''NYSE''), NYSE American LLC, NYSE Arca, Inc., NYSE Chicago, Inc., and NYSE National, Inc. (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 (''Exchange Act'' or ''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend their respective fee schedules for colocation services to offer wireless connectivity to CME Group, Inc. (''CME Group'') market data (''CME Group Data'') and establish associated fees. Each proposed rule change was 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 November 18, 2021.[4]

On December 17, 2021, the Division of Trading and Markets, acting on behalf of the Commission by delegated authority, issued an order instituting proceedings under Section 19(b)(2)(B) of the Act [5] to determine whether to approve or disapprove the proposed rule changes.[6] On May 12, 2022, pursuant to Section 19(b)(2) of the Act,[7] the Commission designated a longer period for Commission action on the proceedings to determine whether to approve or disapprove the proposed rule changes.[8]

On June 30, 2022, the Exchanges withdrew their respective proposed rule changes (File Nos. SR–NYSE–2021–67, SR–NYSEAMER–2021–43, SR–NYSEArca–2021–97, SR–NYSECHX–2021–17, SR–NYSENAT–2021–23).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[9]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–14636 Filed 7–8–22; 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).

[4] *See* Securities Exchange Act Release Nos. 93563 (November 12, 2021), 86 FR 64561 (November 18, 2021) (SR–NYSE–2021–67) (''Notice''); 93561 (November 12, 2021), 86 FR 64580 (November 18, 2021) (SR–NYSEAMER–2021–43); 93564 (November 12, 2021), 86 FR 64570 (November 18, 2021) (SR–NYSEArca–2021–97); 93565 (November 12, 2021), 86 FR 64556 (November 18, 2021) (SR–NYSECHX–2021–17); and 93567 (November 12, 2021), 86 FR 64576 (November 18, 2021) (SR–NYSENAT–2021–23). Comments received on the Notices are available on the Commission's website at: *https://www.sec.gov/comments/sr-nyse-2021-67/srnyse202167.htm.* For ease of reference, citations to the Notice(s) are to the Notice for SR–NYSE–2021–67.

[5] 15 U.S.C. 78s(b)(2)(B).

[6] *See* Securities Exchange Act Release No. 93810 (December 17, 2021), 86 FR 73026 (December 23, 2021).

[7] 15 U.S.C. 78s(b)(2).

[8] *See* Securities Exchange Act Release No. 94899 (May 12, 2022), 87 FR 30321 (May 18, 2022). The Commission designated July 16, 2022, as the date by which it should approve or disapprove the proposed rule changes.

[9] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95197; File No. SR–DTC–2022–007]

Self-Regulatory Organizations; The Depository Trust Company; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Reorganizations Service Guide

July 5, 2022.

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 June 28, 2022, The Depository Trust Company (''DTC'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the clearing agency. DTC filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act [3] and Rule 19b–4(f)(4) thereunder.[4] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change [5] consists of amendments to the Guide to provide Participants with the option to submit voluntary reorganizations instructions via Application Program Interface (''API'') and ISO 20022 real-time messaging (collectively, ''Automated Instruction Messaging'') for Automated Subscription Offer Program (''ASOP'')-eligible offers (each, an ''ASOP Offer'') [6] and for Automated Puts System (''APUT'')-eligible offers (each, an ''APUT Offer''),[7] and to make technical and ministerial changes to the Guide, as discussed more fully below.

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the clearing agency 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 clearing agency has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend the Guide to provide Participants with the option to submit voluntary reorganizations instructions via Automated Instruction Messaging for ASOP Offers and APUT Offers, and to make technical and ministerial

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(4).

[5] Each term not otherwise defined herein has its respective meaning as set forth in the Rules, By-Laws and Organization Certificate of DTC (the ''Rules'') and the Reorganizations Service Guide (the ''Guide''), *available at http://www.dtcc.com/legal/rules-and-procedures.aspx.*

[6] When an agent makes a rights offer through ASOP, a Participant can submit instructions to DTC for transmission to the agent, surrender its rights to the agent's account at DTC, and have its DTC account debited for the associated subscription payment. When the underlying securities are distributed by the agent, DTC credits the securities to the account of the Participant.

[7] A Participant can submit instructions to DTC for the exercise of payment, retainment and relinquishment options on put options securities for transmission to the agent, surrender its put securities to the agent's account at DTC and have its DTC account credited with the payment. APUT allows agents to review and reconcile all the instructions that were made for an offer.

changes to the Guide, as discussed more fully below.

(i) Automated Instruction Messaging

A. Background

When an issuer or agent announces an ASOP Offer, it communicates the details of the offer to DTC, which announces the ASOP Offer to its Participants in accordance with the Guide and applicable Rules. Participants then relay the information to their clients, which, in turn, relay the information to their clients, and so forth, down to the investor level. For example, the ASOP Offer information flows from the issuer/agent to DTC, DTC to Participant, Participant to Investor Manager client, Investment Manager to its investor clients. Each level of the chain solicits and compiles instructions from its clients and submits the instructions back up the chain, until the instructions reach the Participant level. Each Participant compiles and aggregates all instructions received from its clients and submits the instructions to DTC through the PTS PSOP or PBS Rights Subscriptions functions via nonautomated key entry.[8] The whole process needs to be completed before the expiration date and time of the ASOP Offer.[9]

There are certain potential risks and costs associated with manual processing, particularly in connection with voluntary reorganizations instructions. Nonautomated input may increase the likelihood of errors, which can result in rejected instructions or erroneous elections. Rejected instructions and erroneous elections can delay the submission of the instructions for voluntary offers, which typically have to be submitted within a short timeframe. Further, because information about a voluntary offer and the compilation and transmission of instructions flows across different market segments, the lack of automation and standardization can also lead to errors along the chain.

Therefore, DTC is proposing to provide Participants with the ability to use Automated Instruction Messaging via ISO 20022 messages and API functionality for ASOP Offers and APUT Offers.

The functionality for the submission of instructions through standardized ISO 20022 messaging already exists at DTC. Currently, Participants have the option to submit instructions using ISO 20022 messaging for Automated Tender Offer Program (''ATOP'')-eligible voluntary reorganizations offers (each, an ''ATOP Offer'').[10] ISO 20022 is a standard that provides the financial industry with a common language to capture business transactions and associated message flows. The benefits offered by ISO 20022 include, but are not limited to: (i) greater straight through processing by utilizing a data model that conforms to market practice and (ii) improved accuracy and less processing risk due to enhanced data elements.

DTC already offers API functionality for the submission of certain instructions to DTC.[11] For example, Participants can currently engage with the DTC ClaimConnect service via APIs.[12] APIs enable the flow of information between computer applications and provide Participants the ability to easily access and evaluate customer data as well as provide Participants with callable endpoints for deleting data resources and for reading and updating data resource values. Stated another way, APIs provides enhanced flexibility for Participants, making the process of accessing from, and transmitting information to, DTC and its downstream customers more efficient. The flexibility of APIs and its use of modern programming languages provide benefits that include, but are not limited to: (i) less frequent maintenance, (ii) client development and implementation can be quicker to market, and (iii) more efficient integration channels.

B. Automated Instruction Messaging

Pursuant to the proposed rule change, Automated Instruction Messaging would be available for the following actions for ASOP Offers: (i) Accepting an ASOP-Eligible Offer, (ii) Accepting an ASOP-Eligible Offer via Notice of Guaranteed Delivery, and (iii) Submitting a Cover of Protect. Automated Instruction Messaging would also be available for the following action for APUT Offers: Accepting an APUT-Eligible Offer.

Automated Instruction Messaging for the ASOP Offers and APUT Offers would consist of (i) Automated Instruction Messages for the input of instructions and (ii) Automated Response Messages for feedback and status output with respect to submitted instructions. The ISO 20022 Corporate Action Instruction (CAIN) message and the API POST function are Automated Instruction Messages. The ISO 20022 Corporate Action Instruction Status Advice (CAIS) message and the API GET function are Automated Response Messages.

The ISO 20022 Automated Instruction Messages and ISO 20022 Automated Response Messages would be available in Q2 of 2022 for the actions referenced above. The API Automated Instruction Messages and API Automated Response Messages would be available in Q3 of 2022 for the actions referenced above.

As noted above, automating instructions for ASOP Offers and APUT Offers would streamline the flow of information, reducing the costs, errors and risks that are associated with nonautomated processing. Accordingly, pursuant to the proposed rule change, DTC would provide Participants with the ability to automate and standardize the submission of instructions for ASOP Offers and APUT Offers through Automated Instruction Messaging.

(ii) Proposed Rule Changes

Pursuant to the proposed rule change, DTC is proposing to:

1. Add references to ''Automated Instruction Messaging'' or ''Automated Instruction Message,'' as context requires, where other types of instruction input for ASOP Offers (*e.g.,* PTS PSOP/PBS Rights Subscription) and/or for APUT Offers (*e.g.,* PTS PUTS/PBS Put Option Bonds) are referenced.

2. Add references to ''Automated Response Message'' where other types of responses and/or status reports relating to instructions on ASOP Offers (*e.g.,*

[8] PTS (Participant Terminal System) and PBS (Participant Browser System) are user interfaces for DTC settlement and asset services functions. PTS is mainframe-based, and PBS is web-based with a mainframe back-end. Participants may use either PTS or PBS, as they are functionally equivalent. PSOP and Rights Subscriptions are functions of PTS and PBS, respectively, that are currently used by Participants to submit instructions, submit protects, submit cover of protects, submit cover of protects on behalf of another Participant, and submit withdrawals on various subscription events through ASOP. PUTS and Put Bond Options are functions of PTS and PBS, respectively, that are currently used by Participants to exercise put options.

[9] The process is substantially similar for APUT Offers.

[10] *See* Guide, *supra* note 5, at 12. *See also* Securities Exchange Act Release No. 92339 (July 7, 2021), 86 FR 36810 (July 13, 2021) (SR–DTC–2021–010) (''ATOP Automated Messaging Filing'').

[11] The ATOP Automated Messaging Filing also provided for certain API functionality for ATOP Offers. However, DTC has not yet implemented this API functionality. Pursuant to the proposed rule change, the implementation of API functionality for ATOP Offers (as described in the ATOP Automated Messaging Filing) would be implemented at the same time as the implementation of API functionality for ASOP Offers and APUT Offers in Q3 of 2022. This proposed rule change does not apply to the following ATOP actions: (1) Withdrawal/Cancellation and (2) Submitting a Cover of Protect on Behalf of Another Participant, nor (3) to the ASOP action of Submitting a Cover of Protect on Behalf of Another Participant. DTC anticipates that Automated Instruction Messaging for these actions would be available in Q4 of 2022/Q1 of 2023, subject to regulatory approval.

[12] *See* ClaimConnect Service Guide, p.8, *available at http://www.dtcc.com/legal/rules-and-procedures.aspx.*

PTS/PBS, CA Web or Participant Daily Activity Statement) are referenced.

3. Add references to ''a field within Automated Instruction Messaging'' where a field or comments box on the PTS PSOP/PBS Subscriptions screen is referenced.

4. Amend the Guide to reflect that when a Participant uses an Automated Instruction Message, it must check its Automated Response Message, in order to ensure that its transactions were properly processed and recorded, and to note that a Participant could additionally check its Participant Daily Activity Statement and the CA Web.

5. Amend the Guide to reflect that input errors for Automated Instruction Messaging entries would be reported via Automated Response Message.

6. In the ''Automated Instruction Messaging'' Section:

a. Add an asterisk to the title and, as a footnote, insert the sentence ''API functionality for the referenced ATOP, ASOP, and APUT actions would be available in Q3 of 2022.''

b. Add a note that ''Withdrawals for Puts (Survivor Options only) must be performed via PTS/PBS, and cannot be instructed via Automated Instruction Message.''

c. Insert a list of the actions for ASOP Offers for which Automated Instruction Messaging is available, which would be: Accepting an ASOP-Eligible Offer, Accepting an ASOP-Eligible Offer via Notice of Guaranteed Delivery, and Submitting a Cover of Protect.

d. Insert language to reflect that Automated Instruction Messaging would be available for the action ''Accepting an APUT-Eligible Offer'' for APUT Offers.

7. In the ''About the Service'' subsection of the ''Puts'' section, clarify that Participants use the Puts program for APUT-eligible offers, and that Participants can use PTS/PBS functions or Automated Instruction Messaging in connection with the Puts program.

8. In the ''Exercising Put Options'' subsection of ''Puts'' section, clarify that Participants should use PTS PUTS/PBS Put Options Bonds or Automated Instruction Messaging for put options that have an offer to purchase with no withdrawal privilege, and that they should use PTS PTOP/PBS Voluntary Tenders and Exchanges or Automated Instruction Messaging for put options that have an offer to purchase with a withdrawal privilege.

9. In the ''Subscription Instructions'' subsection of the ''About DTC's Automated Subscription Offer Program (ASOP)'' section, insert language to reflect that when a Participant is accepting a right offer by surrendering rights or by Notice of Guaranteed Delivery, Participants instructing via PTS PSOP or PBS Rights Subscriptions can combine up to 12 separate customer reference instructions, and to add that Participants instructing via Automated Instruction Messaging would be able to combine up to 99 separate customer reference instructions into one Automated Instruction Message.

10. In the ''Checklist for Submitting an Acceptance'' subsection of the ''Accepting an ASOP-Eligible Offer'' section, amend the ''Note:'' to add that when a Participant transmits via Automated Instruction Messaging, it can combine up to 99 separate customer reference instructions into one Automated Instruction Message.

11. In the ''Checklist for Submitting a Protect'' section, insert the following language to address how a Participant needs to acknowledge the Notice of Guaranteed Delivery when it transmits an acceptance by Notice of Guaranteed Delivery via Automated Instruction Messaging: ''Likewise, when you transmit an acceptance via Automated Instruction Messaging, you will be required to acknowledge the Notice of Guaranteed Delivery required by the offer identified by the CUSIP you specify in your acceptance. The message must contain your acknowledgement. If your message does not contain your acknowledgement, your acceptance will be rejected. By acknowledging the Notice of Guaranteed Delivery via Automated Instruction Messaging, you agree that (i) you have received, and will be bound by the terms of, the Notice of Guaranteed Delivery required by the offer identified in the acceptance and (ii) the agreement set forth in the preceding clause (i) may be enforced against you by the Offeror in such offer.''

12. In the ''Checklist for Submitting a Cover of Protect via PTS PSOP, or PBS Rights Subscriptions'' section, insert the following language to address how a Participant needs to acknowledge the Subscription Form when it transmits a cover of protect via Automated Instruction Messaging: ''Likewise, when you transmit an instruction to cover a protect via Automated Instruction Messaging, you will be required to acknowledge the Subscription Form required by the offer identified by the CUSIP you specify in your instruction. The message must contain your acknowledgment. If you do not submit your acknowledgement, your instruction will be rejected. By submitting the acknowledgment via Automated Instruction Messaging, you agree that (i) you have received, and will be bound by the terms of, the Subscription Form required by the offer identified in your instruction and (ii) the agreement set forth in the preceding clause (i) may be enforced against you by the Offeror in such offer.''

13. In the ''Checklist for Submitting Sell Instructions'' subsection of the ''Surrendering Rights for Sale via ASOP'' section, insert the following language to address how a Participant needs to acknowledge the Subscription Form when it transmits sell instructions: ''Likewise, when you transmit sell instructions via Automated Instruction Messaging, you will be required to acknowledge the Subscription Form required by the offer identified by the CUSIP you specify in your acceptance. If your message does not contain your acknowledgment, your acceptance will be rejected. By acknowledging the Subscription Form via Automated Instruction Messaging, you agree that (i) you have received, and will be bound by the terms of the Subscription Form required by the offer identified in the acceptance and (ii) the agreement set forth in the preceding clause (i) may be enforced against you by the Offeror in such offer.''

14. Add a reference to ''Automated Instruction Messaging'' to the following section headings: ''Submitting a Cover of Protect via PTS PSOP or PBS Rights Subscriptions for an ASOP-Eligible Offer,'' and ''Checklist for Submitting a Cover of Protect via PTS PSOP or PBS Rights Subscriptions.''

15. Make ministerial changes to correct typos and omissions and to enhance conformity and readability, including, but not limited to:

a. Deleting footnote 1 as redundant.

b. Adding the name of the corresponding PBS function where the equivalent PTS function is referenced.

c. Augmenting mentions of PBS and PTS functions with their full technical names.

d. Inserting references to the CA Web to correctly reflect that a Participant can check the CA Web, in addition to its Participant Daily Activity Statement and Automated Response Messages, to ensure that its transactions were properly processed and recorded.

e. Inserting references to ISO 20022 messaging and the CA Web to correctly reflect them as sources of ASOP Offer details.

f. Inserting references to ISO 20022 messages to reflect them as source for a Participant to receive information about its reorganization account and subaccount activities.

g. Stating that Participants that subscribe to the ISO 20022 Instructions Statement Report (CAST) or Automated Response Messages would be able to

verify instructions status on the message.

h. Enhancing clarity and readability.

i. Correcting typographical errors.

2. Statutory Basis

Section 17A(b)(3)(F) of the Act requires, in part, that the Rules be designed to promote the prompt and accurate clearance and settlement of securities transactions.[13]

The proposed rule change would amend the Guide to provide Participants with the option to use Automated Instruction Messaging for ASOP Offers and APUT Offers. As discussed above, the use of Automated Instruction Messaging for ASOP Offers and APUT Offers would provide greater straight-through processing, improved accuracy, more efficient integration channels and less processing risk than nonautomated processing.

DTC believes that the proposed rule change to amend the Guide to make technical and clarifying changes would enhance the clarity and transparency of the Guide. By enhancing the clarity and transparency of the Guide, the proposed rule change would allow Participants to more efficiently and effectively conduct their business in connection with processing reorganization events and associated securities transactions.

Based on the foregoing, DTC believes that the proposed rule change is designed to promote the prompt and accurate clearance and settlement of securities transactions, consistent with Section 17A(b)(3)(F) of the Act, cited above.

(B) Clearing Agency's Statement on Burden on Competition

DTC believes that the proposed rule change to provide Participants with the option to use Automated Instruction Messaging for ASOP Offers and APUT Offers would not have any impact on competition. Because Automated Instruction Messaging would be an optional service that would be available to all Participants in connection with ASOP Offers and APUT Offers, DTC does not believe that the proposed rule change would impose a burden on competition.[14] In addition, DTC believes that the proposed rule change to make technical and ministerial changes to the Guide, would not have any impact on competition because it would merely enhance the clarity of the procedures relating to ASOP Offers and APUT Offers. In light of the foregoing, DTC does not believe that the proposed rule changes would impose a burden on competition.[15]

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

DTC has not received or solicited any written comments relating to this proposal. If any written comments are received, they would be publicly filed as an Exhibit 2 to this filing, as required by Form 19b–4 and the General Instructions thereto.

Persons submitting comments are cautioned that, according to Section IV (Solicitation of Comments) of the Exhibit 1A in the General Instructions to Form 19b–4, the Commission does not edit personal identifying information from comment submissions. Commenters should submit only information that they wish to make available publicly, including their name, email address, and any other identifying information.

All prospective commenters should follow the Commission's instructions on how to submit comments, *available at https://www.sec.gov/regulatory-actions/how-to-submit-comments.* General questions regarding the rule filing process or logistical questions regarding this filing should be directed to the Main Office of the Commission's Division of Trading and Markets at *tradingandmarkets@sec.gov* or 202–551–5777.

DTC reserves the right to not respond to any comments received.

III. Date of Effectiveness of the Proposed Rule Change, and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)[16] of the Act and paragraph (f)[17] of Rule 19b–4 thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act.

Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–DTC–2022–007 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

All submissions should refer to File Number SR–DTC–2022–007. 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 DTC and on DTCC's website (*http://dtcc.com/legal/sec-rule-filings.aspx*). 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–DTC–2022–007 and should be submitted on or before August 1, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–14633 Filed 7–8–22; 8:45 am]

BILLING CODE 8011–01–P

[13] 15 U.S.C. 78q–1(b)(3)(F).

[14] 15 U.S.C. 78q–1(b)(3)(I).

[15] *Id.*

[16] 15 U.S.C. 78s(b)(3)(A).

[17] 17 CFR 240.19b–4(f).

[18] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

[License No. 02/02–0698]

Star Mountain SBIC Fund, LP; Notice Seeking Exemption Under Section 312 of the Small Business Investment Act, Conflicts of Interest

Notice is hereby given that Star Mountain SBIC Fund, LP, 2 Grand Central Tower, 140 East 45th Street, 37th Floor, New York, NY 10017, a Federal Licensee under the Small Business Investment Act of 1958, as amended (''the Act''), in connection with the financing of a small concern, has sought an exemption under Section 312 of the Act and Section 107.730, Financings which Constitute Conflicts of Interest of the Small Business Administration (''SBA'') Rules and Regulations (13 CFR 107.730). Star Mountain SBIC Fund, L.P. is providing a financing to Southern Ag Carriers, Inc., 3422 Sylvester Rd., Albany, GA 31703.

The financing is brought within the purview of § 107.730(a)(4) of the Regulations because Star Mountain SBIC Fund, LP is providing a financing to Southern Ag Carriers, Inc. that will be used, in part, to discharge an obligation to an Associate. Therefore, this transaction is considered financing a Small Business to discharge an obligation to its Associate, requiring a prior SBA exemption and pre-financing SBA approval.

Notice is hereby given that any interested person may submit written comments on the transaction, within fifteen days of the date of this publication, to the Associate Administrator, Office of Investment and Innovation, U.S. Small Business Administration, 409 Third Street SW, Washington, DC 20416.

U.S. Small Business Administration.

Bailey G. DeVries,

Associate Administrator, Office of Investment and Innovation.

[FR Doc. 2022–14656 Filed 7–8–22; 8:45 am]

BILLING CODE P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #17501 and #17502; Illinois Disaster Number IL–00069]

Administrative Declaration of a Disaster for the State of Illinois

AGENCY: Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Administrative declaration of a disaster for the State of Illinois dated 07/05/2022.

Incident: Condominium Complex Fire.

Incident Period: 05/30/2022.

DATES: Issued on 07/05/2022.

Physical Loan Application Deadline Date: 09/06/2022.

Economic Injury (EIDL) Loan Application Deadline Date: 04/05/2023.

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 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: Cook.

Contiguous Counties:

Illinois: Dupage, Kane, Lake, Mchenry, Will.

Indiana: Lake.

The Interest Rates are:

	Percent
For Physical Damage:	
Homeowners with Credit Available Elsewhere	3.375
Homeowners without Credit Available Elsewhere	1.688
Businesses with Credit Available Elsewhere	5.870
Businesses without Credit Available Elsewhere	2.935
Non-Profit Organizations with Credit Available Elsewhere	1.875
Non-Profit Organizations without Credit Available Elsewhere	1.875
For Economic Injury:	
Businesses & Small Agricultural Cooperatives without Credit Available Elsewhere	2.935
Non-Profit Organizations without Credit Available Elsewhere	1.875

The number assigned to this disaster for physical damage is 17501 5 and for economic injury is 17502 0.

The States which received an EIDL Declaration # is Illinois, Indiana.

(Catalog of Federal Domestic Assistance Number 59008)

Isabella Guzman,

Administrator.

[FR Doc. 2022–14657 Filed 7–8–22; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #17499 and #17500; Oklahoma Disaster Number OK–00157]

Presidential Declaration of a Major Disaster for the State of Oklahoma

AGENCY: Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for the State of Oklahoma (FEMA–4657–DR), dated 06/29/2022.

Incident: Severe Storms, Tornadoes, and Flooding.

Incident Period: 05/02/2022 through 05/08/2022.

DATES: Issued on 06/29/2022.

Physical Loan Application Deadline Date: 08/29/2022.

Economic Injury (EIDL) Loan Application Deadline Date: 03/29/2023.

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 06/29/2022, 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): Adair, Cherokee, Muskogee, Okmulgee, Pottawatomie, Seminole, Tulsa.

Contiguous Counties (Economic Injury Loans Only):

Oklahoma: Cleveland, Creek, Delaware, Haskell, Hughes, Lincoln, Mayes, McClain, Mcintosh, Okfuskee, Oklahoma, Osage, Pawnee, Pontotoc, Rogers, Sequoyah, Wagoner, Washington.

Arkansas: Benton, Crawford, Washington.

The Interest Rates are:

	Percent
For Physical Damage:	
Homeowners with Credit Available Elsewhere	3.375
Homeowners without Credit Available Elsewhere	1.688
Businesses with Credit Available Elsewhere	5.870

	Percent
Businesses without Credit Available Elsewhere	2.935
Non-Profit Organizations with Credit Available Elsewhere	1.875
Non-Profit Organizations without Credit Available Elsewhere	1.875
For Economic Injury:	
Businesses & Small Agricultural Cooperatives without Credit Available Elsewhere	2.935
Non-Profit Organizations without Credit Available Elsewhere	1.875

The number assigned to this disaster for physical damage is 17499 C and for economic injury is 17500 0.

(Catalog of Federal Domestic Assistance Number 59008)

Joshua Barnes,

Acting Associate Administrator for Disaster Assistance.

[FR Doc. 2022–14658 Filed 7–8–22; 8:45 am]

BILLING CODE 8026–09–P

DEPARTMENT OF STATE

[Public Notice 11782]

60-Day Notice of Proposed Information Collection: Employee Self-Certification and Ability To Perform in Emergencies (ESCAPE) Posts, Pre-Deployment Physical Exam Acknowledgement Form

ACTION: Notice of request for public comment.

SUMMARY: The Department of State is seeking Office of Management and Budget (OMB) approval for the information collection described below. In accordance with the Paperwork Reduction Act of 1995, we are requesting comments on this collection from all interested individuals and organizations. The purpose of this notice is to allow 60 days for public comment preceding submission of the collection to OMB.

DATES: The Department will accept comments from the public up to September 9, 2022.

ADDRESSES: Include any address that the public needs to know, such as: attending a public hearing or meeting, examining any material available for public inspection. For public comments, use the following text:

You may submit comments by any of the following methods:

- *Web:* Persons with access to the internet may comment on this notice by going to *www.Regulations.gov.* You can search for the document by entering ''Docket Number: DOS–2022–0018'' in the Search field. Then click the ''Comment Now'' button and complete the comment form.
- *Email: Yellandmj@state.gov.*
- *Regular Mail:* Send written comments to: Medical Director, Office of Medical Clearances, Bureau of Medical Services, 2401 E Street NW, SA–1, Room H–242, Washington, DC 20522–0101.
- *Fax:* 202–647–0292 Attention: Medical Clearance Director.

You must include the DS form number (if applicable), information collection title, and the OMB control number in any correspondence.

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed collection instrument and supporting documents, to Office of Medical Clearances, Bureau of Medical Services, 2401 E Street NW, SA–1, Room H–242, Washington, DC 20522–0101, and who may be reached at 202–663–1657 or at *yellandmj@state.gov.*

SUPPLEMENTARY INFORMATION:

- *Title of Information Collection:* Employee Self-Certification and Ability to Perform in Emergencies (ESCAPE) Posts, Pre-Deployment Physical Exam Acknowledgement Form.
- *OMB Control Number:* 1405–0224.
- *Type of Request:* Revision of a Currently Approved Collection.
- *Originating Office:* Bureau of Medical Services; MED/CP/CL.
- *Form Number:* DS–6570.
- *Respondents:* Contractors deploying to ESCAPE Diplomatic Missions requesting access to the Department of State Medical Program (currently Afghanistan, Iraq, Libya Somalia, Syria, Yemen and Peshawar in Pakistan.
- *Estimated Number of Respondents:* 1,900.
- *Estimated Number of Responses:* 1,900.
- *Average Time per Response:* 40 minutes.
- *Total Estimated Burden Time:* 1,266.
- *Frequency:* Annually for those deployed to an ESCAPE post.
- *Obligation to Respond:* Required to Obtain or Retain a Benefit.

We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary for the proper functions of the Department.
- Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of Proposed Collection

The DS–6570 is completed by an individual and their medical provider to declare that the individual has health concerns that may represent a safety hazard for the individual or others at an ESCAPE Diplomatic Mission. ESCAPE is an acronym used to describe Diplomatic Missions overseas that are in extremely high threat, potentially combat, areas. Current ESCAPE Missions are Iraq, Afghanistan, Somalia, Libya, Yemen, Syria and Peshawar, Pakistan. This program is authorized under the Foreign Service Act of 1980, as implemented by the Department in 13 FAM 301.4–5.

Methodology

The respondent will obtain the DS–6570 from his or her human resources representative or will download the form from a Department website. The respondent will complete and submit the form offline.

Kevin E. Bryant,

Deputy Director, Office of Directives Management, U.S. Department of State.

[FR Doc. 2022–14724 Filed 7–8–22; 8:45 am]

BILLING CODE 4710–36–P

SURFACE TRANSPORTATION BOARD

[Docket No. AB 55 (Sub-No. 807X); Docket No. AB 364 (Sub-No. 17X)]

CSX Transportation, Inc.—Abandonment Exemption—in Muskegon County, Mich.; Michigan Shore Railroad Division, Mid-Michigan Railroad, Inc.—Discontinuance of Service Exemption—in Muskegon County, Mich.

CSX Transportation, Inc. (CSXT), and Michigan Shore Railroad division, Mid-Michigan Railroad, Inc. (MMRR) (collectively, Applicants), have jointly filed a verified notice of exemption under 49 CFR part 1152 subpart F—*Exempt Abandonments & Discontinuances of Service* for CSXT to

abandon, and MMRR to discontinue service over, an approximately 3.81-mile rail line that runs between milepost CGCS 56.35 and milepost CGCS 60.16 on the South Horn Spur in Muskegon County, Mich. (the Line). CSXT is the owner of the Line, and MMRR is the lessee of the Line. The Line traverses U.S. Postal Service Zip Code 49441.

Applicants have certified that: (1) no local traffic has moved over the Line for at least two years; (2) as the Line is not a through line, no overhead traffic has moved over the Line and therefore no traffic needs to be rerouted; (3) no formal complaint filed by a user of rail service on the Line (or by a state or local government entity acting on behalf of such user) regarding cessation of service over the Line either is pending with the Surface Transportation Board (Board) or with any U.S. District Court or has been decided in favor of complainant within the two-year period; and (4) the requirements at 49 CFR 1105.7 and 1105.8 (notice of environmental and historic report), 49 CFR 1105.12 (newspaper publication), and 49 CFR 1152.50(d)(1) (notice to governmental agencies) have been met.

As a condition to these exemptions, any employee adversely affected by the abandonment and discontinuance of service shall be protected under *Oregon Short Line Railroad—Abandonment Portion Goshen Branch Between Firth & Ammon, in Bingham & Bonneville Counties, Idaho,* 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10502(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) has been received,[1] the exemptions will be effective on August 10, 2022, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues,[2] formal expressions of intent to file an OFA under 49 CFR 1152.27(c)(2), and interim trail use/rail banking requests under 49 CFR 1152.29 must be filed by July 21, 2022.[3] Petitions to reopen and requests for public use conditions under 49 CFR 1152.28 must be filed by August 1, 2022.

All pleadings, referring to Docket Nos. AB 55 (Sub-No. 807X) and AB 364 (Sub-No. 17X), must be filed with the Surface Transportation Board via e-filing on the Board's website or in writing addressed to 395 E Street SW, Washington, DC 20423–0001. In addition, a copy of each pleading must be served on CSXT's representative, Louis E. Gitomer, Law Offices of Louis E. Gitomer, LLC, 600 Baltimore Avenue, Suite 301, Towson, MD 21204, and MMRR's representative, Eric M. Hocky, Clark Hill PLC, 2001 Market Street, Suite 2610, Philadelphia, PA 19103.

If the verified notice contains false or misleading information, the exemptions are void ab initio.

Applicants have filed a combined environmental and historic report that addresses the potential effects, if any, of the abandonment on the environment and historic resources. OEA will issue a Draft Environmental Assessment (Draft EA) by July 15, 2022. The Draft EA will be available to interested persons on the Board's website, by writing to OEA, or by calling OEA at (202) 245–0294. Assistance for the hearing impaired is available through the Federal Relay Service at (800) 877–8339. Comments on environmental and historic preservation matters must be filed within 15 days after the Draft EA becomes available to the public.

Environmental, historic preservation, public use, or interim trail use/rail banking conditions will be imposed, where appropriate, in a subsequent decision.

Pursuant to the provisions of 49 CFR 1152.29(e)(2), CSXT shall file a notice of consummation with the Board to signify that it has exercised the abandonment authority granted and fully abandoned the Line. If consummation has not been effected by CSXT's filing of a notice of consummation by July 11, 2023, and there are no legal or regulatory barriers to consummation, the authority to abandon will automatically expire.

Board decisions and notices are available at *www.stb.gov.*

Decided: July 6, 2022.

By the Board, Mai T. Dinh, Director, Office of Proceedings.

Kenyatta Clay,

Clearance Clerk.

[FR Doc. 2022–14711 Filed 7–8–22; 8:45 am]

BILLING CODE 4915–01–P

[1] Persons interested in submitting an OFA must first file a formal expression of intent to file an offer, indicating the type of financial assistance they wish to provide (*i.e.,* subsidy or purchase) and demonstrating that they are preliminarily financially responsible. *See* 49 CFR 1152.27(c)(2)(i).

[2] The Board will grant a stay if an informed decision on environmental issues (whether raised by a party or by the Board's Office of Environmental Analysis (OEA) in its independent investigation) cannot be made before the exemptions' effective date. *See Exemption of Out-of-Serv. Rail Lines,* 5 I.C.C.2d 377 (1989). Any request for a stay should be filed as soon as possible so that the Board may take appropriate action before the exemptions' effective date.

[3] Filing fees for OFAs and trail use requests can be found at 49 CFR 1002.2(f)(25) and (27), respectively.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. 2022–0176]

Agency Information Collection Activities: Requests for Comments; Clearance of Renewal Approval of Information Collection 2120–0776, Airspace Authorizations in Controlled Airspace

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew Information Collection 2120–0776. The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on February 18, 2022. The FAA proposes renewal of the collection of information related to requests to operate small Unmanned Aircraft Systems (sUAS) in controlled airspace. FAA will use the collected information to make determinations whether to authorize or deny the requested authorization of sUAS operation in controlled airspace. The proposed information collection is necessary to issue such authorizations or denials consistent with the FAA's mandate to ensure safe and efficient use of national airspace.

DATES: Written comments should be submitted by August 10, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Victoria Gallagher by email at: *Victoria.Gallagher@faa.gov;* phone: 609–485–5127.

SUPPLEMENTARY INFORMATION: The FAA received three comments from the public. Two were supportive. The first was anonymous and expressed approval of the collection. The second supportive comment was from Airlines for America, which noted that the collection of such information can be used in furtherance of the FAA's regulatory approach for the seamless

integration of UAS operations in the National Airspace System (NAS). Airlines for America commented that FAA must ensure adequate safety precautions to avoid collisions of UAS with manned aircraft and that the proposed collection will help identify compliant from noncompliant operations and further this safety model.

The final comment was from the Air Line Pilots Association, International (ALPA), which commented that the collection of information to process authorization requests has not been subject to sufficient safety risk evaluation and therefore cannot be fully determined whether the information collected is adequate to verify if safe operations can be conducted. Further, ALPA commented that it believes the FAA's current minimum requirements for information in a Low Altitude Authorization and Notification Capability (LAANC) application are not sufficient. According to ALPA, additional information including aircraft registration, make and model information, and post-flight information should be collected. In this Information Collection renewal request, the FAA proposes to use LAANC and the web portal to collect information that provides a means for small UAS operators operating under § 44809 to comply with § 44809's established requirements and safety processes. This proposed information collection is sufficient to meet safety standards and captures essential information.

ALPA also commented that the FAA has not determined through its Safety Management System process the risk that UAS operating in controlled airspace introduce to the NAS and, therefore, ALPA is unable to determine if the information collected is adequate. This second category of comments is substantially the same as comments that ALPA submitted in response to Information Collection 2120–0768's 60 Day Notice published on February 12, 2018 (83 FR 6082) and to the Notice of Proposed Rule Making that was eventually implemented as a final rule at 81 FR 42063 on June 28, 2016 and codified as 14 CFR part 107. The FAA analyzed the proposed information to be collected under § 44809 and determined that the information is adequate for the FAA to meet safety standards.

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: 2120–0776.

Title: Airspace Authorizations in Controlled Airspace under 49 U.S.C. 44809(a)(5).

Form Numbers: There are no forms associated with this collection.

Type of Review: Renewal of existing Information Collection.

Background: There has been an increased number of small UAS operating in the NAS in recent years, and regulations and statutes have been enacted to establish the use of small UAS in the NAS. Included in these is 49 U.S.C. 44809(a)(5), which states that a strictly recreational user of small UAS must have authorization from the FAA to fly a small UAS ''in Class B, Class C, or Class D airspace or within the lateral boundaries of the surface areas of Class E airspace designated for an airport.'' In order to process airspace authorization requests, the FAA requires the operator's name, the operator's contact information, and information related to the date, place, and time of the requested authorization, which can be up to twelve hours in length. This information is necessary for the FAA to meet its statutory mandate of maintaining a safe and efficient national airspace. See 49 U.S.C. 40103, 44701, and 44807. The FAA will use the requested information to determine if the proposed authorization to operate can be conducted safely.

The FAA proposes to use LAANC and an FAA web portal to process authorization requests from the public to conduct flight operations under 49 U.S.C. 44809(a)(5).

Respondents: Small UAS operators seeking to conduct flight operations under 49 U.S.C. 44809(a)(5) within controlled airspace. Between 2022–2025, the FAA estimates that it will receive a total of 757,380 requests for airspace authorization (735,416 through LAANC and 21,964 through the web portal).

Frequency: The requested information is necessary each time a respondent requests an airspace authorization to operate a small UAS under 49 U.S.C. 44809(a)(5) in controlled airspace.

Estimated Average Burden per Response: The FAA estimates the respondents using LAANC will take five (5) minutes per airspace authorization request and those using the web portal will take thirty (30) minutes per request.

Estimated Total Annual Burden: For airspace authorizations, the FAA estimates that the average annual burden will be 24,089 burden hours. This includes 20,428 burden hours for 245,139 LAANC respondents and 3,661 burden hours for 7,321 web portal respondents.

Issued in Washington, DC, on July, 5 2022.

Victoria Gallagher,

UAS LAANC Program Manager, AJM–337.

[FR Doc. 2022–14640 Filed 7–8–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Acceptance of a Noise Exposure Map and Review of a Noise Compatibility Program

AGENCY: Federal Aviation Administration, DOT.

SUMMARY: The Federal Aviation Administration (FAA) announces its determination that the noise exposure map submitted by the Port Authority of New York and New Jersey for LaGuardia Airport is in compliance with applicable statutory and regulatory requirements, see **SUPPLEMENTARY INFORMATION** for details. Further, in conjunction with the noise exposure map, FAA is reviewing the proposed noise compatibility program for LaGuardia Airport, which the FAA will approve or disapprove on or before January 2, 2023. This notice also announces the availability of this noise compatibility program for public review and comment.

DATES: The effective date of the FAA's determination on the noise exposure map is June 16, 2022 and of the start of its review of the associated noise compatibility program is July 6, 2022. The public comment period ends September 4, 2022.

FOR FURTHER INFORMATION CONTACT: Andrew Brooks, Regional Environmental Program Manager, Airports Division, Federal Aviation Administration, 1 Aviation Plaza, Room 516, Jamaica, NY 11434. Phone Number: 718–553–2511. Comments on the proposed noise compatibility program should also be submitted to the above office.

SUPPLEMENTARY INFORMATION: This notice announces that the FAA finds that the revised 2021 noise exposure map (NEM) submitted for LaGuardia Airport is in compliance with applicable requirements of Title 14, Code of Federal Regulations (CFR) part 150, (14 CFR part 150) effective June 16, 2022. Further, FAA is reviewing a proposed noise compatibility program

(NCP) for LaGuardia Airport which will be approved or disapproved on or before January 2, 2023. This notice also announces the availability of this program for public review and comment. Per the Aviation Safety and Noise Abatement Act of 1979, hereinafter referred to as ''the Act'' (also see 49 U.S.C. 47503), an airport operator may submit to the FAA NEMs which meet applicable regulations and which depict non-compatible land uses as of the date of submission of such maps, a description of projected aircraft operations, and the ways in which such operations will affect such maps. The Act requires such maps to be developed in consultation with interested and affected parties in the local community, government agencies, and persons using the airport.

An airport operator who has submitted NEMs that are found by FAA to be in compliance with the requirements of 14 CFR part 150, may submit a NCP for FAA approval which sets forth the measures the operator has taken or proposes to take to reduce existing non-compatible uses and prevent the introduction of additional non-compatible uses.

The Port Authority of New York and New Jersey submitted to the FAA on June 15, 2022 a revised ''With Program'' 2021 NEM, descriptions and other documentation that were produced during the development of the ''LaGuardia Airport Title 14 Code of Federal Regulations (CFR) Part 150 Noise Compatibility Program'' (NCP Report), dated June 2022. The revised ''With Program'' 2021 NEM was submitted to show changes made to the LaGuardia Airport 2021 NEM previously accepted by the Federal Aviation Administration on May 15, 2017 (Noise Exposure Map Notice for LaGuardia Airport, New York City, New York, volume 82, **Federal Register**, pages 22714–5, May 15, 2017). The revisions to the previously approved 2021 NEM depict changes to noise contours from implementation of noise abatement measures contained within the associated NCP. It was requested that the FAA review this material as the NEM, as described in 49 U.S.C. 47503 of the Act, and that the noise mitigation measures, to be implemented jointly by the airport and surrounding communities, be approved as a NCP under 49 U.S.C. 47504.

The FAA has completed its review of the revised ''With Program'' 2021 NEM and related descriptions submitted by The Port Authority of New York and New Jersey. The documentation that constitutes the NEM as defined in 14 CFR 150.7 is the revised ''With Program'' 2021 Future Year NEM, Map 1 of 6, located in Appendix I–2 of the NCP Report. The NEMs contain current and forecast information including the depiction of the airport and its boundaries, the runway configurations, land uses such as single and two-family residential; multi-family residential; mixed residential and commercial; commercial and office; industrial and manufacturing; transportation, parking and utilities; unclassified; vacant land; open space, cemeteries, and outdoor recreation; places of worship; schools; historic structures; and day care/assisted living facilities and those areas within the Day Night Average Sound Level (DNL) 65, 70 and 75 decibel noise contours. The revised ''With Program'' 2021 NEM reflects the previous implementation of noise abatement measure 1 from the noise compatibility program. Accordingly, all estimates for the non-compatible land area and residential populations within these contours for the revised ''With Program'' 2021 noise exposure map are shown in Table 3–2 in Chapter 3 of the NCP Report. The estimates of land use within these contours for the revised ''With Program'' 2021 noise exposure map are shown in Table 2–4 of Chapter 2 of the NCP Report. Flight tracks are found in Maps 2 of 6 through 6 of 6 in Appendix I–2. The type and frequency of aircraft operations (including nighttime operations) are found in Chapter 2, Tables 2–1, 2–2, and 2–3.

The FAA has determined that these maps for LaGuardia Airport are in compliance with applicable requirements. This determination is effective on June 16, 2022. FAA's determination on an airport operator's NEMs is limited to a finding that the maps were developed in accordance with the procedures contained in appendix A of 14 CFR part 150. Such determination does not constitute approval of the applicant's data, information or plans, or constitute a commitment to approve a NCP or to fund the implementation of that program.

If questions arise concerning the precise relationship of specific properties to noise exposure contours depicted on a NEM submitted under 49 U.S.C. 47503, it should be noted that the FAA is not involved in any way in determining the relative locations of specific properties with regard to the depicted noise contours, or in interpreting the NEMs to resolve questions concerning, for example, which properties should be covered by the provisions of 49 U.S.C. 47506. These functions are inseparable from the ultimate land use control and planning responsibilities of local government. These local responsibilities are not changed in any way under 14 CFR part 150 or through FAA's review of NEMs. Therefore, the responsibility for the detailed overlaying of noise exposure contours onto the map depicting properties on the surface rests exclusively with the airport operator that submitted those maps, or with those public agencies and planning agencies with which consultation is required under 49 U.S.C. 47503. The FAA has relied on the certification by the airport operator, under 14 CFR 150.21, that the statutorily required consultation has been accomplished.

The FAA has formally received the NCP for LaGuardia Airport, also submitted on June 15, 2022. Preliminary review of the submitted material indicates that it conforms to the requirements for the submittal of NCPs, but that further review will be necessary prior to approval or disapproval of the program for LaGuardia Airport. The formal review period, limited by law to a maximum of 180 days, was initiated on July 6, 2022 and will be completed on or before January 2, 2023.

The FAA's detailed evaluation will be conducted under the provisions of 14 CFR 150.33. The primary considerations in the evaluation process are whether the proposed measures may reduce the level of aviation safety, create an undue burden on interstate or foreign commerce, or be reasonably consistent with obtaining the goal of reducing existing non-compatible land uses and preventing the introduction of additional non-compatible land uses.

Interested persons are invited to comment on the proposed program with specific reference to these factors. All comments, other than those properly addressed to local land use authorities, will be considered by the FAA to the extent practicable. Copies of the NEMs for LaGuardia Airport, the FAA's evaluation of the maps, and the proposed NCP for LaGuardia Airport are available for examination online at *http://panynjpart150.com/LGA_FNCP.asp.*

The Port Authority of New York and New Jersey has also made a hard copy of the document available for review at the LaGuardia Airport Community Information Center, 98–12 Astoria Boulevard, East Elmhurst, NY 11369. The document will be available for review from Monday to Thursday between the hours of 10 a.m. and 4 p.m. Interested parties should contact Raquel Moss at (718) 607–2297 to arrange for a review.

Questions regarding this notice may be directed to the individual named

above under the heading, **FOR FURTHER INFORMATION CONTACT.**

Issued in Jamaica, NY, on July 6, 2022.

David A. Fish,

Director, Airports Division, Eastern Region.

[FR Doc. 2022–14694 Filed 7–8–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FRA–2022–0923]

Agency Information Collection Activities: Requests for Comments; Clearance of a Renewed Approval of Information Collection: Part 142, Certificated Training Centers

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The collection involves Certificated Training Centers. Operators pay Certificated Training Centers to provide training to their employees, typically pilots, on different types of equipment if training is not done in house. The information to be collected is necessary because it allows aviation safety inspectors (operations) to review and to provide surveillance to training centers to ensure compliance with airman training, testing, and certification requirements specified in other parts of the regulations. If the information were not collected, inspectors would not be able to determine if airmen who are clients are being trained, checked or tested to meet the safety standards established in other parts of the regulations. To date, FAA inspectors have used the information collected to determine and assess regulatory compliance during routine program surveillance.

DATES: Written comments should be submitted by September 9, 2022.

ADDRESSES: Please send written comments:

By Electronic Docket: www.regulations.gov (Enter docket number into search field).

By mail: Sandra L. Ray, 1187 Thorn Run Road, Suite 200, Coraopolis, PA 15108.

By fax: 412–239–3063.

FOR FURTHER INFORMATION CONTACT: Sandra Ray by email at: *Sandra.ray@faa.gov;* phone: 412–329–3088.

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: 2120–0570.

Title: Part 142, Certificated Training Centers.

Form Numbers: None.

Type of Review: Renewal of an information collection.

Background: Part 142 Flight Schools are subject to several collection requirements. 14 CFR part 142 is one of several Federal Regulation parts that implement the Public Law. Section 142.11 provides that application for a training center certificate and training specifications shall be made in a form and manner prescribed by the Administrator, shall provide specific information about each management, instructor position, and evaluator position, and contain certain other administrative information.

Section 142.37 provides that application for approval of training programs must be in a form and manner acceptable to the Administrator, and must provide specific information about curriculum and courses of the training program.

Chapter 447, Section 44701 of Title 49, United States Code, provides, in pertinent part, that the Administrator may find, after investigation, that a person found to possess proper qualifications for a position as an airman may be issued such certificate. That certificate shall contain such terms, conditions, and limitations as to duration thereof, as well as periodic or special examinations, and other matters as the Administrator may determine to be necessary to assure safety in air commerce.

Section 142.73 requires that training centers maintain records for a period of one year to show trainee qualifications for training, testing, or checking, training attempts, training checking, and testing results, and for one year following termination of employment the qualification of instructors and evaluators providing those services.

The respondents may be the Part 142 schools, Part 121 or 135 air carriers who utilize these schools or new applicants seeking Part 142 certification. The information may be collected in electronic forms. No specific forms are required. Information reporting may be done in accordance with the individual FAA office.

Respondents: Part 142 schools, Part 121 and 135 carriers and new certifications.

Frequency: On occasion.

Estimated Average Burden per Response: Varies per requirement.

Estimated Total Annual Burden: 87,112 hours.

Issued in Washington, DC, on July 5, 2022.

Sandra L. Ray,

Aviation Safety Inspector, AFS–260.

[FR Doc. 2022–14632 Filed 7–8–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2021–0158]

Agency Information Collection Activities; Renewal of a Currently Approved Information Collection: Motor Carrier Identification Report

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FMCSA announces its plan to submit the Information Collection Request (ICR) described below to the Office of Management and Budget (OMB) for its review and approval and invites public comment. FMCSA requests approval to renew an ICR titled, ''Motor Carrier Identification Report,'' which is used to identify FMCSA regulated entities, help prioritize the agency's activities, aid in assessing the safety outcomes of those activities, and for statistical purposes. This ICR is necessary to ensure regulated entities are registered with the DOT.

DATES: Comments on this notice must be received on or before August 10, 2022.

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 information collection by selecting ''Currently under 30-day Review—Open for Public

Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Mr. Jeffrey Secrist, Office of Registration and Safety Information, DOT, FMCSA, West Building 6th Floor, 1200 New Jersey Avenue SE, Washington, DC 20590, 202–385–2367, *Jeffrey.secrist@dot.gov.*

SUPPLEMENTARY INFORMATION:

Title: Motor Carrier Identification Report.

OMB Control Number: 2126–0013.

Type of Request: Renewal of a currently approved collection.

Respondents: Motor carriers, freight forwarders, intermodal equipment providers, brokers, motor carriers with hazardous materials (HM) safety permit, cargo tank facilities and Mexican motor carriers.

Estimated Number of Respondents: 416,630 respondents [412,479 respondents for IC–1 + 2,112 respondents for IC–2 + 2,039 respondents for IC–3 = 416,630].

Estimated Time per Response: IC–1: 20 minutes for new filings and 7.5 minutes for biennial updates and changes to complete the Form MCS–150. IC–2: 26 minutes for new filings and five minutes for biennial updates and changes to complete the Form MCS–150B. IC–3: 20 minutes for new filings and 7.5 minutes for biennial updates and changes to complete the Form MCS–150C.

Expiration Date: July 31, 2022.

Frequency of Response: On occasion and biennially.

Estimated Total Annual Burden: 116,072 hours [114,864 hours for IC–1 + 530 hours for IC–2 + 678 hours for IC–3 = 116,072 hours].

Background: Title 49, United States Code Section 504(b)(2) provides the Secretary of Transportation (Secretary) with authority to require carriers, lessors, associations, or classes of these entities to file annual, periodic, and special reports containing answers to questions asked by the Secretary. The Secretary may also prescribe the form of records required to be prepared or compiled and the time period during which records must be preserved (See § 504(b)(1) and (d)). FMCSA will use this data to administer its safety programs using a database of entities that are subject to its regulations. This database necessitates that these entities notify FMCSA of their existence. For example, under 49 CFR 390.19(a), FMCSA requires all motor carriers beginning operations to file a Form MCS–150 titled, ''Motor Carrier Identification Report,'' or MCS–150B titled, ''Combined Motor Carrier Identification Report and HM Permit Applications.'' This report is filed by all motor carriers conducting operations in interstate commerce, in intrastate commerce when transporting hazardous materials, or in international commerce before beginning operations. It asks the respondent to provide the name of the business entity that owns and controls the motor carrier operation; the address and telephone of its principal place of business; its assigned identification number(s), type of operation, and type(s) of cargo usually transported; number of vehicles owned, term leased, and trip leased; driver information; and a certification statement signed by an individual authorized to sign documents on behalf of the business entity.

Existing applicants will use the MCS–150 or MCS–150B to update their information in the Motor Carrier Management Information System. Applicants filing for the first time will be required to file online. Form MCS–150 or MCS–150B will be used for Mexico-domiciled carriers that seek authority to operate beyond the United States municipalities on the United States-Mexico border and their commercial zones. The information collected from the respondents is readily available to the public. This revised ICR captures the burden of continued use of the MCS–150 or MCS–150B for motor carriers updating their registration information and for the registration of Mexico-domiciled carriers.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including: (1) whether the proposed collection is necessary for the performance of FMCSA's functions; (2) the accuracy of the estimated burden; (3) ways for FMCSA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized without reducing the quality of the collected information.

Issued under the authority of 49 CFR 1.87.

Thomas P. Keane,

Associate Administrator, Office of Research and Registration.

[FR Doc. 2022–14629 Filed 7–8–22; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2021–0189]

Agency Information Collection Activities; Renewal of an Approved Information Collection: Hours of Service (HOS) of Drivers Regulations

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Federal Motor Carrier Safety Administration (FMCSA) announces its plan to submit the Information Collection Request (ICR) described below to the Office of Management and Budget (OMB) for its review and approval and invites public comment. FMCSA requests approval to renew an ICR titled, ''Hours of Service (HOS) of Drivers Regulations.'' The HOS regulations require a motor carrier to install, and requires each of its drivers subject to the record of duty status (RODS) rule to use, an electronic logging device (ELD) to report the driver's RODS. The RODS is critical to FMCSA's safety mission because it helps enforcement officials determine if commercial motor vehicle (CMV) drivers are complying with the HOS rules limiting driver on-duty and driving time and requiring periodic off-duty time.

DATES: Comments on this notice must be received on or before August 10, 2022.

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 information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Ms. Pearlie Robinson, FMCSA Driver and Carrier Operations Division, DOT, FMCSA, West Building 6th Floor, 1200 New Jersey Avenue SE, Washington, DC 20590, (202) 366–4225, *MCPSD@dot.gov.*

SUPPLEMENTARY INFORMATION:

Title: Hours of Service (HOS) of Drivers Regulations.

OMB Control Number: 2126–0001.

Type of Request: Renewal of an information collection.

Respondents: Motor Carriers of Property and Passengers, Drivers of CMVs.

Estimated Number of Respondents: 4.24 million CMV drivers; 602,542 Motor Carriers.

Estimated Time per Response: CMV drivers using technology: 2 minutes. Motor Carriers: 2 minutes.

Expiration Date: July 31, 2022.

Frequency of Response: Drivers: 240 days per year; Motor carriers 240 days per year.

Estimated Total Annual Burden: 50.37 million hours.

Background:

CMV drivers are limited in how long they may remain in an on-duty or driving status over specified periods of time. The regulations outlining those limits are found at 49 CFR part 395 and are known as the ''HOS regulations.'' The HOS regulations require a motor carrier to install, and requires each of its drivers subject to the RODS rule to use, an ELD to report the driver's RODS. These RODS are used to enforce compliance with the HOS regulations.

As a condition of receiving certain federal grants, States agree to adopt and enforce the Federal Motor Carrier Safety Regulations, including the HOS regulations, as State law. As a result, State enforcement inspectors use the RODS and supporting documents to determine whether CMV drivers are complying with the HOS regulations. In addition, FMCSA uses the RODS during on-site and offsite investigations of motor carriers and Federal and State courts rely upon the RODS as evidence of driver and motor carrier violations of the HOS regulations. This information collection supports DOT's Strategic Goal of Safety because the information helps the agency ensure the safe operation of CMVs in interstate commerce.

Renewal of This Information Collection (IC)

The current IC burden estimate of the HOS rules, approved by OMB on July 31, 2019, is 41.04 million hours. The expiration date of the current ICR is July 31, 2022. Through this ICR renewal, FMCSA requests a revision of the paperwork burden of 2126–0001. The Agency requests an increase in the burden hours from 41.04 million hours to 50.37 million hours. The increase is the result of the increase in estimated driver population as well as the increase in expected industry growth rate for drivers from 2020 to 2030. Two types of information are collected under this IC: (1) drivers' RODS commonly referred to as a logbook, and (2) supporting documents, such as gasoline and toll receipts, that motor carriers use to verify accuracy of RODS and document expense deductions for income tax filing purposes. The use of ELDs reduces the driver's time to input duty status from 6.5 minutes to 2 minutes. This IC includes only the estimate of 2 minutes for drivers and motor carriers.

On March 18, 2022, FMCSA published a 60-day notice in the **Federal Register** requesting public comments on the proposed revision of this information collection (87 FR 15488). The Agency received comments filed jointly by the Truck Safety Coalition (TSC), Citizens for Reliable and Safe Highways, and Parents Against Tired Truckers and their volunteers in support of this IC. The TSC wrote, ''Our organizations strongly support FMCSA's continuation of the collection Record of Duty Status (RODS) records from Electronic Logging Devices (ELDs) as well as the supporting documentation, to have the information needed to inform safety-oriented rulemaking and life-saving enforcement activities related to HOS.''

Public Comments Invited: You are asked to comment on any aspect of this information collection, including: (1) whether the proposed collection is necessary for the performance of FMCSA's functions; (2) the accuracy of the estimated burden; (3) ways for the FMCSA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized without reducing the quality of the information collected.

The Agency will summarize or include your comments in the request for OMB's clearance of this ICR.

Issued under the authority of 49 CFR 1.87.

Thomas P. Keane,

Associate Administrator, Office of Research and Registration.

[FR Doc. 2022–14628 Filed 7–8–22; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2022–0081]

Agency Information Collection Activities; Renewal of an Approved Information Collection: Safe Driver Apprenticeship Pilot Program

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FMCSA announces its plan to submit the information collection request (ICR) described below to the Office of Management and Budget (OMB) for its review and approval and invites public comment. FMCSA requests approval to renew the ICR titled ''Safe Driver Apprenticeship Pilot Program.'' This ICR was previously approved under emergency procedures on January 24, 2022 and expires on July 31, 2022. The ICR is necessary for FMCSA to conduct a pilot program to determine the safety impacts of allowing 18- to 20-year-old commercial driver's license (CDL) holders to operate commercial motor vehicles (CMVs) in interstate commerce. The ICR will cover data collected on drivers and carriers participating in the pilot program.

DATES: Please send your comments by August 10, 2022. OMB must receive your comments by this date in order to act quickly on the ICR.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Nicole Michel, Office of Analysis, Research, and Technology, Research Division, DOT, FMCSA, West Building, 6th Floor, 1200 New Jersey Avenue SE, Washington, DC 20590–0001. 202–366–4354; *Nicole.michel@dot.gov.* Office hours are from 9 a.m. to 5 p.m., Monday through Friday, except Federal Holidays.

SUPPLEMENTARY INFORMATION:

Background: Current regulations on driver qualifications (49 CFR part 391.11(b)(1)) state that a driver must be 21 years of age or older to operate a CMV in interstate commerce. Currently, drivers under the age of 21 may operate CMVs only in intrastate commerce subject to State laws and regulations. Section 23022 of the Infrastructure Investment and Jobs Act (IIJA), requires the Secretary of Transportation to conduct a commercial driver Apprenticeship Pilot Program. An apprentice is defined as a person under the age of 21 who holds a CDL. Under this program, these apprentices will complete two probationary periods, during which they may operate in interstate commerce only under the supervision of an experienced driver in the passenger seat. An experienced

driver is defined in section 23022 as a driver who is not younger than 26 years old, who has held a CDL and been employed for at least the past 2 years, who has at least 5 years of interstate CMV experience, and meets the other safety criteria defined in the IIJA.

The first probationary period must include at least 120 hours of on duty time, of which at least 80 hours are driving time in a CMV. To complete this probationary period, the employer must determine competency in:

1. Interstate, city traffic, rural 2-lane, and evening driving;
2. Safety awareness;
3. Speed and space management;
4. Lane control;
5. Mirror scanning;
6. Right and left turns; and
7. Logging and complying with rules relating to hours of service.

The second probationary period must include at least 280 hours of on-duty time, including not less than 160 hours driving time in a CMV. To complete this probationary period, the employer must determine competency in:

1. Backing and maneuvering in close quarters;
2. Pre-trip inspections;
3. Fueling procedures;
4. Weighing loads, weight distribution, and sliding tandems;
5. Coupling and uncoupling procedures; and
6. Trip planning, truck routes, map reading, navigation, and permits.

After completion of the second probationary period the apprentice may begin operating CMVs in interstate commerce unaccompanied by an experienced driver.

In addition to data regarding successful completion of the probationary periods, the IIJA requires collection of data relating to any incident in which a participating apprentice is involved as well as other data relating to the safety of apprentices. Additional data will include crash data (incident reports, police reports, insurance reports), inspection data, citation data, safety event data (as recorded by all safety systems installed on vehicles, to include advanced driver assistance systems, automatic emergency braking systems, onboard monitoring systems, and required forward-facing and in-cab video systems) as well as exposure data (record of duty status logs, on-duty time, driving time, and time spent away from home terminal). Additionally, carriers will be asked to report any additional or remedial training being given to participating drivers. This data will be submitted monthly by participating motor carriers. The data collected will be used to report on the following items, as required by section 23022:

1. The findings and conclusions on the ability of technologies or training provided to apprentices as part of the pilot program to successfully improve safety;
2. An analysis of the safety record of participating apprentices as compared to other CMV drivers;
3. The number of drivers that discontinued participation in the apprenticeship program before completion;
4. A comparison of the safety records of participating drivers before, during, and after each probationary period; and
5. A comparison of each participating driver's average on-duty time, driving time, and time spent away from home terminal before, during, and after each probationary period.

FMCSA will monitor the monthly data being reported by the motor carriers and will identify drivers or carriers that may pose a risk to public safety. While removing unsafe drivers or carriers may bias the dataset, it is a necessary feature for FMCSA to comply with § 381.505, which requires development of a monitoring plan to ensure adequate safeguards to protect the health and safety of pilot program participants and the general public. Knowing that a driver or carrier was removed from the pilot program for safety reasons will help FMCSA minimize bias in the final data analysis.

FMCSA and the Department of Labor's Employment and Training Agency (DOL/ETA) will be partnering in the implementation of the Safe Driver Apprenticeship Pilot (SDAP) Program. All motor carriers who are approved for the program by FMCSA will also be required to become Registered Apprenticeships (RAs) under 29 CFR part 29 before they can submit information on their experienced drivers and apprentices. The information collection burden for the DOL/ETA RA Program can be found in approved ICR 1205–0223.

The statutory mandate for this pilot program is contained in section 23022 of the IIJA. FMCSA's regulatory authority for initiation of a pilot program is found in 49 CFR 381.400. The SDAP program supports the DOT strategic goal of economic strength while maintaining DOT and FMCSA's commitment to safety.

Publication History: On January 7, 2022, FMCSA published a notice in the **Federal Register** seeking public comment on the emergency approval of this ICR (87 FR 1001). A total of 144 comments were received on that notice; you may find a discussion of these comments in the 60-day notice that published in the **Federal Register** (87 FR 23010).

On April 18, 2022, FMCSA published a 60-day notice in the **Federal Register**, announcing its intention to request that OMB renew the emergency information collection approval for a full 3-years. FMCSA received 16 comments in the docket for that notice. Of these, nine were comments on the ICR, and seven were misfiled comments on a separate notice issued by FMCSA. Of the nine comments on the ICR, four were submitted by individuals. The remaining three comments were filed by Samsara Inc., the American Trucking Associations (ATA), the Shippers Coalition, the American Property Casualty Insurance Association (APCIA), and jointly by the Truck Safety Coalition (TSC), Citizens for Reliable and Safe Highways (CRASH), and Parents Against Tired Truckers (PATT).

Comment Discussion: The comments received from the Shippers Coalition, ATA, Samsara, Inc., and two of the individuals supported the SDAP Program generally, and the information collection discussed in the 60-day notice. One of the individual commenters caveated his support by noting that both apprentice and experienced drivers must be thoroughly vetted for safety. The other individual questioned why the number of apprentice participants is being capped at 3,000. ATA commended FMCSA on clarifying the burden estimate and recommended that FMCSA re-consider other suggestions posed in their prior comment.

Response: FMCSA appreciates the support and will be ensuring a thorough vetting of participating motor carriers, experienced drivers, and apprentices. As to the number of participants, the IIJA limits the total number of apprentices in the program at any one time to 3000 (see IIJA § 23022(b)(4)). Regarding ATA's suggestion on minimizing burden for the monthly data collection, FMCSA is committed to working with participating carriers to ensure data is collected in a meaningful and least-burdensome method.

The comments submitted by the remaining two individuals focused on elements of or questions on the underlying SDAP Program and were not specific to the ICR. One of these individuals questioned who will insure the ''high risk young drivers.'' The other noted that he does not think the SDAP Program will help alleviate a truck driver shortage, stating that trucking companies will just mistreat young drivers the way they mistreat drivers

over the age of 21, resulting in more drivers leaving the profession.

Response: FMCSA is not in a position to answer the question about who will insure the apprentice drivers, but notes that any motor carrier wishing to participate in the SDAP Program will need to provide proof that their apprentice drivers are covered by a valid insurance policy, or that the motor carrier is a participant in FMCSA's self-insurance program. As to the comment regarding mistreatment of apprentice drivers, FMCSA notes that the requirements for RA programs under DOL regulations provide protection from the type of mistreatment the commenter discussed. This is one reason why FMCSA partnered with the DOL and is requiring that motor carriers participating in the SDAP Program also become Registered Apprenticeship participants.

APCIA's comment raised questions regarding the data FMCSA will collect and the data that FMCSA will use as comparison data. APCIA stated that FMCSA ''must show that participating drivers are no more likely than the current population of interstate commercial truck drivers [to] have highway accidents.'' APCIA also noted that the information collected should capture any additional training that individual motor carriers may add, on top of those required by the SDAP Program, and requested that the final public data set include detailed statistical information on the program's safety results, to aid insurers in making decisions in the future.

Response: While the APCIA has provided statistics on crash rates of younger drivers, one of the key components of this pilot program is to identify how a structured training and probationary period can enhance the safety of younger CMV operators, which can only be determined through conducting the pilot program. FMCSA agrees that it is important to collect information on any remedial or additional training that occurs and has included this information in the monthly data collection plan. FMCSA will publish all detailed statistics collected during the study provided no personally identifiable information is included.

Finally, TSC, CRASH, and PATT noted their opposition to the SDAP Program, and urged that FMCSA immediately terminate it. In the alternative, the commenters requested that FMCSA add several requirements to the SDAP Program, including: extending requirements for the technology that is required to be installed in a CMV past the probationary periods to the entirety of the apprenticeship; requiring both front- and rear-facing cameras; and requiring all participating motor carriers to agree to a compliance review or DOT audit within 18 months of acceptance into the SDAP Program. Additionally, Samsara, Inc. also recommended requiring both forward facing and in-cab camera views.

Response: FMCSA agrees with and accepts the requirement for both forward facing- and rear- (in-cab) facing cameras throughout the participation period of apprentices to be able to collect adequate safety data. Requiring additional technology, such as speed limiters or active braking mitigation devices past the probationary period could be prohibitive to smaller carriers wishing to participate, and therefore FMCSA has decided not to extend the technology requirements past what is in the IIJA. FMCSA will note that the adoption of these technologies is steadily increasing, and it is therefore likely that a large percentage of apprentices, if not all, will continue to utilize these technologies throughout their tenure in the program despite the lack of requirement. FMCSA will collect data on a monthly basis regarding which technologies are actively employed on the vehicles which apprentices are driving. FMCSA requiring a compliance review or DOT audit of up to 1,000 carriers participating in the program would detract resources from carriers who have been flagged for a compliance review or DOT audit due to safety-related reasons. This requirement is not feasible for FMCSA to implement at this time.

Title: Safe Driver Apprenticeship Pilot Program.

OMB Control Number: 2126–0075.

Type of Request: Renewal of an information collection previously approved under emergency authority.

Respondents: Motor carriers; drivers.

Estimated Number of Respondents: 14,830 total (1,600 motor carriers and 13,230 CMV drivers); 5,410 annually (1,000 carriers and 4,410 CMV drivers).

Estimated Time per Response: Application (motor carrier, apprentice driver, and experienced driver): 20 Minutes; safety benchmark certifications: 15 Minutes; monthly driving and safety data: 60 Minutes; miscellaneous data submission: 90 Minutes.

Expiration Date: July 31, 2022.

Frequency of Response: Application (motor carrier, apprentice driver, and experienced driver): Once; safety benchmark certifications: Twice for each apprentice driver; monthly driving and safety data: Monthly; miscellaneous data submissions: Monthly.

Estimated Total Annual Burden: 169,344 hours total, or 56,448 hours annually (motor carriers: 164,934 hours total, or 54,978 hours annually, which includes a one-time application, two safety benchmark certifications for each participating apprentice, and monthly driving and safety data on all participating apprentices as well as miscellaneous data submissions; drivers: 13,797 hours total, or 4,599 hours annually which includes a one-time application for experienced and apprentice drivers).

Definitions: N/A.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including: (1) Whether the proposed collection is necessary for the performance of FMCSA's functions; (2) the accuracy of the estimated burden; (3) ways for FMCSA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized without reducing the quality of the collected information. The Agency will summarize or include your comments in the request for OMB's clearance of this ICR.

Issued under the authority of 49 CFR 1.87.

Thomas P. Keane,

Associate Administrator, Office of Research and Registration.

[FR Doc. 2022–14626 Filed 7–8–22; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket No. FRA–2022–0002–N–11]

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice of information collection; request for comment.

SUMMARY: Under the Paperwork Reduction Act of 1995 (PRA) and its implementing regulations, this notice announces that FRA is forwarding the Information Collection Request (ICR) abstracted below to the Office of Management and Budget (OMB) for review and comment. The ICR describes the information collection and its expected burden. On April 1, 2022, FRA published a notice providing a 60-day period for public comment on the ICR.

DATES: Interested persons are invited to submit comments on or August 10, 2022.

ADDRESSES: Written comments and recommendations for the proposed ICR should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find the particular ICR by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Ms. Hodan Wells, Information Collection Clearance Officer, at email: *Hodan.Wells@dot.gov* or telephone: (202) 868–9412.

SUPPLEMENTARY INFORMATION: The PRA, 44 U.S.C. 3501–3520, and its implementing regulations, 5 CFR part 1320, require Federal agencies to issue two notices seeking public comment on information collection activities before OMB may approve paperwork packages. *See* 44 U.S.C. 3506, 3507; 5 CFR 1320.8 through 1320.12. On April 1, 2022, FRA published a 60-day notice in the **Federal Register** soliciting comment on the ICR for which it is now seeking OMB approval. *See* 87 FR 19176. FRA received one comment from the Association of American Railroads (AAR) related to the proposed collection of information.

In its comment letter, AAR expressed its concerns about the reliability of the data collected by the blocked crossing portal, noting the potential for the public to submit reports of trains moving through highway-rail grade crossings in the ordinary course of operations rather than of avoidable, blocked crossing incidents. AAR also noted that there is no mechanism in place to guard against individuals submitting multiple reports of a single event, asserting that a small number of people could repeatedly submit a high volume of complaints regarding trains at specific locations. Finally, AAR asserted that FRA failed take into account the paperwork burden imposed when FRA requests further information from a railroad as part of its blocked crossing investigation.

As referenced below, the Infrastructure Investment and Jobs Act, (Pub. L. 117–58), also known as the ''Bipartisan Infrastructure Law'' (BIL) requires that FRA maintain an online portal and corresponding database to receive information from the public regarding blocked highway-rail grade crossings. Section 22404(i) of BIL requires FRA to submit a report to Congress that discusses, among other things, whether FRA's blocked crossing portal continues to be an effective method to collect blocked crossing information, as well as changes that could be made to improve its effectiveness. On June 14, 2022, FRA published a request for information (RFI) in the **Federal Register**, soliciting comments on how FRA's engagement with affected parties and changes to the portal and related operations can improve the effectiveness of the portal. *See* 87 FR 36036. FRA encourages AAR and other affected parties to submit its suggestions on how to improve the effectiveness of the portal to the RFI docket.

FRA appreciates AAR's comments about the quality of the blocked crossing portal's collected data and seeks comments through the RFI on ways in which it can be improved. Before FRA follows up with a railroad on a reported blocked crossing, FRA reviews information available about the blocked crossing incident. If FRA determines that the blocked crossing arose because a train moved through a highway-rail grade crossing in the ordinary course of operations, FRA will not investigate the incident further. In addition, if FRA determines that the railroad had an operational justification for blocking the crossing, FRA will include this information in its records.

Since the introduction of the blocked crossing portal in 2020, FRA has streamlined its procedures for following-up with railroads in response to blocked crossing reports. In response to AAR feedback that FRA's inquiries were too onerous, FRA completes the majority of its follow-up requests after a brief phone call with the involved railroad or during stakeholder meetings. Additionally, FRA also recognizes that railroads may not collect the requested information and, in those circumstances, FRA considers the response of ''not known'' sufficient. Nonetheless, FRA agrees with AAR that it should adjust its estimated paperwork burdens to account for railroad responses to FRA's inquiries. Accordingly, FRA is updating its burden estimates in the re-published PRA table to better account for railroads' burdens in response to FRA's follow-up inquiries.

Before OMB decides whether to approve the proposed collection of information, it must provide 30 days for public comment. Federal law requires OMB to approve or disapprove paperwork packages between 30 and 60 days after the 30-day notice is published. 44 U.S.C. 3507(b)–(c); 5 CFR 1320.12(a); *see also* 60 FR 44978, 44983 (Aug. 29, 1995). OMB believes the 30-day notice informs the regulated community to file relevant comments and affords the agency adequate time to digest public comments before it renders a decision. 60 FR 44983 (Aug. 29, 1995). Therefore, respondents should submit their respective comments to OMB within 30 days of publication to best ensure having their full effect.

Comments are invited on the following ICR regarding: (1) whether the information collection activities are necessary for FRA to properly execute its functions, including whether the information will have practical utility; (2) the accuracy of FRA's estimates of the burden of the information collection activities, including the validity of the methodology and assumptions used to determine the estimates; (3) ways for FRA to enhance the quality, utility, and clarity of the information being collected; and (4) ways to minimize the burden of information collection activities on the public, including the use of automated collection techniques or other forms of information technology.

The summary below describes the ICR that FRA will submit for OMB clearance as the PRA requires:

Title: Inquiry into Blocked Highway-Rail Grade Crossings throughout the United States.

OMB Control Number: 2130–0630.

Abstract: In 2020, FRA created a dedicated website allowing the public and law enforcement personnel to use web-based forms to voluntarily submit information about blocked crossings to FRA.[1] Under the currently approved information collection request, users provide information regarding the location, date, time, duration, and immediate impacts of highway-rail grade crossings blocked by slow-moving or stationary trains. FRA uses the data collected to gain a more complete picture of where, when, for how long, and what impacts result from reported blocked crossing incidents.[2] Additionally, FRA uses the information to respond to congressional inquiries so that congressional staff can respond to their constituents. Furthermore, FRA uses the information gathered to facilitate meetings, outreach, and other solutions for stakeholders to reduce or eliminate blocked crossing concerns.

Upon accessing these web-based forms, users are notified there are no Federal laws or regulations that specifically address the length of time a

[1] Access to the web-based form used by the public is unrestricted. Access to the web-based form used by law enforcement personnel and first responders is restricted to law enforcement personnel with usernames and passwords managed by FRA.

[2] The data collection is not designed to provide a representative sample or create generalizable statistics. Additionally, the data gathered from this collection is not suitable for use in budgetary requests or regulatory proposals.

train may occupy a highway-rail grade crossing. Users are also notified that information submitted will not be forwarded to a railroad, State, or local agency, and will only being used for data collection purposes to determine the locations, times, and impacts of blocked crossings.

On November 15, 2021, the BIL was enacted. In addition to mandating that FRA establish an online portal and corresponding database to receive information regarding blocked highway-rail grade crossings, section 22404 of BIL ''encourages each complainant to report the blocked crossing to the relevant railroad.'' Therefore, in preparation for this new statutory mandate, FRA proposes to modify the existing web-based forms by adding one question, ''have you contacted the railroad?'' Otherwise, the rest of the questions on the web-based forms will remain the same.[3]

Currently, there are no Federal laws or regulations that specifically address how long a train may occupy a crossing, whether stationary or operating at slow speeds. Some States and local municipalities have laws that vary in how long trains are permitted to occupy crossings. However, there are legitimate operational reasons why trains may block grade crossings, including trains stopping for compliance with Federal regulatory requirements (such as required safety tests and inspections). Therefore, some courts have found that State laws and regulations that address how long trains may occupy grade crossings have the effect of regulating aspects of railroad operations currently regulated by FRA and are thus preempted by the Federal railroad safety statutes and regulations. (*See CSX Transp., Inc.* v. *City of Plymouth*, 283 F.3d 812 (6th Cir. 2002)). In addition, some courts have found State laws and regulations attempting to limit the time trains are permitted to occupy grade crossings to be preempted by the Interstate Commerce Commission Termination Act, which provides the Surface Transportation Board with broad jurisdiction over railroad operations. (See *Elam* v. *Kansas City So.*, 635 F.3d 796 (5th Cir. 2011)).

There are potential safety concerns with crossings that are blocked by trains. For instance, pedestrians may crawl under or through stationary trains. Also, emergency response vehicles and first responders may be delayed when responding to an incident or transporting persons to a hospital. In addition, drivers may take more risks, such as driving around lowered gates at a crossing or attempting to beat a train through a crossing without gates, in order to avoid a lengthy delay if they are aware that trains routinely block a crossing for extended periods of time. There are also potential economic impacts that affect businesses, such as stores or restaurants not being accessible to their customer base for an extended time period. Finally, highway-rail grade crossings that are blocked for extended time periods may create societal nuisances, such as roadway congestion, delayed mail service and deliveries, disrupted school and work arrival and dismissal, or missed appointments.

Type of Request: Revision of a currently approved collection.

Affected Public: Public individuals, law enforcement personnel, and first responders.

Form(s): FRA F 6180.175.

Respondent Universe: Public individuals, law enforcement personnel, and first responders.

Frequency of Submission: On occasion. *Reporting Burden:*

Section[4]	Total annual responses	Average time per response	Total annual burden hours	Total cost equivalent
	(A)	(B)	(C) = A * B	(D) = C * wage rate[5]
General public via the unrestricted form on the FRA website	15,500 responses	3 minutes	775	$20,925
Law enforcement personnel (including first responders) via the limited access form on the FRA website.	350 responses	3 minutes	17.5	895
Monthly meeting between FRA and Class I railroads on blocked crossings—Review of blocked crossings data from FRA's blocked crossings portal[6].	12 meetings and reviews.	20 hours	240	18,586
Total	15,862 responses	N/A	1,033	40,406

Total Estimated Annual Responses: 15,862.

Total Estimated Annual Burden: 1,033 hours.

Total Estimated Annual Burden Hour Dollar Cost Equivalent: $40,406.

FRA informs all interested parties that it may not conduct or sponsor, and a respondent is not required to respond to, a collection of information that does not display a currently valid OMB control number.

Authority: 44 U.S.C. 3501–3520.

Allison Ishihara Fultz,

Chief Counsel.

[FR Doc. 2022–14710 Filed 7–8–22; 8:45 am]

BILLING CODE 4910–06–P

[3] The average time per response will be remain at 3 minutes per response since the modification made under BIL requirement is *de minimis.*

[4] The current inventory exhibits a total burden of 250 hours while the total burden of this notice is 1,033 hours. The increase in burden hours is due to an anticipated increase in the number of responses.

[5] For the value of the public's time, FRA used an hourly rate of $27 per hour from the Department of Labor, Bureau of Labor Statistics (BLS). For law enforcement and first responder respondents, FRA used an hourly wage rate of $49.74 per hour that includes an average benefit rate of $20.87 from BLS' Occupational Employment Statistics (OES) 33–3000, classified within NAICS 999200, State Government—excluding schools and hospitals. See *https://www.bls.gov/oes/current/naics4_999200.htm.* For railroad respondents, FRA used an hourly wage rate of $77.44 that includes a 75-percent overhead charge from the Surface Transportation Board's 2020 Full Year Wage A&B data series for railroad workers.

[6] FRA adds this row in response to AAR's comments that FRA should account for railroads' estimated paperwork burdens in responding to FRA's follow-up inquiries on blocked crossings.

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

FY 2022 Competitive Funding Opportunity: Passenger Ferry Grant Program, Electric or Low-Emitting Ferry Pilot Program, and Ferry Service for Rural Communities Program

AGENCY: Federal Transit Administration (FTA), U.S. Department of Transportation (DOT).

ACTION: Notice of Funding Opportunity (NOFO).

SUMMARY: The Federal Transit Administration (FTA) announces the opportunity to apply for $294.5 million in competitive grants under the Fiscal Year (FY) 2022 Passenger Ferry Grant Program (Passenger Ferry Program), Electric or Low-Emitting Ferry Pilot Program (Low-No Ferry Program), and Ferry Service for Rural Communities Program (Rural Ferry Program). Of the amount being made available, $36.5 million is for the Passenger Ferry Program, $49 million is for the Low-No Ferry Program, and approximately $209 million is for the Rural Ferry Program. While applicants can choose to apply for only one grant program, this combined solicitation will allow applicants to submit one application to multiple programs. FTA may award additional funding made available to the program prior to the announcement of project selections.

DATES: Complete proposals must be submitted electronically through the *GRANTS.GOV* ''APPLY'' function by 11:59 p.m. Eastern time, September 6, 2022. Prospective applicants should initiate the process by promptly registering on the *GRANTS.GOV* website to ensure completion of the application process before the submission deadline. Instructions for applying can be found on FTA's website at *https://www.transit.dot.gov/funding/grants/applying/applying-fta-funding* and in the ''FIND'' module of *GRANTS.GOV*. The funding opportunity ID for the Passenger Ferry Program is FTA–2022–006–TPM–FERRY, the funding opportunity ID for the Electric or Low-Emitting Ferry Pilot Program is FTA–2022–007–TPM–FERRYPILOT, and the funding opportunity ID for the Rural Ferry Program is FTA–2022–008–TPM–FERRYRURAL. Mail and fax submissions will not be accepted.

FOR FURTHER INFORMATION CONTACT: *FTAFerryPrograms@dot.gov* or Vanessa Williams, FTA Office of Program Management, (202) 366–4818, or Sarah Clements, FTA Office of Program Management, (202) 366–3062.

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A. Program Description

This is a joint NOFO and announces the availability of FY 2022 funding for the Passenger Ferry Grant Program (Passenger Ferry Program), Electric or Low-Emitting Ferry Pilot Program (Low-No Ferry Program), and Ferry Service for Rural Communities Program (Rural Ferry Program). All programs can be found in Federal Assistance Listing: 20.532.

Federal public transportation law (49 U.S.C. 5307(h)) authorizes FTA to award grants for passenger ferries through a competitive process. The Passenger Ferry Program provides funding to designated recipients and direct recipients under FTA's Urbanized Area Formula Program, as well as public entities engaged in providing public transportation passenger ferry service in urban areas that are eligible to be direct recipients. Projects funded under the program will improve the condition and quality of existing passenger ferry services, support the establishment of new passenger ferry services, and repair and modernize ferry boats, terminals, and related facilities and equipment.

Section 71102 of the Bipartisan Infrastructure Law (BIL) (enacted as the Infrastructure Investment and Jobs Act, Pub. L. 117–58) authorizes FTA to award grants for electric or low-emitting ferries through a competitive process, as described in this notice. The Low-No Ferry Program is available to any eligible designated or direct recipient of FTA's Urbanized Area Formula Program or Formula Grants for Rural Areas funding, including States (including territories and Washington, DC), local governmental authorities, and tribal governments. Grants will be awarded under this program for the purchase of electric or low-emitting ferries, the electrification of or other reduction of emissions from existing ferries, and related charging or other fueling infrastructure (for which the applicants will maintain satisfactory continuing control) to reduce emissions or produce zero onboard emissions under normal operation.

Section 71103 of the BIL authorizes FTA to award grants for the Rural Ferry Program through a competitive process, as described in this notice. The Rural Ferry Program provides funding for capital, operating, and planning expenses to States and territories for ferry service to rural areas. Projects funded under this program will support ferry transportation service that operated a regular schedule at any time during the five-year period from March 1, 2015, to March 1, 2020, and includes at least one route segment of at least 50 sailing (nautical) miles between two rural areas. The Consolidated Appropriations Act, 2022 (Pub. L. 117–103) provided an additional $12,965,000 for ferry service that serves at least two rural areas with a single route segment over 20 miles between the two rural areas and is not otherwise eligible under the Passenger Ferry Program, meaning it does not serve an urbanized area.

FTA recognizes that passenger ferries provide critical and cost-effective transportation links throughout the United States but face a critical backlog of state of good repair and safety investments. These programs support FTA's priorities and objectives through investments that (1) renew our transit systems, (2) reduce greenhouse gas emissions from public transportation, (3) advance racial equity, (4) maintain and create good-paying jobs with a free and fair choice to join a union, and (5) connect communities. These programs will be implemented, as appropriate and consistent with law, in alignment with the priorities in Executive Order 14052, Implementation of the Infrastructure Investment and Jobs Act (86 FR 64355). In addition, this NOFO will advance the goals of the President's January 20, 2021, Executive Order 14008, Tackling the Climate Crisis at Home and Abroad and Executive Order 13985, Advancing Racial Equity and Support for Underserved Communities Through the Federal Government.

B. Federal Award Information

Federal public transportation law (49 U.S.C. 5307(h)) authorizes $30 million in FY 2022 contract authority funds for competitive grants under the Passenger Ferry Program. Additionally, the Consolidated Appropriations Act of 2022 appropriated an additional $6.5 million. Of that latter amount, $3.25 million is available only for low or zero-emission ferries or ferries using electric battery or fuel cell components and the infrastructure to support such ferries. FTA may award additional funding made available to the program prior to the announcement of project selections.

In FY 2021, FTA received 24 project proposals to the Passenger Ferry Program from 11 States and territories requesting $114 million in Federal funds. Eleven projects were funded at a total of $45.2 million, using a combination of funding from FY 2021 and funding remaining from prior year appropriations.

Division J of the BIL provides an advance appropriation of $50 million in FY 2022 funds for competitive grants under the Low-No Ferry Program. Of that amount $995,000 is for FTA oversight, $5,000 is transferred to the DOT Office of the Inspector General (OIG), and $49 million is available for award.

Division J of the BIL provides an advance appropriation of $200 million in FY 2022 funds for the Rural Ferry Program. Of that amount $3,980,000 is for FTA oversight, $20,000 is transferred to the OIG, and $196 million is available for award. Additionally, the FY 2022 Consolidated Appropriations Act appropriated an additional $12,965,000 that may be allocated to passenger ferry service that serves at least two rural areas with a single segment over 20 miles between the two rural areas and that is not otherwise eligible for funding under the Passenger Ferry Program.

FTA will grant pre-award authority to incur costs for selected projects beginning on the date the FY 2022 project selections are announced on FTA's website. Funds are available for obligation for five years after the fiscal year in which the awards are announced. Funds are available only for projects that have not already incurred costs prior to the announcement of project selections.

C. Eligibility Information

1. Eligible Applicants

SUMMARY TABLE

Program	Eligible applicants
Passenger Ferry Program	1. Designated Recipients of Section 5307 Funding. 2. Direct Recipients of Section 5307 Funding. 3. Public Entities engaged in providing public transportation passenger ferry service in urban areas that are eligible to be a Direct Recipient.
Low-No Ferry Program	1. Designated Recipients of Section 5307 Funding. 2. Direct Recipients of Section 5307 Funding. 3. Public Entities engaged in providing public transportation passenger ferry service in urban areas that are eligible to be a Direct Recipient. 4. States and Territories. 5. Tribal Governments.
Rural Ferry Program	1. States and Territories.

Eligible applicants for the Passenger Ferry Program are: (1) designated recipients as defined in FTA Circular ''Urbanized Area Formula Program: Program Guidance and Application Instructions'' (FTA.C.9030.1E) and (2) direct recipients of FTA's Urbanized Area Formula Grants, as well as public entities engaged in providing public transportation passenger ferry service in urban areas that are eligible to be direct recipients.

Eligible applicants for the Low-No Ferry Program are any eligible recipient of Section 5307 or Section 5311 funding. Eligible Section 5307 recipients are the same as for the Passenger Ferry Program: (1) designated recipients as defined in FTA Circular ''Urbanized Area Formula Program: Program Guidance and Application Instructions'' (FTA.C.9030.1E) and (2) direct recipients of FTA's Urbanized Area Formula Grants, as well as public entities engaged in providing public transportation passenger ferry service in urban areas that are eligible to be direct recipients. Eligible Section 5311 recipients are States or Territories or Tribal governments. In addition, as required by statute, before the conclusion of the grant competition that utilizes FY 2026 funds, FTA must select: (1) at least one project from a ferry service that serves the State with the largest number of Marine Highway System miles, and (2) at least one project for a bi-State ferry service with an aging fleet and whose development of zero- and low-emission power source ferries will propose to advance the state of the technology toward increasing the range and capacity of zero-emission power source ferries. If an applicant's ferry service operates in the State with the largest number of Marine Highway System miles or is a bi-State ferry service (a ferry service that serves two states) with an aging fleet and whose development of zero- and low-emission power source ferries will propose to advance the state of the technology toward increasing the range and capacity of zero-emission power source ferries, the applicant must identify themselves as such and submit documentation demonstrating those operating characteristics.

Eligible applicants for the Rural Ferry Program are States and Territories in which eligible service is operated. For the $196 million made available under Division J of the BIL, eligible service includes passenger ferry service that operated a regular schedule at any time between March 1, 2015, and March 1, 2020, and operated at least one segment between two rural areas located more than 50 sailing (nautical) miles apart. FTA defines a regular schedule as a published schedule for either seasonal or annual ferry service. For the $12,965,000 appropriated in the Consolidated Appropriations Act, 2022, eligible service also includes any passenger ferry service that operated a regular schedule at any time between March 1, 2015, and March 1, 2020, and operated at least one segment more than 20 sailing (nautical) miles between two rural areas. Applicants must document their eligibility for the Rural Ferry Program by providing the following:

(A) Documentation such as dated and published sailing schedules to demonstrate the operation of regular scheduled service at any time during the five-year period ending March 1, 2020.

(B) Documentation such as route maps to demonstrate provision of service for at least one direct segment between two rural areas that meet the distance requirements described above (either at least 50 or 20 nautical sailing miles) during the five-year period ending March 1, 2020.

FTA will confirm the segment length based upon data reported to the National Census of Ferry Operators maintained by the Bureau of Transportation Statistics.

An eligible applicant that does not currently have an active grant with FTA will, upon selection, be required to work with an FTA regional office to establish its organization as an active grant recipient. This process may require additional documentation to support the organization's technical, financial, and legal capacity to receive and administer Federal funds under this program.

2. Cost Sharing or Matching

a. The maximum Federal share for capital projects selected under each program is 80 percent of the net project cost, with the exceptions described in paragraphs b and c below, per 49 U.S.C. 5323. The maximum Federal share for operating projects selected under the Rural Ferry Program is 50 percent. The maximum Federal share for planning projects selected under the Rural Ferry Program is 80 percent.

b. The maximum Federal share is 85 percent of the net project cost of acquiring vehicles (including clean-fuel or alternative fuel vehicles) for purposes of complying with or maintaining compliance with the Clean Air Act (CAA) or the Americans with Disabilities Act (ADA) of 1990.

c. The maximum Federal share is 90 percent of the net project cost of acquiring, installing, or constructing vehicle-related equipment or facilities (including clean fuel or alternative-fuel vehicle-related equipment or facilities) for purposes of complying with or maintaining compliance with the ADA or CAA. The award recipient must itemize the cost of specific, discrete, vehicle-related equipment associated with compliance with the ADA or CAA to be eligible for the maximum 90 percent Federal share for these costs.

Eligible sources of non-Federal matching funds include:

i. Cash from non-governmental sources other than revenues from providing the ferry services (such as fare revenues, vehicle, or cargo charges, etc.);

ii. Non-farebox revenues from the operation of public transportation service, such as the sale of advertising and concession revenues;

iii. Monies received under a service agreement with a State or local social service agency or private social service organization;

iv. Undistributed cash surpluses, replacement or depreciation cash funds, reserves available in cash, or new capital;

v. Amounts appropriated or otherwise made available to a department or agency of the Government (other than the U.S. Department of Transportation), that are eligible to be expended for public transportation;

vi. In-kind contributions integral to the project;

vii. Revenue bond proceeds for a capital project, with prior FTA approval; and

viii. Transportation Development Credits (formerly referred to as Toll Revenue Credits).

If an applicant proposes a Federal share greater than 80 percent, the applicant must clearly explain why the project is eligible for the proposed Federal share.

3. Eligible Projects

SUMMARY TABLE

Program	Eligible projects
Passenger Ferry Program	1. Capital Projects—purchase, construction, replacement, or rehabilitation of ferries, terminals, related infrastructure and related equipment (including electric or low-emitting ferry vessels and related infrastructure).
Low-No Ferry Program	1. Capital Projects—purchase of electric or low-emitting ferry vessels and related infrastructure.
Rural Ferry Program	1. Capital Projects—purchase, construction, replacement, or rehabilitation of ferries, terminals, related infrastructure and related equipment (including electric or low-emitting ferry vessels and related infrastructure). 2. Planning Projects—for rural ferry service only. 3. Operating Projects—for rural ferry service only.

3A. Passenger Ferry Program—Eligible Projects

Under the Passenger Ferry Program, eligible projects are capital projects for the purchase, construction, replacement, or rehabilitation of ferries, terminals, related infrastructure, and related equipment (including fare equipment and communication devices). Projects are required to support a passenger ferry service that serves an urbanized area, and may include services that operate between an urbanized area and non-urbanized areas. Ferry systems that accommodate cars must also accommodate walk-on passengers to be eligible for funding. Operating costs and planning projects are not eligible.

Under the Passenger Ferry Program only, recipients are permitted to use up to 0.5 percent of their grant award to pay for not more than 80 percent of the cost for workforce development activities eligible under Federal public transportation law (49 U.S.C 5314(b)) and an additional 0.5 percent for costs associated with training at the National Transit Institute. Applicants must identify the proposed use of funds for these activities in the project proposal and identify them separately in the project budget.

3B. Low-No Ferry Program—Eligible Projects

Under the Low-No Ferry Program, eligible projects are capital projects for the purchase of electric or low-emitting ferry vessels that reduce emissions by using alternative fuels or on-board energy storage systems and related charging infrastructure or other fueling infrastructure to reduce emissions or produce zero onboard emissions under normal operation. Ferry systems that accommodate cars must also accommodate walk-on passengers to be eligible for funding. Operating costs and planning projects are not eligible.

Alternative fuel means:

(A) methanol, denatured ethanol, and other alcohols;

(B) a mixture containing at least 85 percent of methanol, denatured ethanol, and other alcohols by volume with gasoline or other fuels;

(C) natural gas;

(D) liquefied petroleum gas;

(E) hydrogen;

(F) fuels (except alcohol) derived from biological materials; and

(G) electricity (including electricity from solar energy).

3C. Rural Ferry Program—Eligible Projects

Under the Rural Ferry Program, eligible projects are capital, operating, or planning assistance. Eligible capital projects include the purchase, construction, replacement, or rehabilitation of ferries, terminals, related infrastructure, and related equipment (including fare equipment and communication devices). Only net operating expenses are eligible for assistance. Net operating expenses are those expenses that remain after the provider subtracts operating revenues from eligible operating expenses. States may further define what constitutes operating revenues, but, at a minimum, operating revenues must include farebox revenues and other fees generated directly by the ferry service such as vehicle fares, cargo fees, and cabin fees. Farebox revenues are fares paid by riders, including those who are later reimbursed by a human service agency or other user-side subsidy arrangement. For more information please see FTA Circular 9040.1G at *https://www.transit.dot.gov/regulations-and-guidance/fta-circulars/formula-grants-rural-areas-program-guidance-and-application.* Eligible projects are

not required to be implemented on the same route segments that resulted in applicant eligibility (*e.g.,* the project need not be implemented on a segment of more than 20 or 50 sailing (nautical) miles). Ferry systems that accommodate cars must also accommodate walk-on passengers to be eligible for funding.

D. Application and Submission Information

1. Address To Request Application Package

Applications must be submitted electronically through *GRANTS.GOV*. General information for accessing and submitting applications through *GRANTS.GOV* can be found at *www.fta.dot.gov/howtoapply* along with specific instructions for the forms and attachments required for submission. Mail or fax submissions will not be accepted. The required SF–424 Application for Federal Assistance can be downloaded from *GRANTS.GOV* and the required supplemental form can be downloaded from *GRANTS.GOV* or the FTA website at: *https://www.transit.dot.gov/grants/fta-ferry-programs.*

2. Content and Form of Application Submission

a. Proposal Submission

A complete proposal submission consists of two forms: (1) the SF–424 Application for Federal Assistance; and (2) the FY 2022 Passenger Ferry Program, Low-No Ferry Program, and Rural Ferry Program supplemental form. An application eligible under the Low-No Ferry Program may also be eligible under either the Passenger Ferry Program or Rural Ferry Program. If an applicant is applying to multiple programs, they must submit the application materials through the *GRANTS.GOV* opportunity ID's listed for each program. If an applicant is submitting different proposals to different programs, the applicant must submit an application for each project to each program separately. The supplemental form and any supporting documents must be attached to the ''Attachments'' section of the SF–424. The application must include responses to all sections of the SF–424 Application for Federal Assistance and the supplemental form, unless designated as optional. The information on the supplemental form will be used to determine applicant and project eligibility for the program, and to evaluate the proposal against the selection criteria described in part E of this notice. Failure to submit the information as requested can delay review or disqualify the application.

FTA will accept only one supplemental form per SF–424 submission. FTA encourages States and other applicants to consider submitting a single supplemental form that includes multiple activities as one project to be evaluated as a consolidated proposal. If a State or other applicant chooses to submit separate proposals for individual consideration by FTA, each proposal must be submitted using a separate SF–424 and supplemental form.

Applicants may attach additional supporting information to the SF–424 submission, including but not limited to documentation supporting the applicant's eligibility for the grant programs, letters of support, project budgets, fleet status reports, or excerpts from relevant planning documents. Supporting documentation should be described and referenced by file name in the appropriate response section of the supplemental form, or it may not be reviewed.

Information such as applicant name, Federal amount requested, local match amount, and description of areas served may be requested in varying degrees of detail on both the SF–424 and supplemental form. Applicants must fill in all fields unless otherwise stated on the forms. Applicants should not place N/A or ''refer to attachment'' in lieu of typing in responses in the field sections. If information is copied into the supplemental form from another source, applicants should verify that pasted text is fully captured on the supplemental form and has not been truncated by the character limits built into the form. Applicants should use both the ''Check Package for Errors'' and the ''Validate Form'' validation buttons on both forms to check all required fields on the forms, and ensure that the Federal and local amounts specified are consistent.

b. Application Content

The SF–424 Application for Federal Assistance and the supplemental form will prompt applicants for the required information:

a. Applicant name
b. Unique entity identifier (generated by *SAM.GOV*)
c. Key contact information (including contact name, address, email address, and phone)
d. Congressional district(s) in which project is located
e. Project information (including title, executive summary, and type)
f. A detailed description of the need for the project
g. A detailed description of how the project will support the program objectives
h. Evidence that the project is consistent with local and regional planning objectives
i. Evidence that the applicant can provide the non-Federal cost share
j. A description of the technical, legal, and financial capacity of the applicant
k. A detailed project budget
l. An explanation of the scalability of the project
m. Details on the non-Federal matching funds
n. A detailed project timeline

3. Unique Entity Identifier and System for Award Management (SAM)

Each applicant is required to: (1) be registered in SAM before submitting an application; (2) provide a valid unique entity identifier in its application; and (3) continue to maintain an active SAM registration with current information at all times during which the applicant has an active Federal award or an application or plan under consideration by FTA. FTA may not make an award until the applicant has complied with all applicable unique entity identifier and SAM requirements. If an applicant has not fully complied with the requirements by the time FTA is ready to make an award, FTA may determine that the applicant is not qualified to receive an award and use that determination as a basis for making a Federal award to another applicant. These requirements do not apply if the applicant has an exception approved by FTA or the U.S. Office of Management and Budget under 2 CFR 25.110(c) or (d).

All applicants must provide a unique entity identifier provided by SAM. Registration in SAM may take as little as 3–5 business days, but since there could be unexpected steps or delays (for example, if there is a need to obtain an Employer Identification Number), FTA recommends allowing ample time, up to several weeks, for completion of all steps. For additional information on obtaining a unique entity identifier, please visit *http://www.sam.gov.*

4. Submission Dates and Times

Project proposals must be submitted electronically through *GRANTS.GOV* by 11:59 p.m. Eastern Time on September 6, 2022. *GRANTS.GOV* attaches a time stamp to each application at the time of submission. Mail and fax submissions will not be accepted.

FTA urges applicants to submit applications at least 72 hours prior to the deadline to allow time to correct any problems that may have caused either

GRANTS.GOV or FTA systems to reject the submission. Proposals submitted after the deadline will be considered only if lateness was due to extraordinary circumstances not under the applicant's control. Deadlines will not be extended due to scheduled website maintenance. *GRANTS.GOV* scheduled maintenance and outage times are announced on the *GRANTS.GOV* website.

Within 48 hours after submitting an electronic application, the applicant should receive an email message from *GRANTS.GOV* with confirmation of successful transmission to *GRANTS.GOV*. If a notice of failed validation or incomplete materials is received, the applicant must address the reason for the failed validation, as described in the email notice, and resubmit before the submission deadline. If making a resubmission for any reason, include all original attachments regardless of which attachments were updated and check the box on the supplemental form indicating this is a resubmission.

Applicants are encouraged to begin the process of registration on the *GRANTS.GOV* site well in advance of the submission deadline. Registration is a multi-step process, which may take several weeks to complete before an application can be submitted. Registered applicants may still be required to take steps to keep their registration up to date before submissions can be made successfully: (1) registration in SAM is renewed annually; and (2) persons making submissions on behalf of the Authorized Organization Representative (AOR) must be authorized in *GRANTS.GOV* by the AOR to make submissions.

5. Funding Restrictions

Funds made available under the Passenger Ferry Program and Low-No Ferry Programs may not be used to fund operating expenses, planning, or preventive maintenance. Any project under those programs that does not include the purchase, construction, replacement, or rehabilitation of ferries, terminals, related infrastructure, or related equipment is not eligible. Applicants to the Rural Ferry Program may apply for capital, operating, or planning assistance.

Funds made available under this NOFO cannot be used to reimburse applicants for otherwise eligible expenses incurred prior to the posting of project selections on FTA's website and the corresponding issuance of pre-award authority. Allowable direct and indirect expenses must be consistent with the Government-wide Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (2 CFR part 200) and FTA Circular 5010.1E. Additionally, as required by statute for the Low-No Ferry Program, prior to the conclusion of the grant competition using FY 2026 funds, FTA must select at least one project from a ferry service that serves the State with the largest number of Marine Highway System miles and at least one project from a bi-State ferry service with an aging fleet and whose development of zero- and low-emission power source ferries will propose to advance the state of the technology toward increasing the range and capacity of zero-emission power source ferries.

As required by statute, an eligible ferry service that receives funds from a state under the Rural Ferry Program shall not be attributed to an urbanized area for purposes of apportioning funds under chapter 53 of Title 49, U.S. Code. In addition, an eligible service that receives funds from a State under the Rural Ferry Program shall not receive funds apportioned under Section 5336 or 5337 of Title 49, United States Code, in the same fiscal year.

6. Other Submission Requirements

Applicants are encouraged to identify scaled funding options in case insufficient funding is available to fund a project at the full requested amount. If an applicant advises that a project is scalable, the applicant must provide an appropriate minimum funding amount that will fund an eligible project that achieves the objectives of the program and meets all relevant program requirements. The applicant must provide a clear explanation of how the project budget would be affected by a reduced award. FTA may award a lesser amount whether or not a scalable option is provided.

E. Application Review Information

1. Criteria

Projects will be evaluated primarily on the responses provided in the supplemental form. Additional information may be provided to support the responses; however, any additional documentation must be directly referenced on the supplemental form, including the file name where the additional information can be found. FTA will evaluate project proposals based on the criteria described in this notice.

a. Demonstration of Need

Applications for capital expenses to the Passenger Ferry Program, Low-No Ferry Program, or Rural Ferry Program will be evaluated based on the quality and extent to which they demonstrate how the proposed project will address an unmet need for capital investment in passenger ferry vehicles, equipment, or facilities. FTA also will evaluate the project's impact on service delivery and whether the project represents a one-time or periodic need that cannot reasonably be funded from FTA formula program allocations or State or local resources. In evaluating applications, FTA will consider, among other factors, certain project-specific criteria as outlined below:

i. For vessel replacement or rehabilitation projects (including low or zero-emission ferries or electric and low-emitting ferries)

- The age of the asset to be replaced or rehabilitated by the proposed project, relative to its useful life—those applicants that are already FTA grantees should reference the useful life benchmark for the vehicles to be replaced identified in their Transit Asset Management Plan and reported to the National Transit Database.
- The condition of the asset to be replaced by the proposed project, as ascertained through inspections or otherwise, if available.

ii. For facility infrastructure improvements or related-equipment acquisitions:

- The age of the facility or equipment to be rehabilitated or replaced, relative to its useful life—those applicants that are already FTA grantees should reference whether the asset to be replaced has been identified in the investment prioritization of their Transit Asset Management Plan.
- The degree to which the proposed project will enable the agency to improve the maintenance and condition of the agency's fleet or related ferry assets.

iii. For vessel or facility-related expansion or new service requests:

- The degree to which the proposed project addresses a current capacity constraint that is limiting the ability of the agency to provide reliable service, meet ridership demands, or maintain vessels and related equipment.
- The degree the proposed new service is supported by ridership demand.

For operating projects under the Rural Ferry Program:

- The degree to which the application addresses how additional operating resources will lead to more reliable or improved service, or meet additional service demands.
- The financial need demonstrated by the applicant, including actual or projected need to maintain or initiate ferry service and a description of how

existing operating resources are insufficient to meet the need.

- For expansion operating projects, projected ridership on the new service and the methodology used by the applicant to determine the projection.

For planning projects under the Rural Ferry Program:

- The degree to which the application addresses how planning resources will lead to more reliable or improved service, or meet additional service demands.

b. Demonstration of Benefits

All Applications will be evaluated based on how the ferry project will either improve the (1) safety of existing ferry systems, (2) the state of good repair of the existing system, (3) provide additional transportation options that foster community development and access to economic opportunities, and/or (4) improve the quality of transit service to underserved communities.

Additionally, all applications will be evaluated on (5) their support for walk-on passengers as follows:

For replacement or rehabilitation projects, benefits will be evaluated in part based on the percentage of riders that are walk-on compared to passengers using the service to transport automobiles.

For expansion projects, benefits will be evaluated in part based on what convenient infrastructure is provided at the origin and destination of the service and at any intermediary stops that supports transit and intercity bus riders, pedestrians, or bicycles. Supporting documentation should include data that demonstrates the number of trips (passengers and vehicles), the number of walk-on passengers, and the frequency of transfers to other modes if applicable.

In addition to the above five elements, projects for low- or zero-emission ferries under any program or projects for operating assistance under the Rural Ferry program will be evaluated as follows:

For low- or zero-emission ferries, applicants should demonstrate how the proposed ferries or infrastructure will reduce the emission of particulates and other pollutants that create local air pollution, which leads to local environmental health concerns, smog, and unhealthy ozone concentrations. Applicants should also demonstrate how the proposed ferries or infrastructure will reduce emissions of greenhouse gases from ferry operations. Projects that propose zero-emission projects will be more competitive.

For operating projects under the Rural Ferry Program, applicants should address and document how the requested operating funds will be used to augment, and not replace, existing state or local operating funds. The applicant should provide the amount of state or local funds provided for operating assistance for the three years of operation prior to the start of the pandemic, January 20, 2020. Applicants, at their discretion, may provide the three years of data ending on the last day of the applicant's fiscal year ending prior to January 20, 2020; end of the Federal fiscal year ending prior to January 20, 2020; or ending January 20, 2020. For any grant that includes operating assistance, FTA will require the State or locality to provide, at a minimum 75 percent of the three-year average on an annual basis to support ferry service. For example, if a state or locality normally provides $1 million in operating assistance annually, an applicant should include at least $750,000 in state or local operating assistance, which can be matched with $750,000 in Federal funds for total operating assistance of $1.5 million.

c. Planning and Local/Regional Prioritization

Applicants must demonstrate how the proposed project is consistent with local and regional planning documents and identified priorities. This will involve assessing whether the project is consistent with the transit priorities identified in the long-range transportation plan and the State and Metropolitan Transportation Improvement Program (STIP/TIP). Applicants should note if the project could not be included in the financially constrained STIP or TIP due to lack of funding, and if selected that the project can be added to the federally approved STIP before grant award.

FTA encourages applicants to demonstrate state or local support by including letters of support from State departments of transportation, local transit agencies, local government officials and public agencies, local non-profit or private sector organizations, and other relevant stakeholders. Applications that include letters of support will be viewed more favorably than those that do not. For FTA to fully consider a letter of support, the letter must be included in the application package. In an area with both ferry and other public transit operators, FTA will evaluate whether project proposals demonstrate coordination with and support of other related projects within the applicant's Metropolitan Planning Organization (MPO) or the geographic region within which the proposed project will operate.

d. Local Financial Commitment

Applicants must identify the source of the local cost share and describe whether such funds are currently available for the project or will need to be secured if the project is selected for funding. FTA will consider the availability of the local cost share as evidence of local financial commitment to the project. Additional consideration will be given to those projects for which local funds have already been made available or reserved. Applicants should submit evidence of the availability of funds for the project, by including, for example, a board resolution, letter of support from the State, a budget document highlighting the line item or section committing funds to the proposed project, or other documentation of the source of non-Federal funds.

An applicant may provide documentation of previous and recent local investments in the project, which cannot be used to satisfy non-Federal matching requirements, as evidence of local financial commitment.

Applicants that request a Federal share for a capital project greater than 80 percent must clearly explain why the project is eligible for the proposed Federal share. For planning projects under the Rural Ferry Program, the Federal share may not exceed 80 percent. For operating projects under the Rural Ferry Program, the Federal share may not exceed 50 percent.

e. Project Implementation Strategy

Projects will be evaluated based on the extent to which the project is ready to implement within a reasonable period of time and whether the applicant's proposed implementation plans are reasonable and complete.

In assessing whether the project is ready to implement within a reasonable period of time, FTA will consider whether the project qualifies for a Categorical Exclusion, or whether the required environmental work has been initiated or completed for projects that require an Environmental Assessment or Environmental Impact Statement under the National Environmental Policy Act of 1969. As such, applicants should submit information describing the project's anticipated path and timeline through the environmental review process. If the project will qualify as a Categorical Exclusion, the applicant must say so explicitly in the application. The proposal must also state whether grant funds can be obligated within 12 months from time of award, if selected, and if necessary, the timeframe under which the

Metropolitan TIP and STIP can be amended to include the proposed project. Additional consideration will be given to projects for which grant funds can be obligated within 12 months from time of award.

In assessing whether the proposed implementation plans are reasonable and complete, FTA will review the proposed project implementation plan, including all necessary project milestones and the overall project timeline. For projects that will require formal coordination, approvals, or permits from other agencies or project partners, the applicant must demonstrate coordination with these organizations and their support for the project, such as through letters of support.

f. Technical, Legal, and Financial Capacity

Applicants must demonstrate that they have the technical, legal, and financial capacity to undertake the project. FTA will review relevant oversight assessments and records to determine whether there are any outstanding legal, technical, or financial issues with the applicant that would affect the outcome of the proposed project. Additional information on the compliance requirements for these grants appears later in this notice.

Applicants with outstanding legal, technical, or financial compliance issues from an FTA compliance review or FTA grant-related Single Audit finding must explain how corrective actions taken will mitigate negative impacts on the project.

2. Review and Selection Process

FTA technical evaluation committees will evaluate proposals using the project evaluation criteria. FTA staff may request additional information from applicants, if necessary. After consideration of the findings of the technical evaluation committees, FTA will determine the final selection of projects for program funding. In determining the allocation of program funds, FTA may consider geographic diversity, diversity in the size of the transit systems receiving funding, walk-on vs. vehicle boardings for the impacted service, and the applicant's receipt of other competitive awards. FTA will also consider whether the project will include low or zero-emission ferries or ferries using electric battery or fuel cell components and the infrastructure to support such ferries. FTA may consider capping the amount a single applicant may receive.

After applying the above criteria, and in support of Executive Order 13985, Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, Executive Order 14008, Tackling the Climate Crisis at Home and Abroad, and Executive Order 14052, Implementation of the Infrastructure Investment and Jobs Act, FTA will give priority to the following additional considerations:

In further support of Executive Order 14008, FTA will give priority consideration to applications that are expected to create significant community benefits relating to the environment, including those projects that incorporate low or no emission technology or specific elements to address greenhouse gas emissions and climate change impacts. FTA encourages applicants to demonstrate whether they have considered climate change and environmental justice in terms of the transportation planning process or anticipated design components with outcomes that address climate change (*e.g.,* resilience or adaptation measures). The application should describe what specific climate change or environmental justice activities have been incorporated, including whether a project supports a Climate Action Plan, whether an equitable development plan has been prepared, and whether tools such as EPA's EJSCREEN (*https://www.epa.gov/ejscreen*) or DOT's Historically Disadvantaged Community tool at Transportation Disadvantaged Census Tracts (arcgis.com) have been applied in project planning. Applicants could also address how a project is related to housing or land use reforms to increase density to reduce climate impacts. The application should also describe specific and direct ways the project will mitigate or reduce climate change impacts including any components that reduce emissions, promote energy efficiency, incorporate electrification or low emission or zero emission vehicle infrastructure, increase resiliency, recycle or redevelop existing infrastructure, or if located in a floodplain be constructed or upgraded consistent with the Federal Flood Risk Management Standard, to the extent consistent with current law.

FTA also will give priority consideration to applications that advance racial equity in two areas: (1) planning and policies related to racial equity and overcoming barriers to opportunity; and (2) project investments that either proactively address racial equity and barriers to opportunity, including automobile dependence as a form of barrier, or redress prior inequities and barriers to opportunity. Applicants could also address how a project is related to housing or land use reforms to address historic barriers to opportunity. This objective has the potential to enhance environmental stewardship and community partnerships, and reflects Executive Order 13985, Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. FTA encourages the applicant to include sufficient information to evaluate how the applicant will advance racial equity and address barriers to opportunity. The applicant should describe any transportation plans or policies related to equity and barriers to opportunity they are implementing or have implemented in relation to the proposed project, along with the specific project investment details necessary for FTA to evaluate if the investments are being made either proactively to advance racial equity and address barriers to opportunity or redress prior inequities and barriers to opportunity. All project investment costs for the project that are related to racial equity and barriers to opportunity should be summarized.

Applicants for facility projects should also describe whether and how project delivery and implementation create good-paying jobs with the free and fair choice to join a union to the greatest extent possible, the use of demonstrated strong labor standards, practices and policies (including for direct employees, contractors, and sub-contractors); distribution of workplace rights notices; the use of local and economic hiring provisions; registered apprenticeships; or other similar standards or practices; or, for facility projects over $35 million, the use of Project Labor Agreements. Applicants should describe how planned methods of project delivery and implementation (for example, use of Project Labor Agreements or local and economic hiring provisions, and training and placement programs for underrepresented workers) provides opportunities for all workers, including workers underrepresented in construction jobs to be trained and placed in good-paying jobs directly related to the project. FTA will give priority consideration to projects that create good paying jobs with the free and fair choice to join a union and these strong labor protections.

In support of Executive Order 14008, DOT has been developing a geographic definition of Historically Disadvantaged Communities as part of its implementation of the Justice40 Initiative. Consistent with OMB's Interim Guidance for the Justice40 Initiative, Historically Disadvantaged Communities include (a) certain

qualifying census tracts, (b) any Tribal land, or (c) any territory or possession of the United States. DOT is providing a mapping tool to assist applicants in identifying whether a project is located in a Historically Disadvantaged Community Transportation Disadvantaged Census Tracts (arcgis.com). Use of this map tool is optional; applicants may provide an image of the map tool outputs, or alternatively, consistent with OMB's Interim Guidance, applicants can supply quantitative, demographic data of their ridership demonstrating the percentage of their ridership that meets the criteria for disadvantage described in Executive Order 14008. Examples of Historically Disadvantaged Communities that an applicant could address using geographic or demographic information include low income, high or persistent poverty, high unemployment and underemployment, racial and ethnic residential segregation, linguistic isolation, or high housing cost burden and substandard housing. Additionally, in support of the Justice40 Initiative, the applicant also should provide evidence of strategies that the applicant has used in the planning process to seek out and consider the needs of those historically disadvantaged and underserved by existing transportation systems. For technical assistance using the mapping tool, please contact *GMO@dot.gov.*

Due to funding limitations, projects that are selected for funding may receive less than the amount originally requested, even if an application did not present a scaled project option. In those cases, applicants must be able to demonstrate that the proposed projects are still viable and can be completed with the amount awarded.

3. Integrity and Performance Review

Prior to making an award with a total amount of Federal share greater than the simplified acquisition threshold (currently $250,000), FTA is required to review and consider any information about the applicant that is in the Federal Awardee Performance and Integrity Information Systems (FAPIIS) accessible through SAM. An applicant may review and comment on information about itself that a Federal awarding agency previously entered. FTA will consider any comments by the applicant, in addition to the 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 2 CFR 200.206.

F. Federal Award Administration Information

1. Federal Award Notices

Final project selections will be posted on the FTA website. Only proposals from eligible recipients for eligible activities will be considered for funding. There is no minimum or maximum grant award amount; however, FTA intends to fund as many meritorious projects as possible. Due to funding limitations, projects that are selected for funding may receive less than the amount originally requested. In those cases, applicants must be able to demonstrate that the proposed projects are still viable and can be completed with the amount awarded.

Recipients should contact their FTA Regional Offices for additional information regarding allocations for projects under the Ferry Program.

2. Administrative and National Policy Requirements

i. Pre-Award Authority

At the time the project selections are announced, FTA will extend pre-award authority for the selected projects. There is no blanket pre-award authority for these projects before announcement, and pre-award authority cannot be used prior to FTA issuance of pre-award authority. FTA does not provide pre-award authority for competitive funds until projects are selected and even then, there are Federal requirements that must be met before costs are incurred. For more information about FTA's policy on pre-award authority, please see FTA's 2022 Apportionment Notice (87 FR 25362).

ii. Grant Requirements

If selected, awardees will apply for a grant through FTA's Transit Award Management System (TrAMS). All Passenger Ferry Program and urbanized area Low-No Ferry Program recipients are subject to the grant requirements of the Urbanized Area Formula Grant program (49 U.S.C. 5307). All rural area Low-No Ferry Program and Rural Ferry Program Recipients are subject to the grant requirements of the Rural Area Formula Grant Program (49 U.S.C. 5311) as applicable, FTA's Master Agreement for financial assistance awards, the annual Certifications and Assurances required of applicants, FTA Circular ''Urbanized Area Formula Program: Program Guidance and Application Instructions'' (FTA.C.9030.1E) or FTA Circular ''Formula Grants for Rural Areas'' (FTA.C.9040.1G). All recipients must also follow the Award Management Requirements (FTA.C.5010.1) and the labor protections required by Federal public transportation law (49 U.S.C. 5333(b)). All these documents are available on FTA's website. Technical assistance regarding these requirements is available from each FTA regional office.

iii. Made in America

FTA requires that all capital procurements meet FTA's Buy America requirements (49 U.S.C. 5323(j)), which require all iron, steel, or manufactured products be produced in the United States. Awards made on or after May 14, 2022, also are subject to the requirements of the Build America, Buy America Act (BABA) (§§ 70901–70927 of the Infrastructure Investment and Jobs Act, Pub. L. 117–58), which require all iron, steel, manufactured products, and construction materials to be produced in the United States. FTA's Buy America requirements for iron, steel, and manufactured products—including rolling stock—meet or exceed BABA's requirements, and therefore, are not affected by BABA. The United States Department of Transportation issued a 180-day waiver of the BABA requirement relating to construction materials on May 19, 2022: *https://www.transportation.gov/regulations/temporary-waiver-buy-america-requirements-construction-materials.* Any proposal that will require a waiver must identify the items for which a waiver will be sought in the application. Applicants should not proceed with the expectation that waivers will be granted.

iv. Civil Rights and Title VI

Recipients of Federal transportation funding will be required to comply fully with Title VI of the Civil Rights Act of 1964 and implementing regulations, the Americans with Disabilities Act, Section 504 of the Rehabilitation Act of 1973, and all other civil rights requirements. The Department's and the applicable Operating Administration's Office of Civil Rights will be providing resources and technical assistance to ensure full and sustainable compliance with Federal civil rights requirements.

v. Disadvantaged Business Enterprise

Projects that include ferry acquisitions are subject to the transit vehicle manufacturer (TVM) rule of the Disadvantaged Business Enterprise (DBE) program regulations (49 CFR 26.49). The TVM rule requires recipients procuring transit vehicles, including ferries, to limit eligible bidders to certified TVMs. To become a certified TVM, a manufacturer of transit vehicles must submit a DBE program plan and annual goal to FTA for

approval. A list of certified TVMs is posted on FTA's web page at *www.transit.dot.gov/TVM.* Recipients should contact FTA before accepting bids from entities not listed on this web-posting.

In lieu of restricting eligibility to certified TVMs, a recipient may, with FTA's approval, establish project-specific goals for DBE participation in the procurement of transit vehicles.

For more information on DBE requirements, please contact Monica McCallum, FTA Office of Civil Rights, 206–220–7519, *Monica.McCallum@dot.gov.*

vi. Planning

FTA encourages applicants to notify the appropriate State Departments of Transportation and MPOs in areas likely to be served by the project funds made available under these initiatives and programs. Selected projects must be incorporated into the long-range plans and transportation improvement programs of States and metropolitan areas before they are eligible for FTA funding. As described under the evaluation criteria, FTA may consider whether a project is consistent with or already included in these plans when evaluating a project.

vii. Standard Assurances

The applicant assures that it will comply with all applicable Federal statutes, regulations, executive orders, directives, FTA circulars, and other Federal administrative requirements in carrying out any project supported by the FTA grant. The applicant acknowledges that it is under a continuing obligation to comply with the terms and conditions of the grant agreement issued for its project with FTA. The applicant understands that Federal laws, regulations, policies, and administrative practices might be modified from time to time and may affect the implementation of the project. The applicant agrees that the most recent Federal requirements will apply to the project, unless FTA issues a written determination otherwise. The applicant must submit the Certifications and Assurances before receiving a grant if it does not have current certifications on file.

vii. Reporting

Post-award reporting requirements include the electronic submission of Federal Financial Reports and Milestone Progress Reports. Applicant should include goals, targets, and indicators referenced in their application to the project in the Executive Summary of the TrAMS application. Recipients or beneficiaries of funds made available through this NOFO are also required to regularly submit data to the National Transit Database. National Transit Database reports include total sources of revenue and complete expenditure reports for all public transportation operations, not just those funded by this project. Applicants partnering with a private operator should ensure that the private operator will meet all of the comprehensive reporting requirements of the National Transit Database.

FTA is committed to making evidence-based decisions guided by the best available science and data. In accordance with the Foundations for Evidence-based Policymaking Act of 2018 (Evidence Act), FTA may use information submitted in discretionary funding applications; information in FTA's Transit Award Management System (TrAMS), including grant applications, Milestone Progress Reports (MPRs), Federal Financial Reports (FFRs); transit service, ridership and operational data submitted in FTA's National Transit Database; documentation and results of FTA oversight reviews, including triennial and state management reviews; and other publicly available sources of data to build evidence to support policy, budget, operational, regulatory, and management processes and decisions affecting FTA's grant programs.

As part of completing the annual certifications and assurances required of FTA grant recipients, a successful applicant must report on the suspension or debarment status of itself and its principals. If the award recipient's active grants, cooperative agreements, and procurement contracts from all Federal awarding agencies exceeds $10,000,000 for any period of time during the period of performance of an award made pursuant to this Notice, the recipient must comply with the Recipient Integrity and Performance Matters reporting requirements described in Appendix XII to 2 CFR part 200.

G. Federal Awarding Agency Contacts

For further information concerning this notice, please contact the *FTAFerryPrograms@dot.gov,* or Vanessa Williams, by phone at (202) 366–4818 or Sarah Clements at (202) 366–3062. A TDD is available for individuals who are deaf or hard of hearing at 800–877–8339. In addition, FTA will post answers to questions and requests for clarifications on FTA's website at *https://www.transit.dot.gov/grants/fta-ferry-programs.* To ensure receipt of accurate information about eligibility or the program, the applicant is encouraged to contact FTA directly, rather than through intermediaries or third parties. For issues with *GRANTS.GOV,* please contact *GRANTS.GOV* by phone at 1–800–518–4726 or by email at *support@grants.gov.* Contact information for FTA's regional offices can be found on FTA's website at *http://www.transit.dot.gov/.*

H. Other Information

This program is not subject to Executive Order 12372, ''Intergovernmental Review of Federal Programs.'' FTA will consider applications for funding only from eligible recipients for eligible projects listed in Section C.

Nuria I. Fernandez,

Administrator.

[FR Doc. 2022–14692 Filed 7–8–22; 8:45 am]

BILLING CODE 4910–57–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2022–0017]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Request for Comment; National Driver Register

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation.

ACTION: Notice and request for comments on an extension of a currently approved information collection.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 PRA), this notice announces that the Information Collection Request (ICR) summarized below is being forwarded to the Office of Management and Budget (OMB) for review and approval. The ICR describes the nature of the information collection and its expected burden. This document describes a currently approved collection of information on NHTSA's National Driver Register for which NHTSA intends to seek approval from OMB for extension. A **Federal Register** Notice with a 60-day comment period soliciting comments on the following information collection was published on March 28, 2022. No comments were received.

DATES: Comments must be submitted on or before August 10, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection, including

suggestions for reducing burden, should be submitted to the Office of Management and Budget at *www.reginfo.gov/public/do/PRAMain.* To find this particular information collection, select ''Currently under Review—Open for Public Comment'' or use the search function.

FOR FURTHER INFORMATION CONTACT: For additional information or access to background documents, contact Miriam Chege, NSA 200, National Highway Traffic Safety Administration, Room W55–210, Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590. Miriam Chege's telephone number is (202) 366–2571. Please identify the relevant collection of information by referring to its OMB Control Number.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501 *et seq.*), a Federal agency must receive approval from the Office of Management and Budget (OMB) before it collects certain information from the public and a person is not required to respond to a collection of information by a Federal agency unless the collection displays a valid OMB control number. In compliance with these requirements, this notice announces that the following information collection request will be submitted to OMB.

A **Federal Register** notice with a 60-day comment period soliciting comments on the information collection was published on March 28, 2022 (87 FR 17408). No comments were received.

Title: National Driver Register (NDR).

OMB Control Number: 2127–0001.

Form Number(s): This collection of information is electronically submitted to NHTSA. There are no standard forms.

Type of Request: Extension of a currently approved information collection.

Type of Review Requested: Regular.

Requested Expiration Date of Approval: 3 years from date of approval.

Summary of the Collection of Information: The National Driver Register Act of 1982, Title 49 U.S.C., Subtitle VI, Part A, Chapter 303 (as amended) requires the Secretary of Transportation (NHTSA by delegation) to maintain a National Driver Register (NDR) to assist the State chief driver licensing officials in the exchange of information about the motor vehicle driving records of individuals. The chief driver licensing official of a participating State must report to the NDR identification information regarding any individual who is denied a motor vehicle operator's license for cause, whose motor vehicle operator's license is withdrawn for cause, or who is convicted of certain serious motor vehicle related offenses (specified in the Act at 49 U.S.C. 30304) or comparable offenses. (23 U.S.C. 30304(a); 23 CFR 1327, appendix A). Participating States are required to submit an inquiry to the NDR on all applicants for driver's licenses before issuing a license to the applicant. In addition, when requested by other authorized users (*e.g.,* the Federal Aviation Administration), participating States are required to submit inquires to the NDR and provide responses to the other authorized users of the NDR for transportation safety purposes. All 50 States and the District of Columbia participate in the NDR.

The NDR maintains the computerized database known as the Problem Driver Pointer System (PDPS) which contains information on individuals whose privilege to operate a motor vehicle has been revoked, suspended, canceled or denied or who have been convicted of serious traffic-related offenses. The records maintained at the NDR consist of identification information including name, date of birth, sex, driver license number, and reporting State which is collected on a daily basis.

States use interactive communication for their routine transactions with the NDR which allows them to submit the required information automatically at the same time the individual's information is entered into the State's system. Specifically, when an individual applies for a driver's license, an inquiry is automatically transmitted to the NDR when the driver's application is entered into the State's system. Likewise, when a State records license actions that have been taken against an individual that require reporting to the NDR, a transaction submitting the individual's identification information is automatically generated and transmitted to the NDR.

Description of the Need for the Information and Proposed Use of the Information: The purpose of the information collection is to improve traffic and transportation safety by assisting States in keeping problem drivers off the nation's highways. The NDR was established to serve as the central repository of information on problem drivers to promote information sharing among States, eliminating the need for States to contact each of the other 50 jurisdictions, and the District of Columbia individually. The information collected is used by State driver licensing agencies to identify problem drivers prior to issuing a driver's license and to develop and implement driver improvement programs. The following groups are also authorized to receive information upon inquiry to a State driver licensing agency for transportation safety purposes:

a. Employers of motor vehicle operators,

b. Employers of locomotive operators,

c. Federal Aviation Administration regarding applications for or holders of airman's certificates,

d. U.S. Coast Guard regarding applicants for or holders of licenses, certificates of registry, or merchant mariner's documents, and for Coast Guard crew members,

e. National Transportation Safety Board and Federal Motor Carrier Safety Administration in connection with accident investigations,

f. Air carriers regarding individuals seeking employment as pilots, and

g. Individuals who have or are seeking access to national security information for purposes under E.O. 12968 or who are being investigated for Federal employment.

60-Day Notice: A **Federal Register** notice with a 60-day comment period soliciting comments on the information collection was published on March 28, 2022 (87 FR 17408). No comments were received.

Affected Public: Participating States.

Estimated Number of Respondents: The number of respondents is 51—all 50 States and the District of Columbia.

Frequency: On a daily basis.

Estimated Total Annual Burden Hours: 13,739 hours.

States use routine electronic interactive communication for transactions with the NDR, which allows the States to submit the required information automatically at the same time the information is entered into the State's own system. Although States are required to report and check for a problem driver when issuing a driver's license, no burden hours are incurred for these queries for this information collection because the State's computer systems automatically transmit the information that is entered as a part of normal business practice. Therefore, the estimated hour burden is based on the States' PDPS IT infrastructure maintenance and States' participation in the optional Clean File process.

To estimate the annual maintenance and infrastructure burden to report and check for problem drivers, NDR asked a small sample of States for information about their annual burden. NDR received formatted estimates from two States which included the maintenance and infrastructure labor hours and cost used to send and maintain information to PDPS. Together, the burden from these two States was 530 hours and the associated labor cost was $17,400. Using

these estimates, NHTSA calculates an average of 265 hours per State, with an annual labor cost of $8,700. There are 51 respondents per year (the 50 States and the District of Columbia). Therefore, total annual burden hours for maintenance and infrastructure is estimated to be 13,515 hours (51 respondents × 265 hours). The total annual maintenance and infrastructure labor cost per year is estimated to be $443,700 ($8,700 × 51).

To ensure that the information contained in the NDR is accurate, States sometimes submit a ''clean file'' which is a confirmation of all drivers of that State who should be listed in the NDR file. NHTSA estimates that an average of 28 clean files will be submitted annually by States. States use SFTP to submit this information, and NHTSA estimates it takes an IT specialist 8 hours to prepare and run the data. NHTSA estimates the cost for IT personnel burden hours using the Bureau of Labor Statistics' mean wage estimate for Software and Web Developers, Programmers, and Testers (Standard Occupational Classification #15–1250, May 2020) of $52.86.[1] The Bureau of Labor Statistics estimates that for State and local government workers, wages represent 61.9% of total compensation.[2] Therefore, the total hourly cost associated with the IT burden hours is estimated to be $85.40 ($52.86 ÷ 61.9%) per hour. The total annual burden hours to prepare and submit clean files is 224 hours (8 × 28). The total annual clean file labor cost per year is estimated to be $19,130 ($85.40 × 224).

Submission type	Annual submissions	Estimated burden per submission	Average hourly labor cost	Labor cost per submission	Total burden hours	Total labor costs
Maintenance and Infrastructure	51	265	N/A	$8,700	13,515	$443,700
Clean files	28	8	85.40	683.20	224	19,130
Total	51				13,739	462,830

Estimated Total Annual Burden Cost: There are no annual costs.

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 the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information collection; and (d) ways minimize the burden of the collection of information on respondents, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended; and 49 CFR 1.49; and DOT Order 1351.29A.

Chou-Lin Chen,

Associate Administrator for the National Center for Statistics and Analysis.

[FR Doc. 2022–14725 Filed 7–8–22; 8:45 am]

BILLING CODE 4910–59–P

[1] May 2020 National Occupational Employment and Wage Estimates United States, Occupational Employment Statistics, Bureau of Labor Statistics, U.S. Department of Labor, *https://www.bls.gov/oes/current/oes_nat.htm#15-0000*, last accessed July 23, 2021.

[2] Employer Costs for Employee Compensation by ownership (Dec. 2020), available at *https://www.bls.gov/news.release/ecec.t01.htm* (accessed July 23, 2021).

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

[Docket No. PHMSA–2022–0043; Notice No. 2022–06]

Hazardous Materials: Request for Information on Electronic Hazard Communication Alternatives

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), Department of Transportation (DOT).

ACTION: Request for information.

SUMMARY: PHMSA seeks input on the potential use of electronic communication as an alternative to current, physical documentation requirements for hazard communication.

DATES: Interested persons are invited to submit comments on or before September 9, 2022. Comments received after that date will be considered to the extent practicable.

ADDRESSES: You may submit comments identified by the Docket Number PHMSA–2021–0043 by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 1–202–493–2251.
- *Mail:* Docket Management System; U.S. Department of Transportation, West Building, Ground Floor, Room W12–140, Routing Symbol M–30, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Docket Management System; Room W12–140 on the ground floor of the West Building, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Instructions: All submissions must include the agency name and Docket Number (PHMSA–2022–0043) for this notice. To avoid duplication, please use only one of these four methods. All comments received will be posted without change to the Federal Docket Management System (FDMS) and will include any personal information you provide.

Docket: For access to the dockets to read background documents or comments received, go to *http://www.regulations.gov* or DOT's Docket Operations Office (see **ADDRESSES**).

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public. 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.*

Confidential Business Information (CBI): 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 notice 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 notice, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' PHMSA will treat such marked submissions as confidential under FOIA, and they will not be placed in the public docket of this notice. Submissions containing CBI should be sent to Eamonn Patrick, Standards and Rulemaking Division, (202) 366–8553, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590–0001. PHMSA will place any commentary not specifically designated as CBI into the public docket for this notice.

FOR FURTHER INFORMATION CONTACT: Eamonn Patrick, Standards and Rulemaking Division, (202) 366–8553, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590–0001.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

PHMSA is considering revisions to the Hazardous Materials Regulations (HMR), which would authorize a performance-based electronic communication alternative to the existing physical, paper-based hazard communication requirements. This revision is meant to facilitate and promote the use of electronic hazard communication. For the purpose of this request for information (RFI), ''hazard communication'' means shipping papers, train consists, dangerous goods manifests, notifications to the pilot in command, and emergency response information, as well as associated administrative documentation including Department of Transportation (DOT) Special Permits (SPs), approvals, and registrations.

The HMR currently require that hazard communication be maintained as physical, printed documents during transportation. However, widely adopted technologies could supplement, or replace, the existing paper-based hazard communication system, and offer opportunities for improved emergency response and oversight, as well as increased efficiency in the operations of transportation networks. PHMSA anticipates that electronic communication would improve transportation safety, efficiency, and effectiveness by providing electronic access to the same required information currently contained in hazard communication documents. With this RFI, PHMSA seeks your input, to help determine the most effective mechanisms and potential impediments for implementing electronic hazard communication.

II. Background

PHMSA's mission is to protect people and the environment by advancing the safe transportation of energy and other hazardous materials that are essential to our daily lives. To achieve this mission, PHMSA establishes national policy, sets and enforces HMR standards, educates, and conducts research to prevent hazardous materials incidents. In doing so, PHMSA collaborates closely with other Federal agencies and operating administrations, including the Federal Motor Carriers Safety Administration, Federal Railroad Administration, Federal Aviation Administration, and United States Coast Guard. Federal hazardous materials law authorizes the Secretary to ''prescribe regulations for the safe transportation, including security, of hazardous materials in intrastate, interstate, and foreign commerce'' 49 U.S.C. 5103(b)(1). The Secretary has delegated this authority to PHMSA in 49 CFR 1.97(b).

The HMR are designed to achieve three primary goals:

(1) Ensure that hazardous materials are packaged and handled safely and securely during transportation.

(2) Effectively communicate the hazards of the materials being transported to transportation workers and emergency responders.

(3) Minimize the consequences of an accident or incident, should one occur.

The HMR provide hazard communication requirements for the transport of hazardous materials in subparts C through G of part 172 of the HMR, with modal specific requirements in parts 174 to 177. This RFI addresses the following topics:

Citation	Topic
Part 172, subpart C	Shipping papers.
Part 172, subpart G	Emergency response information.
§ 174.26	Train consists.
§ 175.33	Notifications to the pilot in command.
§ 176.30	Dangerous cargo manifests.
§ 177.817	Shipping papers in motor vehicles.

This RFI also addresses documents that accompany shipments that may not have a direct emergency response purpose, but either commonly accompany shipments or are present on transportation vehicles, including DOT SPs, approvals, and registrations.

The HMR requires that all copies of the shipping papers used for transportation purposes must be legible and printed (manually or mechanically) in English (see § 172.201(a)(2)). Section 172.201(a)(5) authorizes rail carriers to accept shipping papers information either telephonically (*e.g.,* voice communications and facsimiles) or by electronic data interchange (EDI), however the train consist containing the hazardous materials description carried by the train crew must still be maintained as a physical document (see § 174.26). Emergency response information is required to be maintained in the same manner as a shipping paper, *i.e.,* printed manually or mechanically in English (see § 172.602(c)).

Prior to this RFI, PHMSA considered various alternatives to current requirements for paper-based hazardous materials documentation, primarily focusing on electronic shipping papers. Previous activities related to electronic shipping papers include:

(1) The Environmental Protection Agency (EPA) Hazardous Waste E-Manifest,

(2) Current DOT–SPs for electronic hazard communications information used in highway and rail transportation,

(3) The Hazardous Materials Automated Cargo Communications for Efficient and Safety Shipments (HM–ACCESS) pilot project,

(4) Integrated Communications, Information and Support Platform for Hazardous Materials Stakeholders

Across Multiple Modes (HazSMART) research, and

(5) Transport Canada's (TC) ongoing Regulatory Sandbox on Electronic Shipping Documents.

These activities provide a baseline for PHMSA's development of this RFI. All documents discussed here are available for review in the RFI docket.

EPA Hazardous Waste E-Manifest

The EPA developed the Hazardous Waste Electronic Manifest (e-Manifest) System to aid in the cradle-to-grave tracking of hazardous waste.[a] EPA identified the following benefits of the e-Manifest system:

- Cost savings,
- Accurate and more timely information on waste shipments,
- Rapid notification of discrepancies or other problems related to a particular shipment,
- Creation of a single hub for one-stop reporting of manifest data for use by EPA and states,
- Increased effectiveness of compliance monitoring of waste shipments by regulators, and
- Potential for integrating manifest reporting with the Resource Conservation and Recovery Act (RCRA) biennial reporting process and other federal and state information systems.

The development and maintenance costs of the e-Manifest system is offset by user fees charged to hazardous waste manifest users.

While the goal of the EPA e-Manifest system is related to this DOT-led electronic hazard communication project, there are substantial differences. First, the e-Manifest system is not designed to provide information to emergency response organizations during a hazardous material transportation incident, which is a primary purpose of DOT hazard communication documents. Also, DOT has no legal authority to charge user fees for an electronic hazard communication system. Finally, hazardous wastes are only a small subset of the approximately 1.2 million hazardous materials shipments that transit the United States every day. Despite these differences, the successful implementation of the e-Manifest system is an instructive example for transitioning from a paper-intensive process to a national electronic manifest system.

DOT Special Permits

PHMSA safely allows technological innovation through its special permit program. Special permits set forth requirements for performance of functions not otherwise allowed by—or a variance to—the requirements of the HMR. These functions must either (1) achieve an equivalent level of safety to that required under the regulations, or (2) if a required safety level does not exist, do so in a manner consistent with the public interest. PHMSA's Approvals and Permits Division is responsible for the issuance of DOT special permits in accordance with the requirements of 49 CFR part 107, subpart B.

The HMR often include performance-based standards that provide the regulated community with some flexibility in meeting safety requirements. Even so, not every transportation situation can be anticipated and covered under the regulations. The hazardous materials community is at the cutting edge of development of new materials, technologies, and innovative ways of moving hazardous materials. Special permits provide a mechanism for testing new technologies, promoting increased transportation efficiency and productivity, and ensuring economic competitiveness without compromising safety. In this way, they allow the hazardous materials industry to integrate new products and technologies into production and the transportation stream safely, quickly, and effectively.

PHMSA has issued several DOT–SPs in recent years related to the maintenance of hazard communication information in an electronic format. For rail transportation, PHMSA issued DOT–SPs which permit train crews to maintain the train consist (required by § 174.26) on an electronic device (*e.g.,* a smartphone or tablet) carried by the train crew in the locomotive cab, and to transmit the train consist information electronically to emergency responders or other authorized Federal, state, or local officials in the event of an incident, accident, or inspection. These SPs include:

- DOT–SP 20954 to BNSF Railway Company,
- DOT–SP 21053 to Canadian National Railway Company,
- DOT–SP 21046 to CSX Transportation,
- DOT–SP 21059 to Union Pacific, and
- DOT–SP 21110 to Norfolk Southern.

For highway transportation, PHMSA issued DOT–SP 15747 to United Parcel Service (UPS). Under this SP, the physical shipping papers and emergency response information can be replaced with a document instructing responders to call a specific phone number and provide the trailer's unique identification number. The call center is then required to provide shipping papers and emergency response information in a single electronic transmission within five (5) minutes. The types and quantities of hazardous materials authorized for transportation in accordance with DOT–SP 15747 are limited, and do not encompass all, or even most, types and quantities of hazardous materials transported by highway in the United States.

HM–ACCESS

The John A. Volpe National Transportation Systems Center (Volpe Center) conducted the Hazardous Materials Automated Cargo Communications for Efficient and Safe Shipments (HM–ACCESS) project from 2011–2015 and issued a report to Congress on behalf of PHMSA in 2016. The HM–ACCESS project consisted of consultation with stakeholders; pilot tests with hazardous materials offerors, carriers, inspectors, and emergency responders; and a survey of stakeholders. HM–ACCESS determined that many shippers and carriers in the rail, vessel, and air modes already have electronic systems in place that could be used to accept and transmit hazard communication information. Highway shippers and carriers are a more complex, heterogeneous group, so not all entities would be able to accept and transmit hazard communication information.

Since rail and air modes already utilize electronic systems, most inspectors who perform compliance inspections at rail and air transportation facilities have electronic devices that can receive and display hazard communication information. Inspectors who conduct container inspections in port areas before and after vessel transportation were found to have more limited access to electronic devices. Many highway inspectors who conduct motor vehicle inspections have electronic devices in their vehicles that could be used to receive and display electronic hazard communication information. However, the readiness of highway inspectors to utilize electronic hazard communication is less certain due to the lower usage rate of electronic systems by highway carriers and potential connectivity issues.

The report found that professional emergency responders in urban areas generally have access to electronic devices capable of receiving and displaying hazard communication information, as well as high confidence that their response areas are covered by data networks without connectivity issues. But volunteer organizations, especially those in rural areas, may lack

[a] *https://www.epa.gov/e-manifest.*

both the required systems and necessary data connectivity. These rural and volunteer organizations would potentially need to rely upon hazard communication relayed via voice-only communication from their dispatcher, if a physical hazard communication document was not available at the scene of an incident.

The HM–ACCESS report found that the implementation of a performance-based electronic hazard communication standard could provide safety and economic benefits, but these benefits would depend on numerous variables. Potential safety benefits identified in the report include more timely provision of information during an emergency, increased accuracy of hazard communication, increased redundancy if the electronic system provides multiple methods of information access, and improved access to hazard communication information away from the vehicle involved. The report found that the economic costs and benefits of implementation are likely to vary across different modes, and would depend on the size of the company involved, previous investments made to electronic systems, the range of hazardous materials involved, and the complexity of the system, among other factors.

HazSMART Research Project

PHMSA funded the HazSMART research project and received a final report from Factor, Inc. and Spill Center, Inc. in 2020. The objective of HazSMART was to develop and deploy technologies that could connect hazardous materials transportation industry stakeholders during scenarios in which sharing hazard and shipment information is needed to protect public health and safety, such as in hazardous materials incidents. The project developed a central platform for management of shipping, transport, geographic information systems, and incident data. The HazSMART platform included a response dashboard, which provided protective action distances to emergency responders and other authorized stakeholders. While the HazSMART project was not intended to develop an electronic hazard communication standard, participants in an exercise with emergency responders noted that the technologies developed in the HazSMART project have the capability to receive, send, and display required shipping paper elements and could be further developed into an electronic hazard communication system.

Transport Canada (TC) Regulatory Sandbox on Electronic Shipping Documents

Since early 2020, TC has authorized a pilot project to evaluate electronic hazard communication for highway, rail, and air hazardous materials transportation. This pilot project, known as the ''Regulatory Sandbox on Electronic Shipping Documents,'' was conducted by three rail carriers, three highway carriers, and one Unmanned Aerial Systems carrier in accordance with Equivalency Certificates (ECs) issued by Transport Canada. The ECs authorize each carrier to maintain and transmit shipping paper information in an electronic format, subject to the limitations and conditions of each EC. Important features of the Transport Canada ECs include standardized vehicle markings and redundant electronic hazard communication systems, able to provide necessary information to emergency responders in multiple formats.

III. Questions

PHMSA requests information on the implications of authorizing electronic hazard communication. For the purpose of this RFI, paper ''hazard communication'' means shipping papers, train consists, dangerous goods manifests, notifications to the pilot in command, and emergency response information, as well as associated administrative documentation including DOT–SPs, approvals, and registrations. The questions below are divided into two sections: Section A for emergency response and inspection organizations, and Section B for organizations who offer, transport, or facilitate the movement of hazardous materials. PHMSA requests that you provide as much information as possible and answer as many of the questions as applicable.

We encourage trade associations, labor unions, and other organizations that represent companies and workers in the emergency response, hazardous materials inspection, hazardous material transportation, and technology fields to respond as well. If you represent such an organization, please choose the appropriate section; for the ''Identification'' questions, briefly describe the types of companies and workers that your organization represents.

A. Emergency Response Community and Authorized Officials

Note: In this section, the terms ''inspectors'' and ''inspection organizations'' refer to any local or state entity that is authorized to receive and review shipping paper records, but does not typically respond to incidents, accidents, or other hazardous material transportation emergencies.

1. Identification

a. What type of inspection or emergency response organization do you represent (*e.g.,* law enforcement, fire and rescue (including volunteer), emergency medical services, specialized hazardous materials incident response organization, transportation and public works, towing and recovery, etc.)?

i. What level of hazardous materials response training do you have?

ii. For emergency responders, do you rely on outside support (*e.g.,* state, federal, contract organization) for hazardous materials incident response? Please explain.

iii. Approximately how many employees work in your response or inspection organization?

b. Which description below best describes your typical response or inspection area population density and layout?

i. Urban,

ii. Rural,

iii. Suburban,

iv. Not applicable (Varies widely; not limited to a specific geographic location.)

2. Background (Responsibilities and Capabilities)

a. Please list or identify any major transportation hubs that handle hazardous materials (*e.g.,* airports, ports, rail yards) or routes (*e.g.,* interstate highways, rail corridors) contained in your response or inspection area.

b. For responders, how many incidents involving hazardous materials transportation do you respond to per year, on average? What percentage of your total annual responses is this?

c. For inspectors, how many hazardous materials compliance inspections or investigations do you conduct per year, on average?

d. Approximately what percentage of your response or inspection area is covered by a wireless technology network that supports portable electronic devices capable of communications, data processing, and/or computing?

e. Approximately what percentage of your response or inspection area is covered by a voice-only radio network?

f. Does your organization currently issue, or do persons in your organization have access to, portable electronic devices in vehicles capable of:

(1) receiving and displaying hazard communication information?

(2) accessing the internet consistently during a response or inspection?

i. If yes to either, describe the types of devices. Are they available to all persons or units, or only a subset?

ii. If yes to either, do you currently use an electronic system to receive and display electronic hazard communication that specifically identifies the hazardous materials present in a transport vehicle or container? If so, please identify and describe the system, especially how the data is received and transmitted.

iii. If no to either, are there budgetary or other constraints that would prevent you from upgrading your equipment to accommodate an electronic hazard communication system? Please describe.

3. Responding to a Hazardous Materials Incident (Needs and Systems)

Note: Inspectors, please see the next section (Section 4).

a. What additional hazard communication information would aid in emergency response, beyond what is currently required in the HMR? What currently required hazard communication information is unnecessary for emergency response? Please provide detailed examples.

b. How often are paper-based hazard communication documents inaccessible during a hazardous materials incident response? What are the reasons for this inaccessibility? What steps are taken to obtain needed information if the document is not available during an incident?

c. Do you use existing system(s) designed to provide electronic information to emergency responders arriving at a scene? And if so, which system(s)? Could these systems be adapted for use in transmission of hazard communication information?

d. What role do dispatchers play in obtaining hazard communication information in an incident response for your organization? Do you experience difficulties in relaying information from a dispatcher to responders at a scene? If yes, please explain.

e. What are the differences in type, format, and content of hazard communication you need to respond to incidents in different modes (*e.g.,* highway versus rail, vessel, aircraft at airport)?

f. To respond appropriately to an incident involving mixed freight and less than truckload (LTL) in the highway mode, do you need additional information on the non-hazardous materials that are being transported alongside the hazardous material?

g. Are you concerned that increased reliance on electronic devices for emergency response purposes would create a distraction during emergency responses? Why or why not?

4. Conducting a Hazardous Materials Inspection (Needs and Systems)

Note: emergency response organizations, please see previous section (Section 3).

a. What additional hazard communication information would aid in inspections, beyond what is currently required in the HMR? What currently required hazard communication information is unnecessary for inspection? Please provide detailed examples.

b. How often are paper-based hazard communication documents inaccessible during a hazardous materials inspection? What are the reasons for the lack of information availability? What steps do you take if documents are not available during an inspection?

c. Do you currently use electronic systems for inspections unrelated to hazardous materials and/or hazardous material inspections? If so, please describe. Could systems non-hazardous material inspections be adapted to enhance hazardous material inspections? If so, please describe.

d. Are you concerned that increased reliance on electronic devices for inspection purposes would create a distraction during the inspection? Why or why not?

5. Preferences for an Electronic Hazard Communication Alternative

a. How would you like to receive hazard communication documents if electronic transmission were permitted? What format or means would best suit your organization's current equipment and capabilities?

b. What format or means would you prefer for the electronic transmission of hazard communication, if there were no limitations on cost or capabilities?

c. Should the information content and format for electronic hazard communication be standardized across all modes, to facilitate recognition in an emergency or inspection?

d. Do you have any recommendations for communicating that electronic hazard communication is in use, such as a standardized visual aid (*e.g.,* a marking or placard) on the exterior of the transport vehicle or container, or other means?

e. What is your preference for how electronic hazard communication documents should be maintained, transmitted, and overseen?

f. What additional costs, if any, would there be for your organization to successfully utilize electronic hazard communication (*e.g.,* new electronic devices, upgraded data plans, and training)?

g. Are there certain scenarios in which electronic hazard communication should not be allowed? If so, please provide examples.

h. Approximately how much preparation time would your organization need to be capable of using electronic hazard communication during a hazardous materials incident response or inspection?

i. Do you anticipate new training needs to enable the use of electronic hazard communication? If so, please describe. In particular, describe challenges any new training would pose for your organization.

6. Potential Benefits

a. Are there benefits for having hazard communication available electronically? Do you have any data that can help us quantify your input? How could benefits be maximized over paper-based hazard communication requirements?

7. Potential Concerns

a. What concerns do you have regarding the use of an electronic hazard communication system in place of paper-based hazard communication?

b. What concerns do you have regarding the reliability of a wireless technology network in your response or inspection area? How should access to hazard communication be maintained in situations where area utilities are disabled? Should persons who use an electronic system be required to maintain a backup or redundant system?

c. What concerns do you have regarding the interoperability of equipment maintained by local/county organizations versus state/federal organizations?

d. What concerns do you have regarding import shipments into the United States having access to an electronic hazard communication system?

e. What concerns do you have regarding the security of electronic hazard communication?

8. Overall Perspective and Input

a. Do you support the use of electronic hazard communication as an alternative to the current paper requirements? Please provide your reasoning.

b. Are there any specific knowledge gaps or areas of concern that the Department of Transportation should address, via additional information-gathering or research, before authorizing electronic hazard communication on a broad basis?

c. Is there any additional information that you would like to provide to the Department of Transportation for consideration in the development of an electronic hazard communication standard?

B. Hazardous Materials Shippers, Carriers, and Logistics Facilitators

1. Identification

a. Please provide a general description of your business activities as related to the transportation of hazardous materials (*e.g.,* less than truckload (LTL) highway carrier, bulk chemical shipper, third-party logistics company, trade association, labor union, technology provider, etc.). If you are responding on behalf of a trade association, labor union, or other organization, please answer for your entire membership, if possible.

b. In which mode(s) (highway, rail, vessel, air) do you offer, transport, or facilitate the movement of hazardous materials? Please identify all modes utilized if multi-modal.

c. Please estimate the number of hazardous materials shipments you offer, transport, or provide third-party facilitation for, per year.

d. Please identify the classes, divisions and quantities (bulk, non-bulk, or both) of hazardous materials you offer, transport, or for which you provide third-party facilitation.

e. How many people does your company employ? Is your company (or the companies you represent) a small business, as defined by the Small Business Administration (SBA)?

f. What percentage of your business involves the offering, transportation, or third-party facilitation of hazardous materials shipments?

g. Do you offer, transport, or provide third-party facilitation for hazardous materials transportation solely within a single state, between states, or internationally? Do the shipments you offer, transport, or facilitate cross through urban, rural, or suburban areas? Please identify all that apply.

2. General Participation

a. Would you consider implementing electronic hazard communication if the HMR authorized it as an option? Why or why not? What factors would you consider in your determination? Have you analyzed the developmental and deployment costs with the safety benefits? If so, please share any available data.

b. What value could you gain by using electronic hazard communication? What benefits—financial, organizational, safety, etc.—could you obtain by implementing electronic hazard communication?

c. Would you be more likely to adopt electronic hazard communication if the hazard information was maintained and transmitted utilizing a:

i. central DOT or other government agency-run repository,

ii. central third-party run repository,

iii. performance-based, individual shipper/carrier-based standard,

iv. another option (please describe)?

d. If a centralized database was used to maintain and transmit hazard communication information, do you have any concerns with DOT/other government agencies having permanent, historical access to the database, rather than having access only during transportation?

e. To what extent would you participate in an electronic hazard communication alternative that was not fully multi-modal (*i.e.,* not all modes are authorized for electronic hazard communication)? How high of a priority should it be for electronic hazard communication to encompass all modes? Which modes should be the highest priority?

f. To what extent would you use electronic hazard communication if the applicability for the electronic standard was limited to bulk transport of hazardous materials (*i.e.,* not permitted for LTL and non-bulk shipments)? How high of a priority should it be for electronic hazard communication to encompass all quantities of hazardous materials shipments?

g. Do you anticipate resistance from other entities in the hazardous materials supply chain, if you decide to adopt electronic hazard communication? If yes, please describe.

h. How would implementation of electronic hazard communication by other entities in the supply chain affect your ability to conduct your business activities if you choose to continue to operate using a paper-based concept of operations?

3. Operational and Economic Considerations

a. Do you have access to the electronic equipment and software systems required to accept, transmit, and update electronic hazard communication? Are there scenarios in which you would not? How costly would it be to acquire the necessary equipment and software systems?

b. What additional costs would there be for you to successfully utilize an electronic hazard communication system, beyond equipment procurement (*e.g.,* electronic infrastructure maintenance, training, acquisition of resources)?

c. To what extent do you currently accept or generate electronic shipping documents and utilize electronic systems for non-hazardous material shipments or operations?

d. What electronic systems, if any, do you utilize for shipment tracking, segregation, and consolidation of separate hazardous material shipping papers into a single dangerous goods (DG) manifest or other shipping document?

e. If applicable, describe the capabilities of the electronic systems you use today. What is their potential for adaptation for electronic hazard communication?

f. To what extent would your information technology (IT) infrastructure be capable of providing electronic hazard communication capabilities to your employees, as well as emergency response organizations and inspectors, without delay?

g. If not currently capable, could you develop the necessary IT infrastructure to accept and transmit electronic hazard information? Please provide a cost estimate, if possible.

h. Should PHMSA require standardized information content, format, and electronic data interchange protocol for electronic hazard communication information?

i. What time and cost savings could be gained if electronic hazard communication information was authorized?

j. Do you use paper hazard communication documents for other purposes (*e.g.,* delivery receipts)? Could electronic hazard communication facilitate more efficient use of this documentation?

k. Are there internal technological, administrative, or cultural challenges your organization would have to overcome to implement electronic hazard communication?

l. Do you think adopting electronic hazard communication would positively or negatively impact small businesses? Please explain.

m. For international shipments, are there additional barriers to implementing electronic hazard communication? If yes, please describe.

n. Are there any concerns, issues, or potential benefits related to electronic hazard communication that have not been addressed elsewhere in this RFI? Is so, please discuss.

4. Security and Privacy

a. Do you have any security concerns related to electronic hazard communication, particularly the storage

of electronic data outside of your company systems?

b. Despite the potential benefits, are your security concerns so extensive that you would not be willing to participate in electronic hazard communication? Please explain.

c. Is there any information contained on your paper-based hazard communication documents that you consider proprietary, or otherwise have privacy/business competition concerns with sharing?

d. In what ways could necessary emergency response and hazard communication information be stored in an electronic system separate from the proprietary information described above?

5. Implementation

a. What is your ideal concept of operations for electronic hazard communication?

b. Would it be beneficial to develop a single, industry-standard hazard communication information input system accessible to shippers, carriers, emergency responders, and inspectors across all modes? Please explain.

Signed in Washington, DC, on July 6, 2022, under authority delegated in 49 CFR 1.97.

William S. Schoonover,

Associate Administrator for Hazardous Materials Safety, Pipeline and Hazardous Materials Safety Administration.

[FR Doc. 2022–14655 Filed 7–8–22; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Agency Information Collection Activities: Information Collection Renewal; Submission for OMB Review; Guidance Regarding Unauthorized Access to Customer Information

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury.

ACTION: Notice and request for comment.

SUMMARY: The OCC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on a continuing information collection as required by the Paperwork Reduction Act of 1995 (PRA). In accordance with the requirements of the PRA, the OCC may not conduct or sponsor, and respondents are not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number. The OCC is soliciting comment concerning the renewal of its information collection titled, ''Guidance Regarding Unauthorized Access to Customer Information.'' The OCC also is giving notice that it has sent the collection to OMB for review.

DATES: Comments must be submitted on or before August 10, 2022.

ADDRESSES: Commenters are encouraged to submit comments by email, if possible. You may submit comments by any of the following methods:

- *Email: prainfo@occ.treas.gov.*
- *Mail:* Chief Counsel's Office, Attention: Comment Processing, 1557–0227, Office of the Comptroller of the Currency, 400 7th Street SW, Suite 3E–218, Washington, DC 20219.
- *Hand Delivery/Courier:* 400 7th Street SW, Suite 3E–218, Washington, DC 20219.
- *Fax:* (571) 465–4326.

Instructions: You must include ''OCC'' as the agency name and ''1557–0227'' 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.

Written comments and recommendations for the proposed information collection should also 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.

On April 8, 2022, the OCC published a 60-day notice for this information collection, 87 FR 20932. You may review comments and other related materials that pertain to this information collection following the close of the 30-day comment period for this notice by the method set forth in the next bullet.

- *Viewing Comments Electronically:* Go to *www.reginfo.gov.* Hover over the ''Information Collection Review'' tab and click on ''Information Collection Review'' from the drop-down menu. From the ''Currently under Review'' drop-down menu, select ''Department of Treasury'' and then click ''submit.'' This information collection can be located by searching by OMB control number ''1557–0227'' or ''Guidance Regarding Unauthorized Access to Customer Information.'' Upon finding the appropriate information collection, click on the related ''ICR Reference Number.'' On the next screen, select ''View Supporting Statement and Other Documents'' and then click on the link to any comment listed at the bottom of the screen.
- For assistance in navigating *www.reginfo.gov,* please contact the Regulatory Information Service Center at (202) 482–7340.

FOR FURTHER INFORMATION CONTACT: Shaquita Merritt, OCC Clearance Officer, (202) 649–5490, Chief Counsel's Office, Office of the Comptroller of the Currency, 400 7th Street SW, Suite 3E–218, Washington, DC 20219. If you are deaf, hard of hearing, or have a speech disability, please dial 7–1–1 to access telecommunications relay services.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the OMB for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) to include agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. The OCC asks that OMB extend its approval of the collection in this notice.

Title: Guidance Regarding Unauthorized Access to Customer Information.

OMB Control No.: 1557–0227.

Abstract: Section 501(b) of the Gramm-Leach-Bliley Act (15 U.S.C. 6801(b)) requires the OCC to establish appropriate standards for national banks, Federal savings associations, Federal branches and Federal agencies of foreign banks, and any subsidiaries of such entities (except brokers, dealers, persons providing insurance, investment companies, and investment advisers) relating to administrative, technical, and physical safeguards: (1) to insure the security and confidentiality of customer records and information; (2) to protect against any anticipated threats or hazards to the security or integrity of such records; and (3) to protect against unauthorized access to, or use of, such records or information that could result in substantial harm or inconvenience to any customer.

The Interagency Guidelines Establishing Information Security Standards, 12 CFR part 30, appendix B (Security Guidelines), which implement

section 501(b), require each entity supervised by the OCC to consider and adopt a response program, as appropriate, that specifies actions to be taken when the supervised institution suspects or detects that unauthorized individuals have gained access to customer information.

The Interagency Guidance on Response Programs for Unauthorized Access to Customer Information and Customer Notice (Breach Notice Guidance),[1] which interprets the Security Guidelines, states that, at a minimum, a supervised institution's response program should contain procedures for:

(1) Assessing the nature and scope of an incident, and identifying what customer information systems and types of customer information have been accessed or misused;

(2) Notifying its primary Federal regulator as soon as possible when the supervised institution becomes aware of an incident involving unauthorized access to, or use of, sensitive customer information;

(3) Notifying appropriate law enforcement authorities in situations involving Federal criminal violations requiring immediate attention, such as when a reportable violation is ongoing, consistent with the OCC's Suspicious Activity Report regulations;

(4) Taking appropriate steps to contain and control the incident in an effort to prevent further unauthorized access to, or use of, customer information, for example, by monitoring, freezing, or closing affected accounts, while preserving records and other evidence; and

(5) Notifying customers when warranted.

The Breach Notice Guidance states that, when a financial institution becomes aware of an incident of unauthorized access to sensitive customer information, the institution should conduct a reasonable investigation to promptly determine the likelihood that the information has been or will be misused. If the institution determines that the misuse of its information about a customer has occurred or is reasonably possible, it should notify the affected customer as soon as possible.

Type of Review: Regular.

Affected Public: Businesses or other for-profit.

Estimated Number of Respondents: 20.

Total Estimated Annual Burden: 720 hours.

Frequency of Response: On occasion.

[1] 12 CFR part 30, appendix B, supplement A.

On April 8, 2022, the OCC published a 60-day notice for this information collection, 87 FR 20932. No comments were received. Comments continue to be invited on:

(a) Whether the collection of information is necessary for the proper performance of the functions of the OCC, including whether the information has practical utility;

(b) The accuracy of the OCC's estimate of the burden of the information collection;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of the collection 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.

Theodore J. Dowd,

Deputy Chief Counsel, Office of the Comptroller of the Currency.

[FR Doc. 2022–14630 Filed 7–8–22; 8:45 am]

BILLING CODE 4810–33–P

DEPARTMENT OF THE TREASURY

Financial Crimes Enforcement Network

Agency Information Collection Activities; Proposed Renewal; Comment Request; Renewal Without Change on Information Sharing Between Government Agencies and Financial Institutions

AGENCY: Financial Crimes Enforcement Network (FinCEN), Treasury.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing efforts to reduce paperwork and respondent burden, FinCEN invites comments on the proposed renewal, without change, of a currently approved information collection found in existing Bank Secrecy Act regulations concerning information sharing between government agencies and financial institutions. Specifically, the regulations require that, upon receiving an information request from FinCEN, a financial institution must search its records to determine whether it maintains or has maintained any account or engaged in any transaction with an individual, entity, or organization named in the request. If a financial institution identifies an account or transaction named in the request, it must report such information to FinCEN in the manner and timeframe specified in the request. This request for comment is being made pursuant to the Paperwork Reduction Act of 1995.

DATES: Written comments are welcome and must be received on or before September 9, 2022.

ADDRESSES: Comments may be submitted by any of the following methods:

- *Federal E-rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Refer to Docket Number FINCEN–2022–0008 and the specific Office of Management and Budget (OMB) control number 1506–0049.
- *Mail:* Policy Division, Financial Crimes Enforcement Network, P.O. Box 39, Vienna, VA 22183. Refer to Docket Number FINCEN–2022–0008 and OMB control number 1506–0049.

Please submit comments by one method only. Comments will be reviewed consistent with the Paperwork Reduction Act of 1995 (PRA) and applicable OMB regulations and guidance. Comments submitted in response to this notice will become a matter of public record. Therefore, you should submit only information that you wish to make publicly available.

FOR FURTHER INFORMATION CONTACT: The FinCEN Regulatory Support Section at 1–800–767–2825 or electronically at *https://www.fincen.gov/contact.*

SUPPLEMENTARY INFORMATION:

I. Statutory and Regulatory Provisions

The legislative framework generally referred to as the Bank Secrecy Act (BSA) consists of the Currency and Financial Transactions Reporting Act of 1970, as amended by the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (USA PATRIOT Act), Public Law 107–56 (October 26, 2001), and other legislation, including most recently the Anti-Money Laundering Act of 2020 (AML Act).[1] The BSA is codified at 12 U.S.C. 1829b, 12 U.S.C. 1951–1960, 31 U.S.C. 5311–5314 and 5316–5336, and includes notes thereto, with implementing regulations at 31 CFR chapter X.

The BSA authorizes the Secretary of the Treasury, *inter alia,* to require financial institutions to keep records and file reports that are determined to have a high degree of usefulness in criminal, tax, and regulatory matters, or in the conduct of intelligence or

[1] The AML Act was enacted as Division F, 6001–6511, of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021, Public Law 116–283, 134 Stat 3388 (2021).

counter-intelligence activities to protect against international terrorism, and to implement AML programs and compliance procedures.[2] Regulations implementing the BSA appear at 31 CFR Chapter X. The authority of the Secretary to administer the BSA has been delegated to the Director of FinCEN.[3]

The USA PATRIOT Act charged the Department of the Treasury (Treasury) with developing regulations to facilitate information sharing among governmental entities and financial institutions for the purpose of combatting terrorism and money laundering. On September 26, 2002, FinCEN published a final rule implementing the authority contained in section 314(a) of the USA PATRIOT Act.[4] The rule required financial institutions, upon FinCEN's request (''314(a) request''), to search their records to determine whether they have maintained an account or conducted a transaction with a person that a Federal law enforcement agency has certified is suspected, based on credible evidence, of engaging in terrorist activity or money laundering. The rule was expanded on February 10, 2010, to enable certain entities other than Federal law enforcement agencies to benefit from 314(a) requests to industry. As amended, the rule also enables certain foreign law enforcement agencies, state and local law enforcement agencies, and FinCEN itself, on its own behalf and on behalf of appropriate components of Treasury, to initiate 314(a) requests.[5] Before processing a request, FinCEN requires the requesting agency to certify that, in the case of money laundering, the matter is significant, and that the requesting agency has been unable to locate the information sought through traditional methods of investigation and analysis. The regulations implementing the rules are found at 31 CFR 1010.520.

31 CFR 1010.520(b)(3)(i) requires financial institutions,[6] upon receiving a 314(a) request, to search their records to determine whether they maintain, or have maintained, an account for, or engaged in any transaction with, each individual, entity, or organization named in a 314(a) request. Unless noted otherwise in a request, financial institutions are only required to search their records for the following: (i) current accounts maintained for the named suspect; (ii) any account maintained for a named suspect during the preceding twelve months; and (iii) any transactions[7] conducted by or on behalf of a named suspect, or any transmittal of funds conducted in which the named suspect was either the transmittor or the recipient, during the preceding six months, which are recorded and maintained electronically.

31 CFR 1010.520(b)(3)(ii) requires financial institutions that identify accounts or transactions for the subject of a 314(a) request to report the match to FinCEN in the manner and timeframe specified by FinCEN. 31 CFR 1010.520(b)(3)(iii) requires financial institutions to designate one person to be the point of contact at the institution to receive 314(a) requests.

II. Paperwork Reduction Act of 1995[8]

Title: Information sharing between government agencies and financial institutions (31 CFR 1010.520).

OMB Control Number: 1506–0049.

Report Number: Not applicable.

Abstract: FinCEN is issuing this notice to renew the OMB control number for regulations requiring information sharing between government agencies and financial institutions.

Affected Public: Businesses or other for-profit and non-profit institutions.

Type of Review: Renewal without change of a currently approved collection.

Frequency: As required.

Estimated Number of Respondents: 14,960.[9]

Estimated Annual Responses per Respondent: 365 searches/responses.[10]

Estimated Reporting and Recordkeeping Burden:

In general, FinCEN receives requests from law enforcement, reviews those requests, posts those requests on a secure internet website, and sends notifications to designated contacts within financial institutions across the United States once every two weeks. A 314(a) request contains subject and business names, addresses, and as much identifying data as possible to assist financial institutions in searching their records. Financial institutions must query their records for data matches, including accounts maintained by the named subject during the preceding 12 months and transactions conducted within the last six months. Financial institutions have two weeks from the posting date of the request to respond with any positive matches. Financial institutions are instructed not to reply to the 314(a) request if a search does not uncover any matching of accounts or transactions.

Currently, 100% of 314(a) responses are filed using automated technology. The 314(a) files are posted on FinCEN's secure website. The files are available for download in .csv, .txt, and .doc format to allow for ingestion into various software that financial institutions use to run searches against their systems. All positive responses can be submitted through FinCEN's secure website by checking the box next to each subject for which there is a match and clicking the ''submit'' button to transmit the responses to FinCEN. Providing downloads in a variety of formats reduces burden on financial institutions by allowing them to automate the search of their records in a format that is compatible with their software and systems.

For the following reasons, FinCEN estimates that it will take approximately 4 minutes to research and report, as necessary, each subject of a 314(a) request:

- Financial institutions have well established processes, and in most cases automated processes, in place to conduct 314(a) searches, given the 20 years that the program has been running.
- Financial institutions are only required to search their records for account and transaction information that is maintained electronically.

[2] Section 358 of the USA PATRIOT Act added language expanding the scope of the BSA to intelligence or counter-intelligence activities to protect against international terrorism. Section 6101 of the AML Act added language further expanding the scope of the BSA but did not amend these longstanding purposes.

[3] Treasury Order 180–01 (re-affirmed Jan. 14, 2020).

[4] FinCEN, *Final Rule—Special Information Sharing Procedures to Deter Money Laundering and Terrorist Activity,* 67 FR 60579, (Sept. 26, 2002).

[5] FinCEN, Final Rule—Expansion of Special Information Sharing Procedures To Deter Money Laundering and Terrorist Activity, 75 FR 6560, (Feb. 10, 2010).

[6] Defined for the purposes of this requirement at 31 CFR 1010.520(a)(1).

[7] As defined at 31 CFR 1010.505(d).

[8] The PRA does not apply to the requirement in section 1010.520(b) concerning reports by financial institutions in response to a request from FinCEN on behalf of a Federal law enforcement agency. *See* 5 CFR 1320.4(a)(2). Therefore, this renewal applies only to the use of the 314(a) requests with respect to queries initiated by non-Federal law enforcement entities.

[9] On an annual basis, FinCEN sends 314(a) requests to approximately 14,960 financial institutions, consisting of certain commercial banks, savings associations, and credit unions, broker or dealers in securities, future commission merchants, trust companies, life insurance companies, mutual funds and money services businesses.

[10] Based on the number of 314(a) requests issued between May 2021 and April 2022, FinCEN estimates the annual number of requests subject to the PRA to include: 3 from FinCEN, 45 from state/local law enforcement, and 9 from European Union countries approved by treaty, for a total of 57 requests per year, with each request containing an average of 6.4 subjects (including aliases). 57 requests multiplied by 6.4 subjects per request equals 364.8 (rounded up to 365) searches and potential responses annually.

• Only positive responses confirming a match are required to be reported to FinCEN by checking a box corresponding to the match on FinCEN's secure website.

• FinCEN has been estimating a burden of 4 minutes per subject in PRA renewals since the expansion of the rule in 2010.[11] We have not received public comments questioning or contradicting this estimate.

Estimated Burden Hours per Respondent: 24 hours annually.[12]

Estimated Total Annual Burden Hours: 363,827.[13]

Estimated Total Annual Cost: $34,563,565.[14]

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.

Request for Comments

(a) Specific request for comments on the PRA hourly burden and cost.

FinCEN invites comments on any aspect of the PRA burden set out in section II of this notice. In particular, FinCEN seeks comments on the adequacy of: (i) FinCEN's assumptions underlying its estimate of the burden; (ii) the estimated amount of time per subject; and (iii) the organizational levels of employees engaged in responding to requests.

(b) Specific questions for comment regarding compliance with information requests as outlined in 31 CFR 1010.520 (if the commenter represents a financial institution, FinCEN asks that the comment provide information particular to that financial institution.)

1. To what extent can a financial institution rely on existing software to conduct its 314(a) search?

2. On average, how long does it take your financial institution to perform a search for a particular subject of a 314(a) request (''314(a) subject'')?

3. How often does your financial institution generate a positive match to a 314(a) subject that requires additional research to confirm if the account or transaction is in fact connected to that subject?

4. What steps does your financial institution take once your automated system generates a match to a 314(a) subject to determine if it is an actual match or a false positive? What type of records does your financial institution maintain to document the results of this type of research?

5. How frequently does your financial institution's automated system identify matches to a 314(a) subject that ultimately result in a false positive?

6. What type of records does your financial institution maintain to document that a 314(a) search has been conducted?

7. What is the role of the individual at your financial institution that acts as the point of contact for 314(a) requests?

8. Is more than one employee at your financial institution involved in conducting the biweekly 314(a) searches?

9. Does senior management play a role in reviewing the results of your financial institution's biweekly search for subjects of 314(a) requests?

(c) General 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: (1) 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; (2) the accuracy of the agency's estimate of the burden of the collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; (4) 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 (5) estimates of capital or start-up costs and costs of operation, maintenance and purchase of services to provide information.

Himamauli Das,

Acting Director, Financial Crimes Enforcement Network.

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BILLING CODE 4810–02–P

[11] *See supra* note 5.

[12] FinCEN estimates each subject requires 4 minutes to research and report, resulting in approximately 24 hours per year per respondent (365 searches/responses multiplied by 4 minutes per subject and divided by 60 minutes). FinCEN welcomes comments on the accuracy of this assumption.

[13] The total annual burden computation is as follows: approximately 24 hours per year per respondent multiplied by 14,960 respondents equals 363,827 hours.

[14] The total annual cost computation is as follows: 363,827 hours times the financial institution fully loaded wage estimate of $95 per hour equals $34,563,565. To estimate an average hourly financial institution employee wage, FinCEN uses hourly wage data for the following six occupations in each of the nine categories of covered financial institutions that face BSA requirements: chief executives (OCC-code: 11–1010); financial managers (OCC-code: 11–3031); compliance officers (OCC-code: 13–1041); financial clerks (OCC-code: 43–3099); lawyers and judicial clerks (OCC-code: 23–1010); and computer and information systems managers (OCC-code: 11–3021). The 54 hourly wage estimate inputs (9 financial industry categories multiplied by six occupations) yield a comprehensive financial institution hourly wage estimate of $67.23. The ratio between benefits and wages for private industry workers is $11.22 (hourly benefits)/$26.86 (hourly wages) = 0.42, as of December 2021. The benefit factor is 1 plus the benefit/wages ratio, or 1.42. See U.S. Bureau of Labor Statistics, ''Employer Costs for Employee Compensation Historical Listing,'' *https://www.bls.gov/web/ecec/ececqrtn.pdf.* The private industry workers series data for December 2021 is available at *https://www.bls.gov/web/ecec/ecec-private-dataset.xlsx.* Multiplying the hourly wage estimate of $67.23 by the benefits factor of 1.42 and rounding to the nearest dollar produces a fully loaded hourly compensation amounts of $95 per hour.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel Taxpayer Assistance Center Improvements Project Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel's Taxpayer Assistance Center Improvements Project Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service. This meeting will still be held via teleconference.

DATES: The meeting will be held Thursday, August 11, 2022.

FOR FURTHER INFORMATION CONTACT: Matthew O'Sullivan at 1–888–912–1227 or (510) 907–5274.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Taxpayer Advocacy Panel's Taxpayer Assistance Center Improvements Project Committee will be held Thursday, August 11, 2022, at 3:00 p.m. Eastern Time. The public is invited to make oral comments or submit written statements for consideration. Due to limited time and structure of meeting, notification of intent to participate must be made with Matthew O'Sullivan. For more information please contact Matthew O'Sullivan at 1–888–912–1227 or (510) 907–5274, or write TAP Office, 1301 Clay Street, Oakland, CA 94612–5217 or contact us at the website: *http://www.improveirs.org.* The agenda will include various IRS issues.

Dated: July 5, 2022.

Kevin Brown,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2022–14646 Filed 7–8–22; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel's Special Projects Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel's Special Projects Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service. This meeting will still be held via teleconference.

DATES: The meeting will be held Wednesday, August 10, 2022.

FOR FURTHER INFORMATION CONTACT: Antoinette Ross at 1–888–912–1227 or 202–317–4110.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Taxpayer Advocacy Panel's Special Projects Committee will be held Wednesday, August 10, 2022, at 11:00 a.m. Eastern Time. The public is invited to make oral comments or submit written statements for consideration. Due to limited time and structure of meeting, notification of intent to participate must be made with Antoinette Ross. For more information please contact Antoinette Ross at 1–888–912–1227 or 202–317–4110, or write TAP Office, 1111 Constitution Ave. NW, Room 1509, Washington, DC 20224 or contact us at the website: *http://www.improveirs.org*. The agenda will include various IRS issues.

Dated: July 5, 2022.

Kevin Brown,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2022–14645 Filed 7–8–22; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel Taxpayer Communications Project Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel's Taxpayer Communications Project Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service. This meeting will be held via teleconference.

DATES: The meeting will be held Wednesday, August 10, 2022.

FOR FURTHER INFORMATION CONTACT: Conchata Holloway at 1–888–912–1227 or 214–413–6550.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that a meeting of the Taxpayer Advocacy Panel Taxpayer Communications Project Committee will be held Wednesday, August 10, 2022, at 12:00 p.m. Eastern Time. The public is invited to make oral comments or submit written statements for consideration. Due to limited time and structure of meeting, notification of intent to participate must be made with Conchata Holloway. For more information, please contact Conchata Holloway at 1–888–912–1227 or 214–413–6550, or write TAP Office, 1114 Commerce St MC 1005 Dallas, TX, 75242 or contact us at the website: *http://www.improveirs.org*. The agenda will include various IRS issues.

Dated: July 5, 2022.

Kevin Brown,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2022–14644 Filed 7–8–22; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel's Tax Forms and Publications Project Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel's Tax Forms and Publications Project Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service. This meeting will be held via teleconference.

DATES: The meeting will be held Tuesday, August 9, 2022.

FOR FURTHER INFORMATION CONTACT: Fred Smith at 1–888–912–1227 or (202) 317–3087.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. app. (1988) that a meeting of the Taxpayer Advocacy Panel's Tax Forms and Publications Project Committee will be held Tuesday, August 9, 2022, at 1:00 p.m. Eastern Time. The public is invited to make oral comments or submit written statements for consideration. Due to limited time and structure of meeting, notification of intent to participate must be made with Fred Smith. For more information, please contact Fred Smith at 1–888–912–1227 or (202) 317–3087, or write TAP Office, 1111 Constitution Ave. NW, Room 1509, Washington, DC 20224 or contact us at the website: *http://www.improveirs.org.*

Dated: July 5, 2022.

Kevin Brown,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2022–14642 Filed 7–8–22; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel Joint Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel Joint Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service.

DATES: The meeting will be held Thursday, August 25, 2022.

FOR FURTHER INFORMATION CONTACT: Gilbert Martinez at 1–888–912–1227 or (737) 800–4060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Taxpayer Advocacy Panel Joint Committee will be held Thursday, August 25, 2022, at 1:30 p.m. Eastern Time via teleconference. The public is invited to make oral comments or submit written statements for consideration. For more information, please contact Gilbert Martinez at 1–888–912–1227 or (737–800–4060), or write TAP Office 3651 S IH–35, STOP 1005 AUSC, Austin, TX 78741, or post comments to the website: *http://www.improveirs.org*.

The agenda will include various committee issues for submission to the IRS and other TAP related topics. Public input is welcomed.

Dated: July 5, 2022.

Kevin Brown,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2022–14647 Filed 7–8–22; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel's Notices and Correspondence Project Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel's Notices and Correspondence Project Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service. This meeting will be held via teleconference.

DATES: The meeting will be held Tuesday, August 9, 2022.

FOR FURTHER INFORMATION CONTACT: Robert Rosalia at 1–888–912–1227 or (718) 834–2203.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. app. (1988) that an open meeting of the Taxpayer Advocacy Panel's Notices and Correspondence Project Committee will be held Tuesday, August 9, 2022, at 12:00 p.m. Eastern Time. The public is invited to make oral comments or submit written statements for consideration. Due to limited time and structure of meeting, notification of intent to participate must be made with Robert Rosalia. For more information, please contact Robert Rosalia at 1–888–912–1227 or (718) 834–2203, or write TAP Office, 2 Metrotech Center, 100 Myrtle Avenue, Brooklyn, NY 11201 or contact us at the website: *http://www.improveirs.org*. The agenda will include various IRS issues.

Dated: July 5, 2022.

Kevin Brown,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2022–14643 Filed 7–8–22; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel Joint Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel Joint Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service.

DATES: The meeting will be held August 9, 2022, and August 10, 2022.

FOR FURTHER INFORMATION CONTACT: Gilbert Martinez at 1–888–912–1227 or (737) 800–4060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Taxpayer Advocacy Panel Joint Committee will be held Tuesday, August 9, 2022, and Wednesday August 10, 2022, from 8:30 a.m. to 5:00 p.m. Eastern Standard Time. The public is invited to make oral comments or submit written statements for consideration. For more information, please contact Gilbert Martinez at 1–888–912–1227 or (737–800–4060), or write TAP Office 3651 S IH–35, STOP 1005 AUSC, Austin, TX 78741, or post comments to the website: *http://www.improveirs.org*.

The agenda will include various committee issues for submission to the IRS and other TAP related topics. Public input is welcomed.

Dated: July 1, 2022.

Kevin Brown,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2022–14648 Filed 7–8–22; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel's Toll-Free Phone Lines Project Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel's Toll-Free Phone Lines Project Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service. This meeting will be held via teleconference.

DATES: The meeting will be held Tuesday, August 9, 2022.

FOR FURTHER INFORMATION CONTACT: Rosalind Matherne at 1–888–912–1227 or 202–317–4115.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. app. (1988) that an open meeting of the Taxpayer Advocacy Panel Toll-Free Phone Lines Project Committee will be held Tuesday, August 9, 2022, at 3:00 p.m. Eastern Time. The public is invited to make oral comments or submit written statements for consideration. Due to limited time and structure of meeting, notification of intent to participate must be made with Rosalind Matherne. For more information, please contact Rosalind Matherne at 1–888–912–1227 or 202–317–4115, or write TAP Office, 1111 Constitution Ave. NW, Room 1509, Washington, DC 20224 or contact us at the website: *http://www.improveirs.org*. The agenda will include various IRS issues.

Dated: July 5, 2022.

Kevin Brown,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2022–14641 Filed 7–8–22; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–XXXX]

Agency Information Collection Activity: Veteran Rapid Retraining Assistance Program (VRRAP) 30, 60, 90, 180-Day Experience Survey, and VRRAP Experience Survey After Employment

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the Veterans Benefits Administration (VBA), Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden and it includes the actual data collection instrument.

DATES: 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. Refer to ''OMB Control No. 2900–XXXX.

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–XXXX'' 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: Public Law 117–2 § 8006 and Public Law 117–16.

Title: Veteran Rapid Retraining Assistance Program (VRRAP) 30, 60, 90, 180-Day Experience Survey, and VRRAP Experience Survey After Employment.

OMB Control Number: 2900–XXXX.

Type of Review: New Information Collection.

Abstract: These VRRAP Surveys submitted for OMB's approval through regular ICR 3-year collection for the Collection of Qualitative Feedback on Agency Service Delivery'' is being submitting based on the recently enacted ''Training in High-demand Roles to Improve Veteran Employment Act'' (THRIVE ACT) legislation. This new Public Law 117–16 amended the Veteran Rapid Retraining Assistance Program (VRRAP), Public Law 117–2 Section 8006 by requiring VA, in coordination with Department of Labor (DOL), to contact each Veteran who completes a covered program of education under the retraining assistance program 30, 60, 90, and 180 days after the Veteran completes the program of education to ask about their experience in the retraining assistance program and their employment status.

The Thrive Act legislation also specifies that a Veteran participating in a covered program of education solely through distance learning on a half-time basis or less would not receive a housing stipend, and it clarifies the housing stipend amount provided to a Veteran when participating in a program on a half-time basis or less. The Thrive Act also requires VA, in consultation with the DOL to contact each participating Veteran no later than 30 days after the date the Veteran begins the program of education, to notify them of employment placement services available upon completion of the program; and to, no later than 14 days after the date the Veteran completes, or terminates participation in the program, to facilitate the provision of employment placement services to the Veteran.

The Thrive Act also requires VA to enter into a Memorandum of Understanding with one or more qualified nonprofit organizations to facilitate the employment of Veterans who participate in the retraining assistance program. A qualified non-profit organization is an organization that is an association of businesses and has at least two years of experience providing job placement services for Veterans. And finally, the legislation requires DOL, no later than one year after the date of the Thrive Act enactment, to submit a report to the Committees on Veterans' Affairs of the Senate and House of Representatives.

The report must contain the percentage of Veterans who found employment before the end of the second calendar quarter after exiting the program; the percentage of Veterans who found employment before the end of the fourth calendar quarter after exiting the program; the median earnings of Veterans for the second quarter after exiting the program; and the percentage of Veterans who attain a recognized postsecondary credential during the 12-month period after exiting the program, and would require the Comptroller General of the United States to submit a report to Congress on the outcomes and effectiveness of the retraining program not later than 180 days after the termination of the retraining assistance program, December 11, 2022. Feedback from the Surveys will be used for that purpose.

The feedback will also provide insights into the eligible beneficiaries' perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training, or changes in operations might improve delivery of products or services. This collection will allow for ongoing, collaborative and actionable communications between VA and Veteran Rapid Retraining Assistance Program (VRRAP) participants regarding their needs for employment assistance. It will also allow feedback to contribute directly to the improvement of the VRRAP program management.

Improving agency programs requires ongoing assessment of service delivery, by which we mean systematic review of the operation of a program compared to a set of explicit or implicit standards, as a means of contributing to the continuous improvement of the program. VA will collect, analyze, and interpret information gathered through this regular ICR submission survey to identify strengths and weaknesses of current services and make improvements in service delivery based on feedback. The solicitation of feedback will target areas such as: timeliness, appropriateness, accuracy of information, courtesy, efficiency of service delivery, and resolution of issues with service delivery. Responses will be assessed to plan and inform efforts to improve or maintain the quality of service offered to the public. If this information is not collected, vital feedback from customers and stakeholders on VA's services will be unavailable.

The type of regular ICR survey collection is limited only as:

- Web-Based or other forms of social media and email

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 **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at 87 FR 84 on May 2, 2022, page 25701.

Affected Public: Individuals and households.

Estimated Annual Burden: 830 hours.

Estimated Average Burden per Respondent: 2 minutes.

Frequency of Response: Four (4) per year (Quarterly).

Estimated Number of Respondents: 6,225.

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. 2022–14670 Filed 7–8–22; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0095]

Agency Information Collection Activity: Pension Claim Questionnaire for Farm Income

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the Veterans Benefits Administration (VBA), Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden and it includes the actual data collection instrument.

DATES: 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. Refer to ''OMB Control No. 2900–0095.

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. 2900–0095'' in any correspondence.

SUPPLEMENTARY INFORMATION:

Authority: 38 U.S.C. 1503 and 38 U.S.C. 1522.

Title: Pension Claim Questionnaire for Farm Income (21P–4165).

OMB Control Number: 2900–0095.

Type of Review: Revision of a currently approved collection.

Abstract: The Department of Veterans Affairs (VA) through its Veterans Benefits Administration (VBA) administers an integrated program of benefits and services, established by law, for Veterans, service personnel, and their dependents and/or beneficiaries.

Entitlement to pension benefits for Veterans and their surviving dependents is based on the family's countable annual income under the authority of 38 U.S.C. 1503 and under the authority of 38 U.S.C. 1522. VA Form 21P–4165 is used to gather the necessary information to evaluate the claimant's countable income and net worth related to the operation of a farm for the purpose of establishing entitlement to pension benefits and to evaluate a beneficiary's ongoing entitlement to pension benefits.

The respondent burden has decreased due to the estimated number of receivables averaged over the past year. No other changes have been made to this form.

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 **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at 87 FR 86 on May 4, 2022, page 26393.

Affected Public: Individuals or Households.

Estimated Annual Burden: 109 hours.

Estimated Average Burden per Respondent: 30 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 218.

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. 2022–14669 Filed 7–8–22; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 493

Clinical Laboratory Improvement Amendments of 1988 (CLIA) Proficiency Testing Regulations Related to Analytes and Acceptable Performance

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 493

[CMS–3355–F]

RIN 0938–AT55

Clinical Laboratory Improvement Amendments of 1988 (CLIA) Proficiency Testing Regulations Related to Analytes and Acceptable Performance

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS; Centers for Disease Control and Prevention (CDC), HHS.

ACTION: Final rule.

SUMMARY: This final rule updates proficiency testing (PT) regulations under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) to address current analytes (that is, substances or constituents for which the laboratory conducts testing) and newer technologies. This final rule also makes technical changes to PT referral regulations to better align them with the CLIA statute.

DATES: Effective August 10, 2022, except for the amendments to §§ 493.2 and 493.801 through 493.959 (amendatory instructions 2 and 5 through 21), which are effective July 11, 2024.

FOR FURTHER INFORMATION CONTACT: Sarah Bennett, CMS, (410) 786–3531; or Nancy Anderson, CDC, (404) 498–2741.

SUPPLEMENTARY INFORMATION:

I. Background

On October 31, 1988, Congress enacted the Clinical Laboratory Improvement Amendments of 1988 (Pub. L. 100–578) (CLIA '88), codified at 42 U.S.C. 263a, to ensure the accuracy and reliability of testing in all laboratories, including, but not limited to, those that participate in Medicare and Medicaid, that test human specimens for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment, or the assessment of health, of human beings. The Secretary established the initial regulations implementing CLIA on February 28, 1992 at 42 CFR part 493 (57 FR 7002). Those regulations required laboratories conducting moderate or high-complexity testing to enroll in an approved proficiency testing (PT) program for each specialty, subspecialty, and analyte or test for which the laboratory is certified under CLIA. PT referral was further addressed by enactment of the Taking Essential Steps for Testing Act of 2012 (Pub. L. 112–202, December 4, 2012) (TEST Act) and our implementing regulations (79 FR 25435 and 79 FR 27105). As of January 2020, approximately 35,967 CLIA-certified laboratories were required to enroll in a U.S. Department of Health and Human Services (HHS)-approved PT program and comply with the PT regulations.

Participation in PT is required under the CLIA statute for laboratories that perform moderate or high complexity testing. PT evaluates a laboratory's performance by testing unknown samples just as it would test patient samples. An HHS-approved PT program sends unknown samples to a laboratory for analysis. After testing, the laboratory reports its results to the PT program. The program grades the results using the CLIA grading criteria and provides the laboratory with its scores. PT is crucial to maintaining the quality of laboratory testing because it independently verifies the accuracy and reliability of laboratory testing, including the competency of testing personnel.

Testing has evolved significantly since 1992, and today's technology is more accurate and precise than the methods used when the PT regulations became effective in 1994. In addition, many tests for analytes for which PT was not initially required are now in routine clinical use. For example, tests for troponins, which are used to diagnose myocardial infarction, and the hemoglobin A1c test commonly used to monitor glycemic control in persons with diabetes were not routinely performed prior to 1992. Recognizing these changes, we proposed revisions to update the existing PT regulations in a proposed rule entitled, ''Clinical Laboratory Improvement Amendments of 1988 (CLIA) Proficiency Testing Regulations Related to Analytes and Acceptable Performance'', published in the February 4, 2019 **Federal Register** (84 FR 1536) (hereinafter the proposed rule).

Generally, a final rule must be issued within 3 years of publishing a proposed rule, except under exceptional circumstances. As discussed in a notice entitled, ''Clinical Laboratory Improvement Amendments of 1988 (CLIA) Proficiency Testing Regulations Related to Analytes and Acceptable Performance; Extension of Timeline for Publication of Final Rule'', published in the January 19, 2022, **Federal Register** (87 FR 2736) (hereinafter the notice of extension), we could not meet the February 4, 2022 deadline due to the necessary reallocation of resources to respond to the COVID–19 public health emergency. Therefore, in the notice of extension, we announced an extension of the timeline to publish the final rule by 1 year until February 4, 2023.

As part of the process for developing the proposed rule, HHS solicited input from the Clinical Laboratory Improvement Advisory Committee (CLIAC), the official Federal advisory committee charged with advising HHS regarding appropriate regulatory standards for ensuring accuracy, reliability, and timeliness of laboratory testing. Taking CLIAC's recommendations into account, CMS and CDC collaborated to develop a process to revise the list of required PT analytes listed in subpart I to determine which analytes should be retained, which should be deleted, and which analytes not currently listed in subpart I should be added to the regulations. Following the data-driven process and step-wise criteria used to select the candidate analytes to be included in the proposed rule, CMS and CDC sought feedback from PT programs on the following topics: current PT program practices using ''peer grouping'' to determine target values; the potential to include new analytes as required PT; the mechanism for grading current analytes; possible changes to the criteria for acceptable performance; and potential changes to microbiology subspecialties, including the replacement of the types of service as outlined currently at §§ 493.911(a), 493.913(a), 493.915(a), 493.917(a) and 493.919(a), with the proposed categories of required PT for each microbiology subspecialty at the above citations and the replacement of the list of specific organisms for each subspecialty with a proposed list of types of microorganisms.

Based on empirical data and clinical relevance, CMS and CDC next worked to determine or revise the acceptance limits (ALs) (as defined in § 493.2) for new and existing required analytes, respectively. Whenever possible, we proposed ALs as percentages. For each analyte, PT programs voluntarily provided data simulations using real PT data as a means of pilot testing our potential ALs. As stated in the proposed rule, ALs are intended to be used for scoring PT performance by PT programs and are not intended to be used by individual laboratories to satisfy the requirement at § 493.1253(b) to establish performance specifications.

II. Provisions of the Proposed Regulations

The proposed rule, if finalized, would amend the definitions and PT

requirements in subpart A—General Provisions, § 493.2 Definitions; subpart H—Participation in Proficiency Testing for Laboratories Performing Nonwaived Testing; and subpart I—Proficiency Testing Programs for Nonwaived Testing in the CLIA regulations.

A. Proposed Changes to Microbiology PT

1. Categories of Testing

Subpart I of the CLIA regulations includes PT requirements for each subspecialty of microbiology, §§ 493.911 through 493.919, which describe ''Types of services offered by laboratories'' for each subspecialty. In addition, since the regulations do not specify required analytes for microbiology as they do for other specialties, they include descriptions of levels or extents (for example, identification to the genus level only, identification to the genus and species level) used to determine the type of laboratory for PT purposes. CLIAC discussed the usefulness and limitations of the types of services listed in subpart I in helping laboratories enroll properly or in helping surveyors conduct laboratory inspections. It was noted that the types of services listed in subpart I do not allow for reporting growth or no growth, presence or absence, or presumptive identification of microorganisms on PT samples, which are common ways that physician office laboratories report patient results. CLIAC suggested revision of the regulations to include broad categories for the types of PT required for each microbiology subspecialty to allow flexibility for the inclusion of new technologies.

After deliberation, CLIAC made the following recommendations:

- A system for categorizing types of service should be maintained in the regulations to help laboratories determine what PT they need to perform and assist surveyors in monitoring PT performance and patient testing.
- The regulations should include four categories of testing for each microbiology subspecialty, as applicable: stain(s), susceptibility and resistance testing, antigen and/or toxin detection, and microbial identification or detection.

Based on these recommendations, we conducted a review of the PT modules offered by HHS-approved PT programs and consulted with CDC microbiology subject matter experts, who concurred that not all four recommended categories above are applicable to each microbiology subspecialty nor do PT programs have PT available for each category. If at some point in the future PT becomes available, we may propose to include additional categories of testing for microbiology subspecialties in future rulemaking. Based on these recommendations and our review, we proposed to modify §§ 493.911 through 493.919 to remove the types of services listed for each microbiology subspecialty and to add the recommended categories of testing (that is, replace the list with broader categories of organisms) for each microbiology subspecialty as described in the bullets below. We believe that the revised microbiology PT regulations would better reflect current practices in microbiology.

++ Section 493.911(a): For bacteriology, we proposed that the categories required include, as applicable: Gram stain including bacterial morphology; direct bacterial antigen detection; bacterial toxin detection; detection and identification of bacteria which includes either: detection of growth or no growth in culture media or identification of bacteria to the highest level that the laboratory reports results on patient specimens; and antimicrobial susceptibility or resistance testing on select bacteria.

++ Section 493.911(a)(3): We proposed that the bacteriology annual PT program content described must include representatives of the following major groups of medically important aerobic and anaerobic bacteria if appropriate for the sample sources: Gram-negative bacilli; Gram-positive bacilli; Gram-negative cocci; and Gram-positive cocci.

++ Section 493.913(a): For mycobacteriology, we proposed that the categories for which PT is required include, as applicable: acid-fast stain; detection and identification of mycobacteria which includes one of the following: detection of growth or no growth in culture media or identification of mycobacteria; and antimycobacterial susceptibility or resistance testing.

++ Section 493.913(a)(3): For mycobacteriology, we proposed that the annual program content must include *Mycobacterium tuberculosis* complex and *Mycobacterium* other than tuberculosis (MOTT), if appropriate for the sample sources.

++ Section 493.915(a): For mycology, we proposed the categories for which PT is required include, as applicable: direct fungal antigen detection; detection and identification of fungi and aerobic actinomycetes which included one of the following: detection of growth or no growth in culture media or identification of fungi and aerobic actinomycetes; and antifungal susceptibility or resistance testing.

++ Section 493.915(a)(3): We proposed that annual program content must include the following major groups of medically important fungi and aerobic actinomycetes if appropriate for the sample sources: yeast or yeast-like organisms; molds that include dematiaceous fungi, dermatophytes, dimorphic fungi, hyaline hyphomycetes, and mucormycetes; and aerobic actinomycetes.

++ Section 493.917(a): For parasitology, we proposed requiring PT for direct parasite antigen detection and detection and identification of parasites.

++ Section 493.917(a)(3): We proposed that the annual program content must include intestinal parasites and blood and tissue parasites, if appropriate for the sample source.

++ Section 493.919(a): For virology, we proposed requiring PT, as applicable, for viral antigen detection; detection and identification of viruses; and antiviral susceptibility or resistance testing.

++ Section 493.919(a)(3): We proposed that the annual program content must include respiratory viruses, herpes viruses, enterovirus, and intestinal viruses, if appropriate for the sample source.

We proposed revising the requirements for evaluating a laboratory's performance at §§ 493.911(b) through 493.919(b) to be consistent with these categories. We did not propose to include antigen and toxin detection in the mycobacteriology subspecialty because no PT program currently offers applicable PT modules. We did not propose to include stains and antiparasitic susceptibility or resistance testing in the subspecialty of parasitology because no PT program offers applicable PT modules. We invited the public to comment on these proposals and specifically on the proposed categories of testing for the subspecialties listed above. We stated that if public comments indicate that applicable PT modules are available for antigen and toxin detection or stains and antiparasitic susceptibility or resistance testing, we may finalize their inclusion in the final rule, as applicable. If PT becomes available at some point in the future for mycobacteriology antigen and toxin detection testing, and stains and antiparasitic susceptibility or resistance testing, we may propose to include this category of testing for PT in future rulemaking. We summarize and respond to the public comments on these proposals and summarize our final policies in section III.E. of this final rule.

++ Sections 493.911(b)(1), 493.913(b)(1), 493.915(b)(1), 493.917(b)(1), and 493.919(b)(1): We proposed amending these provisions to clarify that to achieve consensus, PT programs must attempt to grade using both participant and referee laboratories [1] before determining that the sample is ungradable. We believe that this change will enhance consistency among the PT programs when grading samples. The current regulations noted above allow for scoring either with participants or with referees before calling a sample ungradable. We summarize and respond to the public comments we received on these proposals and summarize our final policies in section III.D. of this final rule.

2. Major Groups of Microorganisms

In the proposed rule (84 FR 1536, 1538), we proposed to remove the lists of specific example organisms from each microbiology subspecialty and add a more general list of organisms. This change clarifies that PT programs are able to be flexible in selecting which samples to provide to laboratories for PT, especially as new organisms are identified as being clinically important.

Each subspecialty of microbiology, §§ 493.911 through 493.919, currently includes a list of the types of microorganisms that might be included in an HHS-approved PT program over time. Several PT programs have suggested to HHS that the regulations should include a more general list of types of organisms that must be included in required PT instead of a specific list. CLIAC considered whether there needs to be a more general list of organisms in the regulations to ensure a variety of challenges are offered over the course of the year. Following their deliberation, CLIAC made the following recommendation:

• Require PT for a general list of types of organisms in each subspecialty. For example, in bacteriology, the groups listed should include Gram-negative bacilli, Gram-positive bacilli, Gram-negative cocci, and Gram-positive cocci.

Generally, we have found that PT programs include only those organisms listed in the current regulations, and do not include additional organisms outside the current regulatory list. By restructuring to a more general list of organisms, it will be more apparent that PT programs are able to be flexible in selecting which samples to provide to laboratories for PT, especially as new organisms are identified as being clinically important. Therefore, we proposed to remove the lists of specific example organisms from each microbiology subspecialty, §§ 493.911 through 493.919, and to add the following list of types of organisms to each.

++ Section 493.911(a)(3): For bacteriology, we proposed that the annual program content must include representatives of the following major groups of medically important aerobic and anaerobic bacteria if appropriate for the sample sources: Gram-negative bacilli; Gram-positive bacilli; Gram-negative cocci; and Gram-positive cocci. The more general list of types of organisms will continue to cover the six major groups of bacteria currently listed in the regulations.

++ Section 493.913(a)(3): For mycobacteriology, we proposed that the annual program content must include *Mycobacterium tuberculosis* complex and *Mycobacterium* other than tuberculosis (MOTT), if appropriate for the sample sources.

++ Section 493.915(a)(3): For mycology, we proposed that the annual program content must include the following major groups of medically important fungi and aerobic actinomycetes if appropriate for the sample sources: yeast or yeast-like organisms; molds that include dematiaceous fungi, dermatophytes, dimorphic fungi, hyaline hyphomycetes, and mucormycetes; and aerobic actinomycetes.

++ Section 493.917(a)(3): For parasitology, we proposed that the annual program content must include intestinal parasites and blood and tissue parasites, if appropriate for the sample sources.

++ Section 493.919(a)(3): For virology, we proposed that the annual program content must include respiratory viruses, herpes viruses, enterovirus, and intestinal viruses, if appropriate for the sample sources.

We summarize and respond to the public comments we received on these proposals and summarize our final policies in section III.E. of this final rule.

3. Declaration of Patient Reporting Practices

The PT requirements at § 493.801(b) specify that laboratories must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. CLIAC considered this requirement as applied to microbiology and agreed that PT programs should instruct laboratories to perform all testing as they normally would on patient specimens, including reporting PT results for microorganism identification to the same level reported on patient specimens. CLIAC deliberated on this issue and made the following recommendation:

• Laboratories should declare their patient reporting practices for organisms included in each PT challenge. However, PT programs should only gather this information as the inspecting agency is responsible for reviewing and taking action if necessary.

We believe that laboratories should be instructed to report PT results for microbiology organism identification to the ''highest'' level that they report results on patient specimens to ensure that they do so to the ''same'' level that they report results on patient specimens. As a result, we proposed to amend §§ 493.801(b), 493.911(b), 493.913(b), 493.915(b), 493.917(b), and 493.919(b), to state that laboratories must report PT results for microbiology organism identification to the highest level that they report results on patient specimens. If finalized, this proposal should address an issue we identified during the PT program reapproval process in which we found laboratories inappropriately deciding whether to participate in a PT event based on the reporting criteria required by the PT program. We believe that this change will enhance consistency among the PT programs when grading samples.

We summarize and respond to the public comments we received on these proposals and summarize our final policies in sections III.C. and III.E. of this final rule.

4. Gram Stain PT

CLIAC considered whether the required PT for Gram stains should include both stain reaction and morphology. CLIAC concluded it should and recommended:

• PT results for Gram stains should include both stain reaction and morphology.

We agree with this recommendation because knowing the bacterial morphology is essential for accurate identification of specific groups of bacteria. Therefore, we proposed the following in § 493.911:

++ Section 493.911(a): The addition of required morphology for Gram stains.

++ Section 493.911(b): The evaluation of a laboratory's performance would be modified to include bacterial morphology as one part of the performance criterion for scoring the Gram stain.

We summarize and respond to the public comments on these proposals

[1] *https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493#493.2.*

and summarize our final policies in section III.E. of this final rule.

5. Mixed Culture Requirement

The current CLIA requirements for bacteriology §§ 493.911(b)(1), mycobacteriology 493.913(b)(1), and mycology 493.915(b)(1) specify that at least 50 percent of the PT samples in an annual program must be mixtures of the principal organism and appropriate normal flora. This requirement aims to simulate the findings that would occur with actual patient specimens. In bacteriology, this 50 percent mixed culture requirement must be met for two required sample types, those that require laboratories to report only organisms that the testing laboratory considers to be a principal pathogen that is clearly responsible for a described illness (excluding immunocompromised patients) and those that require laboratories to report all organisms present. The CLIA requirements for mycobacteriology and mycology PT do not specify two sample types. Still, they include the 50 percent requirement for cultures containing a mixture of the principal organism and appropriate normal flora. None of the 50 percent mixed culture requirements in these subspecialties applies to samples that would only contain normal flora and no reportable organisms.

CLIAC considered whether PT should include mixed cultures and discussed the difficulties of having mixed cultures in challenges for antimicrobial susceptibility testing. CLIAC considered lowering the mixed culture requirement to 25 percent for all subspecialties in microbiology. Upon deliberation, CLIAC made the following recommendation:

• Lower the mixed culture requirement from 50 percent to 25 percent for PT challenges of both sample types (those that require laboratories to report only the principal pathogen and those that require laboratories to report all organisms present).

We agree it is appropriate to lower the mixed culture requirement from 50 percent to 25 percent for bacteriology, mycobacteriology, and mycology to better reflect actual patient samples. As a result, we proposed the following changes:

++ Section 493.911(a)(2): In bacteriology, we proposed to decrease the required mixed cultures from 50 percent to 25 percent for culture challenges that require laboratories to report only the principal pathogen and those that require laboratories to report all organisms present.

++ Sections 493.913(a)(2) and 493.915(a)(2): In mycobacteriology and mycology, respectively, we proposed to decrease the mixed culture requirement from 50 percent to 25 percent.

Since the requirements for parasitology and virology do not currently include requirements for mixed cultures (or mixed PT challenges), we did not propose to make any changes to these subspecialties. We summarize and respond to the public comments we received on these proposals and summarize our final policies in section III.E. of this final rule.

6. Antimicrobial Susceptibility Testing

PT for antimicrobial susceptibility testing is currently required for bacteriology at § 493.911(b)(1) and mycobacteriology at § 493.913(b)(1), but it is not required for mycology, parasitology, or virology. For antimicrobial susceptibility testing in bacteriology at § 493.911(b)(3), at least one sample per testing event must include one Gram-positive or Gram-negative sample, and for mycobacteriology at § 493.913(b)(3), at least one sample per testing event must include a strain of *Mycobacterium tuberculosis* with a predetermined pattern of susceptibility or resistance to the common antimycobacterial agents. In some instances, laboratories appreciate the opportunity to participate in additional susceptibility testing challenges as educational tools. Under the current regulations, some laboratories may perform the minimum required susceptibility testing on some organisms, such as Gram-positive cocci. When CLIAC discussed this issue, the point was made that by increasing the frequency and number of required susceptibility testing PT challenges for different groups of organisms, potential issues with patient testing in a laboratory may be detected sooner. CLIAC considered recommending increasing the susceptibility testing challenges to two per event and requiring one Gram-positive and one Gram-negative organism in each bacteriology testing event. CLIAC also considered whether PT should be required for resistance as well as susceptibility testing and whether these requirements should be extended to other microbiology subspecialties. Following this deliberation, CLIAC made the following recommendations:

• Required PT for antimicrobial susceptibility and/or resistance testing should be increased to two challenges per event for a total of six challenges per year in bacteriology and should include one Gram-positive and one Gram-negative organism in each event.

• PT should be required for laboratories that perform susceptibility and/or resistance testing in all microbiology subspecialties. It should include two challenges per event and should include resistant organisms.

In considering these recommendations, we reviewed the modules currently offered by PT programs that include susceptibility testing and noted that there is a limited number of applicable PT modules currently available for resistance testing. Also, no PT program currently offers applicable PT modules for antiparasitic susceptibility or resistance testing in the subspecialty of parasitology. We believe it could be beneficial to increase the number of challenges per event from one to two for each microbiology subspecialty to increase the likelihood of detecting a problem in a laboratory. Antiparasitic susceptibility or resistance testing is not included in the subspecialty of parasitology because no PT program currently offers applicable PT modules. Therefore, we proposed the following:

++ Section 493.911(a)(4): For bacteriology, we proposed requiring at least two PT samples per event for susceptibility or resistance testing, including one Gram-positive and one Gram-negative organism with a predetermined pattern of susceptibility or resistance to common antimicrobial agents.

++ Section 493.913(a)(5): For mycobacteriology, we proposed requiring at least two PT samples per event for susceptibility or resistance testing, including mycobacteria that have a predetermined pattern of susceptibility or resistance to common antimycobacterial agents.

++ Section 493.915(a)(4): For mycology, we proposed requiring at least two PT samples per event for susceptibility or resistance testing, including fungi that have a predetermined pattern of susceptibility or resistance to common antifungal agents.

++ Section 493.919(a)(4): For virology, we proposed requiring at least two PT samples per event for susceptibility or resistance testing, including viruses that have a predetermined pattern of susceptibility or resistance to common antiviral agents.

In each of these subspecialties, we also proposed to revise the requirements for the evaluation of a laboratory's performance at §§ 493.911(b), 493.913(b), 493.915(b), and 493.919(b) to account for the fact that PT would be required for susceptibility or resistance

testing and that the scoring should be consistent with the testing performed.

We summarize and respond to the public comments we received on these proposals and summarize our final policies in section III.E. of this final rule.

7. Direct Antigen Testing

PT for direct antigen testing is only required for bacteriology and virology under §§ 493.911(a) and 493.919(a), respectively, not for the other microbiology subspecialties of mycobacteriology, mycology, and parasitology. Since this type of testing is commonly used for testing patient specimens, especially in mycology and parasitology, CLIAC considered whether PT for direct antigen testing should be part of all of the microbiology subspecialty requirements. CLIAC indicated that direct antigen PT should be required in subspecialties where these methods are used, and PT is available and made the following recommendation:

• PT for direct antigen testing should be required for all microbiology subspecialties.

We reviewed the modules currently offered by PT programs and determined that several modules include direct antigen testing for all microbiology subspecialties except mycobacteriology, for which this technology is not commonly used for testing patient specimens. In addition, we recognized that in bacteriology, PT for direct antigen testing to detect toxins produced by organisms such as *Clostridioides* (formerly *Clostridium*) *difficile* is also commonly available. Based on the information collected from the PT programs, availability of the modules, and importance to the health and safety of the public, we proposed to:

++ Retain the requirement for direct antigen detection for:

—Section 493.911(a)(1)(ii): Bacteriology.
—Section 493.919(a)(1)(i): Virology.

++ Add the requirement for direct antigen testing detection for:

—Section 493.915(a)(1)(i): Mycology.
—Section 493.917(a)(1)(i): Parasitology.

++ Require PT for bacterial toxin detection under § 493.911(a)(1)(iii). No changes were proposed for mycobacteriology.

++ Add the evaluation criteria of a laboratory's performance for two of the affected subspecialties under §§ 493.911(b) and 493.917(b) to include performance and scoring criteria that address direct antigen and toxin detection. Evaluation of a laboratory's performance for direct antigen testing at § 493.917(b) would align with the other microbiology subspecialties and reflect current microbiology practices in reporting patient results. Evaluation of a laboratory's performance for bacterial toxin detection at § 493.911(b) would reflect the current practice of reporting patient test results (that is, absence or presence of bacterial toxin).

We summarize and respond to the public comments we received on these proposals and summarize our final policies in section III.E. of this final rule.

B. Proposed Changes to PT for Non-Microbiology Specialties and Subspecialties

In addition to determining which analytes should be added or deleted, CMS and CDC proposed to establish or change, if necessary, the criteria for acceptable performance, which include the target value and ALs, for the analytes. Currently, the CLIA regulations at §§ 493.927(c)(2), 493.931(c)(2), 493.933(c)(2), 493.937(c)(2), and 493.941(c)(2) prescribe a variety of ALs, including: a multiple of the standard deviation (SD) of results from the mean of all laboratories in the peer group; fixed limit as a percentage of the assigned value; fixed limit in concentration units; and a mixture of percentage and concentration units, depending on the concentration of the analyte. As discussed in section II.B. of the proposed rule, for all new and currently required non-microbiology analytes, we proposed to amend certain analytes in §§ 493.927, 493.931, 493.933, 493.937, and 493.941 to include percentages with or without fixed ALs. Additionally, we proposed to tighten ALs for certain current analytes in §§ 493.927, 493.931, 493.933, 493.937, 493.941, and 493.959.

We summarize and respond to the public comments we received on these proposals and summarize our final policies in section III.F. of this final rule.

1. Analytes Proposed for Addition to Subpart I

The CLIA statute requires the PT standards established by the Secretary to require PT for each examination and procedure for which the laboratory is certified ''except for examinations and procedures for which the Secretary has determined that a proficiency test cannot reasonably be developed'' (42 U.S.C. 263a(f)(3)(A)). In determining whether PT can reasonably be developed for a given analyte, we considered whether the estimated cost of PT is reasonable in comparison to the expected benefit. We attempted to maximize improvements to the effectiveness of PT to improve accuracy, reliability and timeliness of testing while minimizing costs to the laboratories. In addition, we recognize that requiring PT for every analyte to derive benefits generalizable to all test methods is unnecessary. For example, systematic analytical problems on a multichannel analyzer might be detected by participation in PT for any of the analytes tested. Further, laboratories are already required under § 493.1236(c)(1) to verify the accuracy of any test or procedure they perform that is not included in subpart I at least twice annually. Also, based on the results of the national PT survey conducted by CDC and the Association of Public Health Laboratories (APHL) in 2013, many laboratories voluntarily purchased PT materials for many nonrequired analytes. Keeping this in mind, as discussed in section II.B.2. of the proposed rule, we proposed adding the most crucial analytes based upon the following criteria:

(1) Current availability of PT materials and the number of PT programs offering PT.

(2) Volume of patient testing performed nationwide.

(3) Impact on patient health and/or public health.

(4) Cost and feasibility of implementation.

2. Process for Ranking Analytes Proposed for Addition to Subpart I

We used a sequential process to narrow the list of eligible analytes for addition based on each of the four criteria listed above.

a. Current Availability of PT Materials and the Number of PT Programs Already Offering PT

We believe that the availability of these PT samples for a particular analyte is an appropriate criterion for narrowing the list of eligible analytes and that scaling up a program would be relatively less difficult than creating a PT sample for a particular analyte that had not previously been offered. For the reasons noted below, we believe that at least three PT programs offering PT samples for a particular analyte under consideration would provide a sufficient number of programs to offer immediate access to PT by laboratories and a reasonable starting point for the analytes under consideration. CMS and CDC want to ensure that the laboratories could choose the best PT program for the services that their laboratories offered as well as not create a market advantage for a small number of PT programs. To evaluate the current availability of PT materials and PT

programs offering PT samples for a particular analyte, we analyzed the distribution of available PT programs for analytes for which PT is currently not required by subpart I of the CLIA regulations. The supporting data were collected from available sources, including data from PT program catalogs and data routinely reported by PT programs, including enrollment data. We examined the number of PT programs offering these analytes at any number of events per year and any number of challenges per event. We initially determined the number of analytes under consideration for which PT was offered by at least two, three, or four of the 11 existing PT programs. We determined that limiting the analytes under consideration to those for which PT was offered by at least three PT programs allowed a sufficient number of programs to offer immediate access to PT by laboratories and provided a reasonable starting point of 199 for the number of analytes under consideration (96 in routine chemistry, 27 in endocrinology, 28 in toxicology, 25 in general immunology, 21 in hematology, two for antibody identification). The expected impact on laboratories and PT programs was also considered (for example, minimizing the cost of purchasing and providing samples) when determining the minimum number of PT programs. Decreasing the minimum PT programs to two rather than three would increase the number of analytes under consideration to 303 but presumably decrease PT program availability and access for a given analyte. Conversely, increasing the minimum number of PT programs to four while presumably increasing PT program availability and access for a given analyte decreased the number of analytes under consideration to 164. This was the first cut based upon available PT modules.

b. Volume of Patient Testing Being Performed Nationwide

For the second cut, we prioritized the remaining 199 analytes under consideration based upon estimated national testing volumes. We decided that an estimated national test volume of 500,000 per analyte annually was an appropriate threshold as it was based upon testing volumes of the majority (68 out of 81) of analytes currently listed in subpart I. For comparison, of the analytes currently required under subpart I, 63 had a total national test volume above 1,000,000; five had national test volumes between 500,000 and 1,000,000, and 13 had national test volumes below 500,000. We used 500,000 annual tests as a preliminary cut-off for retention on the list of analytes under consideration. We also retained analytes below the 500,000 threshold that we determined to be clinically important based on literature already footnoted in section II.B.2.b. of the proposed rule and consultation with CDC health experts. The following analytes with test volumes less than 500,000 that were retained are: carbamazepine, alpha-1-antitrypsin, phenobarbital, hepatitis Be antigen, antibody identification, theophylline, gentamicin, and tobramycin.

In estimating national testing volumes to rank the remaining 199 analytes under consideration in the proposed rule, we were unable to identify a single source of available data for all patient testing being performed nationwide. We had complete data for Medicare payment, as well as the most current MarketScan Commercial Claims and Encounters (CCAE) and MarketScan Medicaid Multi-state data sets [2] and extrapolated accordingly. We used data provided by an HHS-approved accreditation organization, specifically a list of the number of their accredited laboratories offering each test we considered for addition to, or deletion from, subpart I to determine how many laboratories were performing testing for the proposed analytes. We also considered smaller representative data sets, including data sets obtained from a large healthcare network, a large reference laboratory, and a university hospital network, to evaluate the testing trends for the proposed analytes. We analyzed national testing trends based upon Medicare Part B payment data [3] to determine the analytes in each specialty that are increasingly used for patient diagnosis and/or management. We concluded that the trends revealed in the data could continue to show increases in payment for the proposed analytes.

We estimated the 2009 national test volumes based upon two data sets: (1) Medicare Part B payment statistics (excluding waived testing); and (2) CCAE. For all analytes under consideration for the addition to subpart I, we used Current Procedural Terminology (CPT) codes from claims data. We identified all possible occurrences of a particular analyte and combined them into one count. For example, if bicarbonate could be performed in a panel and by itself, we included all possible occurrences.

A complete count was available for the Medicare Part B data, and no estimation of total counts was necessary for this sector. MarketScan data, a sample of approximately 40 million covered individuals, was necessary to estimate CCAE data and approximately 6.5 million covered individuals for Medicaid data. Therefore, we estimated the total number of tests in both categories for the entire United States. The Agency for Healthcare Research and Quality (AHRQ) data showed that an estimated total of 181.5 million covered individuals enrolled in CCAE healthcare insurance; from this we derived a factor of 4.5 (181.5 million individuals/40 million individuals) by which to multiply the MarketScan CCAE estimates to extrapolate estimates for the entire United States. Similarly, for the Medicaid estimates, we knew from CMS data that there were approximately 52.5 million individuals covered by Medicaid, so we derived a factor of 8.0 (52.5 million individuals/6.5 million individuals) by which to multiply the MarketScan Medicaid estimates to extrapolate estimates for the entire United States.

We note that these estimates did not account for some inpatient testing that was paid through capitation arrangements for inpatient testing. Testing paid directly by patients was also not counted because, in these cases, CPT codes would not be captured in the data because there was no request for reimbursement. Even with this limitation, we believe that these estimates provide a relative sense of the number of tests being performed annually per analyte. No other accurate data were available to us.

As noted previously in this section, for the second cut, based upon our estimates of national testing volumes, we decided that an estimated national test volume of 500,000 per analyte annually was an appropriate threshold as most of the analytes listed in subpart I had national testing volumes above this threshold. Together with the above-described analytes below the 500,000 threshold that we determined to be clinically important, this narrowed our list of potential analytes under consideration for addition to subpart I to 73, representing analytes in five specialties or subspecialties

c. Impact on Patient and/or Public Health

For the third cut, we considered the evidence available related to each analyte under consideration to assess patient and public health impact of

[2] 2009 Truven Health MarketScan® data, *https://truvenhealth.com/your-healthcare-focus/life-sciences/data_databases_and_online_toolsMarkets/Life-Sciences/Products/Data-Tools/MarketScan-Databases.*

[3] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4698806/.*

testing. Because there was no standardized, generally accepted way to assess this impact on clinical care and public health, we used the following to get a relative sense of the importance of the analytes under consideration: a review of published laboratory practice guidelines (LPGs); a review of critical values; and a review of the analyte's classification by the Food and Drug Administration (FDA).[4] We accessed several data sources, including tests listed in the CDC Guide to Community Preventive Services;[5] National Healthcare Priorities/Disparities reports;[6] clinical practice guidelines including the National Guideline Clearinghouse (NGC) database available from AHRQ (*https://www.guideline.gov/*); critical values available in publications; and (CAP) Q-Probes.

In reviewing published LPGs, we hypothesized that if there were a relatively large number of LPGs available for a particular analyte, that analyte would be important for health testing. To estimate the number of LPGs, we used the AHRQ's NGC database. For example, there were 60 LPGs listed in the NGC for LDL cholesterol, 31 for hemoglobin A1c, and 27 for troponin, all of which are proposed for addition in Table 1. However, this approach did not differentiate analytes for which there were conflicting recommendations. For example, there are controversies about the value of screening men with prostate specific antigen (PSA) testing, and there is an ongoing debate about the prudence of testing vitamin D in asymptomatic adults (Kopes-Kerr, 2013).

To review critical values, which are pre-determined limits for specific analytes that, when exceeded, may suggest that immediate clinical intervention is required, we assessed analytes included in published on ''critical values'' lists. This approach allowed us to gauge the importance of an accurate result because an incorrect result could lead to a life-threatening intervention or a failure to intervene. We reviewed published literature and critical values posted online from 16 institutions, including small hospitals, university hospitals, and reference laboratories.

As mentioned earlier in this proposed rule, we also assessed the clinical impact of an analyte by reviewing its medical device classification (Class I, II, or III) as categorized by the Food and Drug Administration's risk classification list. Similarly, we assessed the public health importance of the eligible analytes by counting the number of recommendations for testing the analytes from CDC's Morbidity and Mortality Weekly Report, the Infectious Disease Society of America, and the Council of State and Territorial Epidemiologists for surveillance of health conditions related to the particular analyte under consideration. We found supporting evidence for national prioritization in some of the following: the U.S. Preventive Services Task Force,[7] the National Healthcare Quality and Disparities Report,[8] and the CDC Hormone Standardization Program.[9] For some analytes that are important to measure towards addressing health disparities and have public health impact, such as blood lead, we consulted with subject matter experts in CDC's National Center for Environmental Health, which promotes national testing and/or has standardization programs for some priority analytes, specifically estradiol and testosterone. CMS and CDC used this information to help determine which analytes should be included in the proposed rule.

After assessing patient and public health impact on a case-by-case basis for the third cut, we narrowed the analytes down to 34 for consideration of addition to the proposed list of analytes in subpart I.

d. Cost and Feasibility of Implementation

For the final analysis to determine whether an analyte would be proposed for inclusion in subpart I of the CLIA regulations, we focused on feasibility and costs of conducting PT for each of the remaining 34 analytes under consideration. We provided each of the HHS-approved PT programs the opportunity to submit comments in writing related to: inclusion/deletion of analytes, grading schemes, method(s) for determining target values, evaluating data using peer groups, cost of including new analytes, and structure of microbiology PT. Analytes for which it would be difficult for the PT programs to scale up production to meet the CLIA required frequency of three events per year with five challenges per event were eliminated from consideration because we believe that the costs passed down to laboratories to purchase the PT would be overly burdensome. In other cases, the decisions were based on the difficulty of finding any suitable PT materials. Some potential analytes were eliminated because they were too unstable for product development or shipping or because the testing methodology was not sufficiently standardized to support PT, such as vitamin D testing. After assessing the cost and feasibility of implementing PT on a case-by-case basis, we made the final cut, narrowing the analytes down to 29 potential analytes for the proposed list of analytes in subpart I.

3. Specific Analytes Proposed for Addition to Subpart I

Based upon the sequential process described previously in this final rule, information received from the PT programs, and consultation between CDC and CMS, we narrowed the list down to 29 analytes that we are proposing to add to subpart I of the CLIA regulations (Table 1).

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[4] *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/Search.cfm.*

[5] *https://www.thecommunityguide.org.*

[6] *https://www.ahrq.gov/research/findings/nhqrdr/index.html.*

[7] *https://www.uspreventiveservicestaskforce.org/Page/Name/recommendations.*

[8] *https://www.ahrq.gov/research/findings/nhqrdr/index.html.*

[9] *https://www.cdc.gov/labstandards/hs.html.*

TABLE 1: Analytes Proposed for Addition to Subpart I

CLIA Regulation	Analytes
General Immunology § 493.927	Anti-HBs Anti-HCV C-reactive protein (high sensitivity)
Routine Chemistry § 493.931	B-natriuretic peptide (BNP) ProBNP Cancer antigen (CA) 125 Carbon dioxide Carcinoembryonic antigen Cholesterol, low density lipoprotein, direct measurement Ferritin Gamma glutamyl transferase Hemoglobin A1c Phosphorus Prostate specific antigen, total Total iron binding capacity (TIBC), direct measurement Troponin I Troponin T
Endocrinology § 493.933	Estradiol Folate, serum Follicle stimulating hormone Luteinizing hormone Progesterone Prolactin Parathyroid hormone Testosterone Vitamin B12
Toxicology § 493.937	Acetaminophen, serum Salicylate Vancomycin

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4. Analytes Proposed for Removal From Subpart I

Recognizing that changes in the practice of clinical medicine have resulted in less frequent use of certain analytes, we used the same process to review the existing list of analytes in subpart I to determine which should be retained. In addition to requesting CLIAC's recommendations, we generally used the same criteria for retention of an analyte in subpart I as those used for determining which PT analytes to propose adding; however, as such PT testing was already available on the market, we did not consider the availability of PT material or the feasibility of implementation; therefore, we believe that PT programs already have the mechanism(s) in place to manufacture and ship PT for these analytes.

5. Process for Ranking and Assessing Existing Analytes and Proposals for Removal From Subpart I

a. Estimating Nationwide Testing Volume

We generally used the same rationale to select currently required analytes to propose for deletion. Specifically, we used the same threshold of 500,000 tests performed annually as an initial criterion for considering PT analytes. Those estimated to be lower than this threshold were considered for deletion from required PT. In particular, we focused on PT for several therapeutic drugs (ethosuximide, quinidine, primidone, and procainamide and its metabolite, N-acetyl procainamide). New drugs that are more effective or safer have entered the market since 1992 and may have replaced the use of therapeutic drugs that were included in the 1992 regulations. If so, we would expect to see a continued decline in the volume of testing for the use of such drugs. In addition to identifying decreases in testing for these drugs, we looked for probable causes of those decreases. These decreases in testing could result from new and emerging tests, including methodologies, replacing older tests, new technology, and changes to the way that the medical community orders laboratory testing. For example, the decrease in testing for LDH isoenzymes could be explained by the increased reliance on better alternative cardiac markers, especially troponin. For some anticonvulsant drugs, there may have been changes in medical practice, including alternative drugs and other treatments, possibly decreasing the need to measure them. We identified 13 currently required analytes with national test volumes less than our 500,000 annual test volume threshold.

b. Estimated Impact on Patient and Public Health

For any analyte still under consideration for removal, we performed literature reviews to determine if testing for alternative analytes or other diagnostic strategies had begun to supplant testing for the considered analyte. We took into account testing trends over the past 10 years and we attempted to project

expected testing trends. We then assessed the critical importance of candidates for deletion from subpart I based upon the number of guidelines available in the AHRQ NGC and the same sources used for considering inclusion in subpart I, bearing in mind that for all analytes and tests that are not listed in subpart I, laboratories must demonstrate accuracy twice per year as specified at § 493.1236(c)(1). We also considered the potential impact of deleting these analytes on clinical medicine and public health. Based on our literature review and consultation with CDC health experts, we decided not to propose the elimination of eight analytes based upon their critical importance for patient testing: carbamazepine, alpha-1-antitrypsin, phenobarbital, hepatitis B e antigen (HBeAg), antibody identification, theophylline, gentamicin and tobramycin. These are used for making important health decisions, for example, diagnosing hepatitis B (HBeAg), performing crossmatching for blood transfusions (antibody identification), or assessing compliance with medication for critically ill asthmatic patients (theophylline).

6. Analytes Proposed for Deletion From Subpart I

Based upon the sequential process described previously in this final rule, we proposed that the following analytes be deleted from subpart I: at § 493.931 LDH isoenzymes and at § 493.937 ethosuximide, quinidine, primidone, and procainamide (and its metabolite, N-acetyl procainamide).

7. Determining Criteria for Acceptable Performance

''Criteria for Acceptable Performance'', as that term is used in §§ 493.923, 493.927, 493.931, 493.933, 493.937, 493.941, and 493.959, is defined by the target value and acceptance limits. Criteria for acceptable performance is meant for PT scoring only and not intended to be used to set acceptability criteria for a laboratory's verification or establishment of performance specifications.

8. Setting Target Values

Under § 493.2, ''target value'' for quantitative tests is currently generally defined as either the mean of all participant responses after removal of outliers (those responses greater than 3 standard deviations from the original mean) or the mean established by definitive or reference methods acceptable for use in the National Reference System for the Clinical Laboratory (NRSCL) by the National Committee for the Clinical Laboratory Standards (NCCLS). However, in instances where definitive or reference methods are not available or a specific method's results demonstrate bias that is not observed with actual patient specimens, as determined by a defensible scientific protocol, a comparative method or a method group (''peer'' group) may be used. If the method group is less than 10 participants, ''target value'' means the overall mean after outlier removal (as defined above) unless acceptable scientific reasons indicate that such an evaluation is inappropriate.

Based on input from PT programs, we recognize, that peer grouping is generally the way that target values are set for most analytes. Therefore, in the proposed rule, we proposed to continue allowing PT programs to use peer grouping to set the target values. In addition, we proposed removing the reference to the NRSCL and NCCLS, while retaining the other options for setting target values.

9. Changing Acceptance Limits

Because there have been improvements in technology resulting in better sensitivity, specificity, and precision, routinely using peer grouping to set target values means that the AL that were originally specified in each specialty and subspecialty of the CLIA '88 regulations in subpart I effectively allow for more tolerant acceptance criteria for most analytes than would occur if targets were set by a reference method or overall mean. Based on feedback from several HHS-approved PT programs, we believe it would be appropriate to update the ALs to reflect advancements in technology and analytical accuracy since the PT regulations were implemented in 1992. While narrowing limits may increase miss rates per challenge, we do not expect a high unsuccessful rate based on the data simulations provided by the PT programs. We expect the rates of unsatisfactory events would be low based on the simulation data and that the rates of unsuccessful events (two consecutive or two out of three testing events being unsatisfactory) would be even lower; therefore, we believed it was reasonable to propose tighter limits given current analytic accuracy. We used all data available to us to minimize the negative consequences of the proposed changes (for example, too many unsuccessful performances) to acceptance limits, including simulations provided by PT programs.

10. Changes to Percentage Acceptance Limits (ALs)

a. Basis for Using Fixed Percentage PT ALs

Currently, the CLIA regulations at §§ 493.927(c)(2), 493.931(c)(2), 493.933(c)(2), 493.937(c)(2), and 493.941(c)(2) prescribe a variety of ALs, including: a multiple of the SD of results from the mean of other participants in the peer group; fixed limit as a percentage of the assigned value; fixed limit in concentration units; and a mixture of percentage and concentration units, depending on the concentration of the analyte. For all new and currently required non-microbiology analytes, we proposed to use fixed ALs, preferably as percentage limits rather than concentration units.

There are 53 analytes (existing or proposed) for which we proposed a percentage-based AL, for which biological variability data were published. There were no biological variability data for several analytes (for example, therapeutic drugs). Where there were such data, we used AL to get as close to, or below, an accuracy goal for the test that was based on biological variability data. Then we simulated several percentage-based ALs to see if their results would have passed or failed at each simulation. We wanted to get miss rates (that is, percent of laboratories that did not meet the criteria for acceptable performance per PT challenge) of somewhere in the 1 to 2 percent range as was observed in the data provided by the PT programs for current ALs. Of the 53 analytes, 34 of the proposed ALs were tighter than or equal to biological variability limits. For 19 analytes, the limits we are proposing are looser (greater) than the limits required to meet accuracy based upon biological variability. For these 19 analytes, using ALs based on biological variability would be untenable because the current analytical accuracy for such testing would not be expected to meet such limits. White blood cell differential is the only remaining analyte that would have ALs in SD. In this case there were no biological variability data available.

In general, fixed ALs, either in percentages or concentration units, are preferred to SDs for PT for several important reasons: they can be tied directly to objective goals for performance, such as goals for analytical accuracy and technical expectations; they are constant in all PT events and do not vary because of statistical randomness, masked outliers, or small sample size; they assure the same evaluation criteria are used by all PT programs and discourage opportunities

for participants to ''shop'' for PT programs with less stringent criteria for which it is easier to achieve acceptable performance; they do not unfairly result in tighter effective ALs for peer groups that use analyzers that have tighter analytical precision; they can combine a fixed percentage and a fixed absolute concentration to allow for more robust evaluation while also fairly evaluating low analyte concentrations; and they are commonly used worldwide in other PT and external quality assessment programs.

Our analysis of existing PT and external quality assessment programs showed that ALs using two or three SDs have been used in PT in a wide variety of settings for several reasons, such as: limited experience with PT or matrix effects for a particular analyte; lack of consensus on criteria for acceptable performance; inertia with no compelling pressure for change; and analytical performance so poor that multiples of the overall SD are considered to be the only fair approach. We believe all of these reasons to some extent contributed to initial reliance on SD limits for certain analytes when CLIA '88 was implemented. We also note that while regulations promulgated under CLIA '67 used ALs of three SD for several analytes, regulations finalized under CLIA'88 replaced these with fixed limits and PT programs successfully made the transition. Therefore, we believe it is likely that the proposed changes from SD-based ALs to fixed ALs will not be problematic.

Therefore, as discussed in section II.B. of the proposed rule, we proposed to amend certain analytes in §§ 493.927, 493.931, 493.933, 493.937, and 493.941 to include fixed ALs with or without percentages. Three analytes have only concentration-based ALs (that is, no percentage-based ALs): pH, potassium, and sodium.

b. Adding Fixed Concentration Units to Fixed Percentage Units

A percentage-based criterion can be unnecessarily stringent at low concentrations—either because of technical feasibility or because medical needs at the low concentration do not require such tight precision. Thus, when percentage-based fixed criteria are used for ALs, it may be necessary to place a minimum on the percentage as currently occurs with the criterion for acceptable performance for glucose (§ 493.931) for which the AL switches from 10 percent to 6 mg/dL below a concentration of 60 mg/dL. The combined ALs direct PT programs to score with whichever of the specifications is more tolerant; at lower limits of the analytical range this will be the fixed concentration limit. Therefore, to allow for fairer and more realistic ALs, we proposed to use combinations of percentage and concentration limits as appropriate. These combination limits are similar to limits that already exist in CLIA '88 regulations for glucose and other analytes.

Therefore, we proposed to amend certain analytes in §§ 493.927, 493.931, 493.933, 493.937, 493.941, and 493.959 to include percentage-based ALs with or without additional fixed ALs.

c. Establishing ALs Based on Analytical Accuracy Goals for Proposed New and Several Current Analytes

For the newly proposed analytes and several current analytes for which current ALs are in units other than percentages such as three SDs or concentration units, we proposed to change the ALs to percentages. Over the years, there have been many proposed criteria for establishing goals for analytical performance. The various possible approaches were reviewed and a hierarchy was established based on a 1999 consensus conference. These strategies were reconsidered at the 2014 European Federation of Clinical Chemistry and Laboratory Medicine Strategic Conference in Milan. Participants in both conferences acknowledged that the ability of a test method to meet clinical needs is the highest priority, and the most defensible approach would be clinical trials in which patient outcomes could be compared using different analytical accuracy goals. This approach was not feasible for many reasons. Although clinical outcomes studies would be the most rigorous basis for establishing analytical performance goals, these are seldom possible, leaving the natural dispersion of levels for each analyte (biological variability) as the next best scientifically defensible approach for establishing analytical accuracy goals. The less the biological variability, the more stringent the analytical accuracy needs to be. This approach makes sense for two of the most important reasons to conduct patient testing: diagnosis of disease, that is, differentiating an abnormal result from a normal one, and monitoring a patient's progress during treatment. In the former case, we believe that the ''within-group'' biological variability is the important limiting factor defining an appropriate error goal for a test method. Furthermore, we believe the most important factor for monitoring progress is the ''within individual'' variability. It was not possible for us to differentiate how analytes are being used or will be used clinically, with respect to diagnosis versus monitoring. Therefore, we accounted for both needs and used an approach that accounted for both kinds of biological variability to estimate analytical accuracy goals as the basis for our proposals for acceptance limits in percentages. The advantage of using analytical accuracy goals that are expressed in terms of percentages is that they can be directly related to ALs in a mathematical way expressed as percentages.

We have assumed that a laboratory that can meet the clinical needs for test accuracy based upon biological variability should perform successfully on PT most or all of the time. Therefore, whenever possible, we have used publicly available estimates of allowed total error based upon estimates of biological variability to approximate the proposed AL. CDC has shown in a recent poster [10] that it is possible to design ALs based upon such accuracy goals, and it is possible to simulate the ability of a PT program to identify laboratories that cannot meet such goals, while minimizing the likelihood of misidentifying laboratories that are meeting analytical accuracy goals based upon biological variability.

Therefore, we proposed to amend ALs for certain current analytes as well as establish ALs for analytes proposed for addition in §§ 493.927, 493.931, 493.933, 493.937, 493.941 and 493.959 based on analytical accuracy goals.

d. Tightening Existing Percentage ALs as Needed

There have been significant improvements in laboratories' performance in PT for the great majority of analytes and PT unsatisfactory rates have dropped for all types of laboratories. The improvements are such that, for many analytes, laboratories that began to use PT to comply with CLIA '88 now perform as well as the hospital and independent laboratories that were previously required to perform PT under CLIA '67. Howerton, et al., showed that for almost all analytes examined, PT performance improved somewhat after CLIA '88 was implemented, but the improvements were greater for laboratories that were not previously required to perform PT. The rates of unsatisfactory PT are now roughly the same for analytes listed in subpart I, regardless of the laboratory type. This is consistent with CLIA's intent to ensure accurate clinical testing regardless of the setting where testing is performed. There are several factors

[10] Astles, Tholen, and Mitchell, 2016, *https://www.aacc.org/science-and-practice/annual-meeting-abstracts-archive.*

contributing to the improvements in PT performance, including improved analytical methods being used in all settings, technological advances resulting in improved precision, sensitivity and specificity, and increased familiarity with handling preparation, and reporting of PT samples. Therefore, for the reasons above as well as supporting simulation data date from the PT programs, we proposed to make criteria for acceptable performance for existing analytes listed in subpart I (§§ 493.927, 493.931, 493.933, 493.937, 493.941 and 493.959) tighter, so they are in closer agreement with analytical accuracy goals which are based upon biological variability and simulation data.

e. Simulating the Impact of New ALs on Unacceptable Scores for Challenges and Unsatisfactory Rates for Events

We evaluated a very specific PT data set to help set appropriate limits. The total simulations reproduced PT that covered 2 years, representing 30 challenges (three events per year; five challenges per event; 2 years) of each proposed new analyte and for the analytes for which we propose to modify ALs. We reviewed the aggregated percentage of unacceptable scores for each PT challenge using retrospective data. We then reviewed the simulation data which applied two or three new ALs for each of 84 analytes (consisting of 27 new analytes and 57 existing analytes). Based on the simulation data, we were able to make informed decisions to help us create or adjust the ALs.

Based upon our analysis of the simulation results, we further refined the proposed ALs and added potential absolute concentrations in lieu of percentage ALs, as was described previously in this final rule. We then requested narrowly tailored data from PT programs as described previously in this final rule using retrospective PT data and peer group data for scoring, as they ordinarily would do. We focused on unsatisfactory scores with the data so that we could calculate the unsatisfactory rate per analyte among all participating laboratories that might occur with each proposed AL. The final simulations were conducted by several of the PT programs and this set of data was used to determine the proposed ALs.

We compared the unacceptable scores for each challenge and each proposed AL to determine at which concentrations it would be necessary to switch to a fixed concentration AL. Using this approach, we were able to identify an AL for each analyte and, in some cases, an additional concentration-based AL. This approach enabled us to identify an AL that would be sensitive enough to identify poor-performing laboratories, yet not so sensitive that it will incorrectly identify laboratories that likely meet requirements for accuracy.

f. Limitation in Our Ability To Predict the Number of New Unsatisfactory and Unsuccessful Scores

It is not possible for us to predict the precise effect of the proposed changes on the number of unsatisfactory and unsuccessful scores. The occurrence of an unsatisfactory score for a PT event depends upon at least two of five challenges being graded as unacceptable or outside the criteria for acceptable for performance. PT programs select different combinations of samples for each event and it is impossible to predict how their selection could be modeled statistically. Finally, the distribution of unsatisfactory and unsuccessful PT scores is not randomly distributed across all participants.

++ Sections 493.923(a), 493.927(a), 493.931(a), 493.933(a), 493.937(a), 493.941(a), and 493.959(b): We proposed to amend these provisions to remove the option that PT samples, ''at HHS' option, may be provided to HHS or its designee for on-site testing''.

++ Section 493.927: We proposed to amend the criteria for acceptable PT performance to permit scoring of quantitative test results for the following immunology analytes: antinuclear antibody; antistreptolysin O; rheumatoid factor; and rubella. For these analytes, we have determined that there are one or more test systems that currently report results in quantitative units; therefore, we added ALs based on percentages or target values in addition to retaining the qualitative target values. We proposed to make this allowance in CLIA for reporting PT which reflects current practice.

++ Section 493.931(b): We proposed making a technical change to the description for creatine kinase isoenzymes to be CK–MB isoenzymes, which may be measured either by electrophoresis or by direct mass determination.

++ Section 493.933: We proposed adding the following analytes: estradiol, folate (serum), follicle stimulating hormone, luteinizing hormone, progesterone, prolactin, parathyroid hormone, testosterone, and vitamin B12.

++ Section 493.937(a): We proposed revising this provision by including the requirement that annual PT programs must provide samples that cover the full range of values that could occur in patient specimens. We proposed this amendment so that PT programs must provide samples across a toxicology sample's entire reportable range rather than just provide samples within a sample's therapeutic range.

++ Section 493.941: We differentiated the criteria for units of reporting of the analyte prothrombin time. We proposed to amend the criteria for acceptable performance to reflect both in seconds and/or INR (international normalized ratio) and to add the requirement that laboratories must report prothrombin time for PT the same way they report it for patient results. We also proposed to add criteria for acceptable performance for directly measured INR for prothrombin time. Additionally, we proposed to require laboratories performing both cell counts and differentials to conduct PT for both (that is, the ''or'' would be changed to an ''and''). Finally, we proposed changing the criteria for acceptable performance for ''cell identification'' from 90 percent to 80 percent. We proposed this change as the requirement of five samples per event does not allow for a score of 90 percent (that is, five samples would allow for scores of zero percent, 20 percent, 40 percent, 60 percent, 80 percent, or 100 percent). PT for cell identification is currently required in § 493.941. Further, § 493.851(a) states that ''failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory performance for the testing event.'' If the requirement for acceptable performance remains at 90 percent, a laboratory can only have satisfactory performance if they receive 100 percent; however, § 493.851(a) allows satisfactory performance for both 80 percent and 100 percent.

++ Section 493.959: We proposed changing the criteria for acceptable performance for unexpected antibody detection from 80 percent accuracy to 100 percent accuracy. We proposed this change because it is critical for laboratories to identify any unexpected antibody when crossmatching blood in order to protect public health and not impact patient care.

++ Sections 493.923(b)(1), 493.927(c)(1), 493.931(c)(1), 493.933(c)(1), 493.937(c)(1), 493.941(c)(1), and 493.959(d)(1): We proposed amending these provisions to clarify that to achieve consensus, PT programs must attempt to grade using both participant and referee laboratories before determining that the sample is ungradable. We believe that this change will enhance consistency among the PT programs when grading samples. The current regulations noted previously

allow for scoring either with participants or with referees before calling a sample ungradable.

C. Additional Proposed Changes

We proposed to amend § 493.2 by modifying the definition of an existing term and defining new terms as follows:

• *Target value:* We proposed removing the reference to NRSCL and NCCLS and retaining the other options for setting target values in this final rule.

• *Acceptance Limit:* We proposed defining this term to mean the symmetrical tolerance (plus and minus) around the target value.

• *Unacceptable score:* We proposed defining this term to mean PT results that are outside the criteria for acceptable performance for a single challenge or sample.

• *Peer group:* We proposed defining this term as a group of laboratories whose testing process utilizes similar instruments, methodologies, and/or reagent systems and is not to be assigned using the reagent lot number. PT programs should assign peer groups based on their own policies and procedures and not based on direction from any manufacturer.

We proposed the following revisions to the regulation text at subpart A:

• Sections 493.20 and 493.25: We proposed to amend the regulations to reflect that if moderate and high complexity laboratories also perform waived tests, compliance with § 493.801(a) and (b)(7) are not applicable. However, we proposed to continue to require compliance with § 493.801(b)(1) through (6) to align the regulations with the CLIA statute (42 U.S.C. 263a (i)(4)), which does not exclude waived tests from the ban on improper PT referral.

We proposed to revise the regulation text at subpart H:

• Section 493.861: We proposed amending the satisfactory performance criteria for failure to attain an overall testing event score for unexpected antibody detection from ''at least 80 percent'' to ''100 percent.'' We proposed this change because it is critical for laboratories to identify any unexpected antibody when crossmatching blood to protect the public health and not impact patient care.

We proposed to revise the regulation text at subpart I:

• Section 493.901(a): We proposed to require that each HHS-approved PT program must have a minimum of 10 laboratory participants before offering any PT analyte. We recognize that PT programs do not grade results when there are fewer than 10 laboratory participants. This would require the laboratory to perform additional steps to verify the accuracy of their results. If at any time a PT program does not meet the minimum requirement of 10 participating laboratories during the reapproval process for an analyte or module, HHS may withdraw approval for that analyte, specialty, or subspecialty. This change reduces some burden on laboratories that have incurred the expense of enrolling in a PT program but do not receive a score or receive an artificial score requiring the laboratory to take additional steps to verify the accuracy of the analyte as required by § 493.1236(b)(2).

• Section 493.901(c)(6): We proposed to add the requirement that PT programs limit the participants' online submission of PT data to one submission or that a method be provided to track changes made to electronically reported results. Many PT programs currently allow laboratories an option to report PT results electronically, while some other PT programs only allow laboratories to report PT results electronically with no other option such as facsimile or mailed PT submission forms. However, at this time, the PT programs that do participate in the online reporting have no mechanism to review an audit trail for the submitted result. In some cases of PT referral, it has been discovered that laboratories have sent PT samples to another CLIA-certified laboratory for testing, received results from the other laboratory, and then changed their online reported results to the PT program since those results can be modified up until the PT event close date. In an effort to assist in PT referral investigations and determinations, an audit trail that includes all instances of reported results would aid in determining if a laboratory compared PT results obtained from another laboratory and changed their previously submitted results.

• Section 493.901(c)(8): We proposed to add to the requirement previously found at § 493.901 that contractors performing administrative responsibilities as described in §§ 493.901 and 493.903 must be a private nonprofit organization or a Federal or State agency or nonprofit entity acting as a designated agent for the Federal or State agency. Several PT programs have divided their administrative and technical responsibilities into separate entities or have had the administrative responsibilities performed by a contractor. We were made aware that administrative responsibilities were being performed by a for-profit entity. Because the CLIA statute (42 U.S.C. 263a(f)(3)(C)) requires PT programs to be administered by a private nonprofit organization or a State, we are proposing to amend § 493.901 to state that all functions and activities related to administering the PT program must be performed by a private nonprofit organization or State.

• Section 493.901(e): We proposed the requirement that HHS may perform on-site visits for all initial PT program applications for HHS approval and periodically for previously HHS-approved PT programs either during the reapproval process or as necessary to review and verify the policies and procedures represented in its application and other information, including, but not limited to, review and examination of documents and interviews of staff.

• Section 493.901(f): We proposed an additional requirement to the regulation that specifies we may require a PT program to reapply for approval using the process for initial applications if widespread or systemic problems are encountered during the reapproval process. The initial application for the approval as an HHS PT program requires more documentation in the application process than that which is required of PT programs seeking HHS reapproval.

• Section 493.903(a)(3): It has come to our attention that PT programs may have on occasion modified a laboratory's PT result submission by adding information such as the testing methodology which was inadvertently omitted by the laboratory. Therefore, we proposed adding the requirement that PT programs must not change or add any information on the PT result submission for any reason, including, but not limited to, the testing methodology, results, data, or units.

• Section 493.905: We proposed adding that HHS may withdraw the approval of a PT program at any point in the calendar year if the PT program provides false or misleading information that is necessary to meet a requirement for program approval or if the PT program has failed to correct issues identified by HHS related to PT program requirements. We also proposed adding a requirement that the PT program may request reconsideration should we determine that false or misleading information was provided if the PT program has failed to correct issues identified by HHS related to PT program requirements.

III. Analysis of and Responses to Public Comments

We received 107 public comments in response to the February 4, 2019,

proposed rule. The commenters represented individuals, PT programs, accreditation organizations, laboratory professional organizations, and businesses, including in vitro diagnostics manufacturers. Commenters were generally supportive of the proposed changes, and some noted that these changes would increase flexibility and be a positive change for both laboratories and PT programs, especially in the specialty of microbiology. A few commenters recommended clarification of proposed changes or suggested specific changes, including alternative language, to the proposed requirements. After analyzing the comments received, we have modified or deleted several provisions in this final rule. A few commenters raised issues that are beyond the scope of our proposals. We are not summarizing or responding to those comments in this final rule. However, we reviewed the comments to consider whether to take other actions, such as revising or clarifying the CLIA program operating instructions or procedures, based on the information or recommendations in those comments. Our responses to specific comments are as follows:

A. Delayed Effective Date and Ongoing Process for Updating PT Regulations (§§ 493.2 and 493.801 Through 493.959)

Comment: Several commenters requested that there be a delayed effective date or phase in approach for implementation of the updated PT requirements to give all affected constituents time to accommodate the changes. Two commenters suggested that CMS develop an ongoing process to make changes to the PT regulations to ensure timely implementation of the updates.

Response: We recognize that time will be needed for laboratories, PT programs, accreditation organizations, exempt States, and surveyors to adopt the updated PT requirements related to subparts H and I. As such we are delaying the effective date of the revisions to §§ 493.2 and 493.801 through 493.959 until 2 years after the publication of this final rule in the **Federal Register**. The delayed effective date reflects the timeframe that we believe PT programs will need to produce the PT samples to meet the revised regulations and incorporate any updates to PT reporting requirements. In addition, laboratories will need to implement the new PT requirements after the samples are available from the PT programs. We encourage laboratories to enroll in the new and revised analytes prior to the delayed effective date. We also appreciate the commenters' suggestions for a process to address needed PT changes more quickly on an ongoing basis. We will consider possible ways to streamline the process going forward in light of the required timeframe for rulemaking. We note that the regulations related to laboratories performing tests of moderate complexity and high complexity testing that also perform waived testing and proficiency testing enrollment, §§ 493.20 and 493.25, respectively, will be effective 30 days after the publication date of this final rule.

B. Definitions (§ 493.2)

Comment: A commenter stated that the term ''unacceptable score,'' as defined at § 493.2, was confusing and should be replaced with ''unacceptable result.'' Other commenters pointed out that the organization of sub-bullets under the definition of ''target value'' was incorrect as the content in (iv) does not belong under (1), but should be included as (2) under the definition.

Response: We agree with commenters that the term ''unacceptable score'' could be confusing because it could be interpreted to mean a total analyte event score rather than the intended meaning of referring to a single challenge or sample result. Since this term is not included in the CLIA regulations except for the proposed amendments to § 493.2, we are not finalizing this term in § 493.2 in this final rule. With respect to the proposed definition of ''target value'', we agree with the commenter about the paragraphs included under that definition and are making the recommended change in this final rule.

Comment: While several commenters supported the inclusion of a definition for ''peer group'' in the proposed rule, other commenters expressed concerns about our proposal. Three commenters approved of our proposal to disallow peer-grouping to the reagent lot level, while two commenters did not agree with the proposal. One commenter noted that matrix effects, known to cause PT materials to behave differently from unmodified patient samples, are the reason underlying the need to use peer grouping to set target values and grade PT results. This commenter was concerned that the final rule would not account for the existence of matrix effects by not allowing peer grouping. One commenter suggested we consider conducting a scientific study to assess the contribution of calibration errors versus matrix effects in causing differences in PT results.

Response: In response to the comments about peer-grouping to the reagent lot level, PT is one of the important ways to detect problems in FDA-cleared/approved test methods. Differences between reagent lots used during testing may occur due to the manufacturing process. Allowing peer grouping to the lot level may inhibit the detection of these problems. We are not prohibiting PT programs from interacting with manufacturers to discover problems with reagent lots. However, the PT program has the responsibility for interpreting correct PT results. If a PT program determines that a specific reagent lot failure occurred, it should inform the affected laboratories and manufacturer. Concerning the comment about matrix effects, currently CLIA requires PT programs to demonstrate through a scientific protocol that bias, such as matrix effects, existed in PT materials before allowing peer-grouping to grade results. We are aware that PT programs have typically not used a scientific approach to determine if a peer group should be used as the process of demonstrating matrix effects is expensive and time-consuming. This rule finalizes the proposed definitions for both ''peer group'' and ''target value'' and will continue to allow peer-grouping for evaluation of PT results, without requiring prior demonstration of matrix effects. We do not expect there will be a change in how peer groups are identified by PT programs. Therefore, there will be no change in how target values are determined based upon the mean of peer group results. In response to the proposed study of commutability to demonstrate differences in PT results based on calibration errors, the comment is outside the scope of this final rule.

Comment: Two commenters suggested that CLIA should not require removal of outliers using a three standard deviation (3 SD) criterion when grading PT, as required under the proposed definition of target value in § 493.2. One commenter noted that the requirement to remove outliers was done to get a better estimate of the SD, which would only apply to one analyte after the final rule is effective. The other commenter stated that outlier removal using a 3 SD limit is not recommended according to ISO 13528:2015. Both commenters noted the need for robust methods to remove outliers, which can be especially problematic when the PT peer group is very small, such as a group that includes only 5 to 20 results.

Response: It is important that outliers be removed to set target values. Because a spurious PT result, including one due to a transcription error, could affect the peer group mean, especially when the peer group has relatively few laboratory

participants, PT programs should continue to discard aberrant results when calculating the peer group target. At this time, we do not have sufficient information to provide additional or alternative options for outlier removal. However, we recognize the need for PT programs to have valid modern approaches for outlier removal. Therefore, we are retaining the requirement to remove outliers as described in the definition for target value, using a 3 SD criterion. Regarding the comment referencing ISO requirements, we note that ISO standards do not apply to CLIA.

Summary of Final Actions

- We did not receive any comments on the proposed definition of ''acceptance limit'' and are finalizing the definition with a clarifying technical edit.
- Based on the public comments received, we are finalizing the proposed definition of ''peer group'' with a clarifying technical edit.
- We are revising and finalizing the proposed definition for ''target value.'' We have corrected the organization of the paragraphs and have moved the content of subparagraph (iv) to paragraph (2).
- We are not finalizing the proposed definition of ''unacceptable score.''

C. Enrollment and Testing of Samples (§§ 493.20(c) and 493.25(d))

Comment: A number of commenters expressed concerns or requested clarification about the proposal to amend §§ 493.20(c) and 493.25(d) to reflect that if laboratories certified to perform moderate and high complexity testing, respectively, also perform waived tests, compliance with § 493.801(a), which requires enrollment in PT, and (b)(7), requiring PT for the primary method of patient testing, are not applicable for the waived tests. However, as proposed, if laboratories voluntarily enrolled in PT for their waived testing, § 493.801(b)(1) through (6) would apply in cases of improper PT referral for those tests. Commenters expressed that laboratories may be discouraged from voluntarily enrolling in PT for waived tests if the possibility of sanctions for referred PT existed. Two commenters recommended that PT should be required for all testing, including waived testing. One commenter requested clarification of whether laboratories would need to verify the accuracy of waived tests twice per year.

Response: Subsection (d)(2)(C) of the CLIA statute states that subsections (f) and (g) shall not apply to a laboratory issued a Certificate of Waiver. Subsection (f) is related to issuing standards that, at a minimum, allow a laboratory to consistently perform testing to ensure accurate and reliable test results, including the requirement for all laboratories that perform nonwaived testing to enroll in an approved PT program and to verify the accuracy of tests twice per year. Subsection (g) speaks to inspecting laboratories for compliance with subsection (f) and are generally done on a biennial basis. However, sanctions related to PT referral are in subsection (i), which is not limited to nonwaived laboratories but rather allows sanctions to be taken against ''any laboratory'', including a Certificate of Waiver laboratory, that intentionally refers PT samples to another laboratory. Some Certificate of Waiver laboratories and other laboratories that perform waived testing have voluntarily chosen to enroll in PT for waived testing over the history of the CLIA program to ensure the quality of their testing. We have no reason to believe these laboratories will be discouraged from continuing their enrollment in PT. As a result, we are finalizing the new requirements at §§ 493.20(c) and 493.25(d) to ensure that the CLIA regulations align with the statute.

Summary of Final Actions

- We are finalizing the proposed revisions at §§ 493.20(c) and 493.25(d).
- We are finalizing the proposed revisions at §§ 493.801 and 493.861. Section 493.801 will require laboratories to report PT results for microbiology organism identification to the highest level that they report results on patient specimens. Section 493.861 will amend the satisfactory performance criteria for failure to attain an overall testing event score for unexpected antibody detection from ''at least 80 percent'' to ''100 percent.'' We received no comments on the proposed revisions at §§ 493.801 and 493.861.

D. PT Program Approval and Administration (§§ 493.901, 493.903, 493.905)

Comment: Two commenters urged CMS not to change the current codes used for specific analytes when PT programs report PT results to CMS and to create new codes for the analytes being added.

Response: We understand the commenters to be referring to certain analyte-specific codes that are used as an internal data system designation for PT programs to report PT analyte results to us. Although these codes are not explicitly referenced in the regulations, we agree with the commenters and note that the current analyte-specific codes for PT will remain the same. New analyte-specific codes will be generated for the newly required PT analytes.

Comment: Many commenters remarked on the requirement proposed at § 493.901(a) having at least 10 laboratory participants for an analyte before a program is approved to offer that analyte. Commenters stated that this requirement could inhibit development of new PT, and be detrimental to both laboratories and PT programs, especially smaller programs, which could find it harder to compete. Some commenters pointed out that PT programs offering newly required analytes would naturally have relatively fewer participating laboratories. One commenter requested clarification on whether this requirement would apply only to newly required analytes or to all PT analytes. Some commenters pointed out that PT programs may not initially know how many laboratories would enroll, and the programs would need time to develop their market. One commenter stated that this requirement would be a burden and result in more ungraded events.

Response: The requirement for at least 10 laboratory participants would only apply for PT analytes required in subpart I, and therefore, should not impact the development of PT for new or emerging analytes to the extent that they are not listed in subpart I. We realize that PT programs seeking HHS approval for the first time may not know how many laboratories would enroll in their program, and we did not intend to require at least 10 laboratory participants when PT programs apply for initial approval. We intend to review the number of laboratory participants for each program and each HHS-approved analyte during the annual reapproval process. If a PT program has fewer than 10 participants, we may not reapprove the PT program for a specific analyte. As a result of the comments, in this final rule, we are clarifying the requirement at § 493.901(a) to state ''for each specialty, subspecialty, and analyte or test for which the proficiency testing program is seeking reapproval'' to better reflect the PT approval process.

Comment: A number of commenters representing several PT programs and accreditation organizations commented on the requirement proposed at § 493.901(c)(6) that for those results submitted electronically, a mechanism to track changes to any result reported to the proficiency testing program and the reason for the change. There was general opposition due to perceived burden and expense, both to PT

programs and laboratories, and possibilities for errors. Some commenters stated that they are currently unable to know when every PT result is entered or changed if done electronically based on the technology used for laboratories to submit results. There were also questions about the circumstances under which PT programs would be required to provide audit trails. One commenter agreed with this proposed change but recommended that we provide more guidance to laboratories on how to meet this requirement.

Response: We appreciate the information provided by the commenters expressing the challenges with meeting this requirement. We do require laboratories to maintain documentation of their submissions to PT programs (see § 493.801(b)(5)). However, based on the comments received, we are not finalizing the requirement proposed at § 493.901(c)(6).

Comment: Several commenters expressed concerns about the requirement proposed at § 493.901(c)(9) that a contractor performing administrative responsibilities as described in §§ 493.901 and 493.903 must be a private nonprofit organization or a Federal or State agency, or an entity acting as a designated agent for the Federal or State agency. A commenter noted that many essential PT program functions are currently performed by for-profit entities or subcontractors. There was a general consensus among commenters that many important administrative functions could not be performed without contractual arrangements with for-profit entities, such as transportation services.

Response: We recognize that some functions required as part of the PT process, such as transportation services, are provided by for-profit entities. Other business functions may also be provided by for-profit contractors, such as obtaining and manufacturing the PT specimens/products, initial testing to establish approximate target values as prescribed by the PT program, aliquoting and labeling samples, testing to assure homogeneity and stability of samples, long-term storage of samples for use in future PT events, and storage of aliquoted PT samples for additional testing as may be requested by the clients, or required by us. Also, ''for-profit'' entities can be used or contracted for distributing/mailing out the PT kits to the laboratories. This proposed requirement was not intended to address those aspects of PT program operations, but rather the technical and scientific responsibilities as described in §§ 493.901 and 493.903. These technical and scientific responsibilities include, but are not limited to, processes for selecting appropriate target values to be included in challenges as part of the annual PT program or grading PT results, determining target values, reporting scores to CMS, and determining organisms included in microbiology PT samples. In an effort to clarify the intent of the proposed requirement, we are changing ''administrative responsibilities'' to ''technical and scientific responsibilities'' in the provision being finalized at § 493.901(c)(8), previously proposed at § 493.901(c)(9).

Comment: While commenters agreed with the requirement proposed at §§ 493.901(e) to allow HHS to require on-site visits as part of the initial approval of PT programs, they indicated the need for sufficient advance notice of an on-site visit. Also, there were two suggestions to use an independent third party if on-site visits were to be conducted.

Response: We would coordinate the timing of the visit with the PT program and generally provide advance notice of the on-site visit. On-site visits will be conducted by CMS, and not by a third party. As a result, we are finalizing the new requirement at § 493.901(e) as proposed.

Comment: We received comments concerning the requirement proposed at § 493.901(f) that HHS may require a PT program to reapply for approval using the process for initial applications if significant problems are encountered during the reapproval process. While no commenters disagreed with the proposed requirement, one commenter requested that we use this option sparingly, and another commenter requested clarification on when this option would be used.

Response: We intend to use this option cautiously and only when issues arise that we consider be significant, for example, complaints of quality issues related to the PT program. As a result, we are finalizing the new requirement at § 493.901(f).

Comment: Commenters suggested clarification was needed regarding the requirement proposed at § 493.903(a)(3) that PT programs must not change or add any information on the PT result submission. They requested clarification on what data could not be changed, noting that some changes, such as adding or changing a method code, would not necessarily affect test results submitted but would be important for appropriate peer grouping. Commenters expressed concern that PT programs would not be able to add a methodology if inadvertently left off by the laboratory, thus affecting appropriate peer grouping. Commenters questioned if exceptions might be made if errors were made by the PT program and not the laboratory.

Response: As explained in the proposed rule (84 FR 1536, 1547), it is not appropriate for a PT program to change or add information on the PT result submission from a laboratory, including, but not limited to, the testing methodology, results, data, or units. If a laboratory inadvertently enters the wrong methodology or omits a methodology, the PT program should not assume to know the correct methodology and make that change or addition. We would consider it acceptable for the PT program to enter the methodology in cases where the PT program form does not include the methodology used by the laboratory for testing and the laboratory has manually written the methodology on the result submission form. This would also apply to units of measure. Under no circumstances should a PT program change a laboratory's submitted result. It is the laboratory's responsibility to provide correct and complete information and to investigate and correct errors that lead to PT failures. As a result, we are finalizing the requirement at § 493.903(a)(3) as proposed.

Comment: Commenters expressed concerns regarding the potential impact on laboratories and PT programs of the requirement proposed at § 493.905(a) allowing HHS to withdraw the approval of a PT program at any point in the calendar year if the PT program provides false or misleading information required for program approval or if the PT program fails to correct issues identified by HHS related to PT program requirements.

Response: We may withdraw approval of the PT program if HHS determines the PT program fails to meet any of the required criteria for approval. After we withdraw approval of a PT program, approval of the PT program would remain in effect for 60 days from the date of written notice to the PT program of this action. A PT program will be required to notify all of its participating laboratories of our withdrawal of approval within 30 days from the date of written notice to the PT program. We believe the 30-day notification by the PT program in this situation, and the additional 30 days before approval is withdrawn, gives laboratories sufficient time to enroll in an alternative PT program. PT programs may request reconsideration from us in accordance with subpart D of part 488 regarding the

withdrawal of approval if the false or misleading information or issues identified by us have been addressed within 60 days. We believe that the 60-day timeframe gives the PT programs sufficient time to mitigate any issues related to withdrawal of approval.

Summary of Final Actions

- We are finalizing the proposed changes to §§ 493.901(a), (c)(8), (e), (f), 493.903(a)(3), and 493.905.
- Based on comments received, we are not finalizing the proposed addition at § 493.901(c)(6).

E. Proposed Changes to Microbiology PT (§§ 493.911 Through 493.919)

Comment: Commenters suggested clarification is needed regarding methods or platforms for which PT is proposed to be required, specifically for laboratories that use molecular, nucleic acid amplification, mass spectrometry testing or next generation sequencing for microorganism identification and susceptibility testing in all microbiology subspecialties. A commenter also questioned whether PT is required only for FDA-cleared test systems. The commenters stated this clarification would help prevent confusion among laboratories.

Response: PT is not required by method or specific technology for microbiology subspecialties (§§ 493.911 through 493.919), including whether a test system is FDA-cleared, or analytes in non-microbiology specialties or subspecialties (§§ 493.921 through 493.959). Regardless of the method, a laboratory uses for microorganism identification and susceptibility testing, PT is required for these categories of microbiology testing. When CLIAC deliberated on appropriate PT for microbiology, they suggested the inclusion of broad categories of testing performed in microbiology, rather than the types of services offered by laboratories, described in §§ 493.911 through 493.919, to allow flexibility for the inclusion of new technologies. Each laboratory needs to identify the method or test system used when submitting PT results for programs to properly grade the PT. If a laboratory performs microbiology testing for which PT is not available or required, they need to verify the accuracy of those procedures at least twice per year, as described at § 493.1236(c)(1). If available, voluntary PT may be a way the laboratory chooses to meet this requirement.

Comment: Commenters supported the removal of the types of services offered by laboratories in each microbiology subspecialty and replacement of the types of services with general categories of testing for which PT is required. However, they had questions about the proposed option in bacteriology for detection of growth or no growth in culture media. They questioned whether this option was included or relevant for all microbiology subspecialties and all specimen types and whether it should be removed as an option under the category for identification of bacteria since bacteria are not identified when only growth is detected. A commenter also noted that this category may not be appropriate for cultures from normally sterile sites or those that are expected to contain normal flora. Another commenter requested for clarification of how this category would apply to urine colony counts. A commenter suggested changing the language in bacteriology to ''presence or absence of bacteria without identification,'' with similar changes in other subspecialties. Another commenter suggested changing the language in bacteriology to ''growth or no growth in culture media or identification of bacteria to the highest level that the laboratory reports results on patient specimens.'' Other language changes suggested by commenters included revising this category to ''growth or no growth of acid-fast bacilli'' in mycobacteriology and ''growth of yeast, growth of mold, or specimen negative for fungi'' in mycology.

Response: We recognize the need for clarification of this option based on the comments received. The option was proposed in bacteriology at § 493.911(a)(1)(iv)(A); mycobacteriology at § 493.913(a)(1)(ii)(A); and mycology at § 493.915(a)(1)(ii)(A) under the proposed categories for microorganism detection and identification. Similar language proposed for parasitology at § 493.917(a)(1)(ii)(A) specified detection of the presence or absence of parasites. This option was not proposed for virology. Specimen types are not included in any of the PT categories in microbiology and a challenge for growth or no growth, or presence or absence, was not proposed and may not be appropriate for all specimen types or sites, or appropriate as a response for all laboratories. It is one of two options included under the category of detection and identification of bacteria, mycobacteria, fungi and aerobic actinomycetes, and parasites, in the respective microbiology subspecialties. It was proposed as an option for laboratories that perform limited microbiology testing to detect the presence of microorganisms and then refer growth from culture or specimens containing the microorganisms detected to another laboratory for identification. In response to the question about applicability of this option for laboratories that perform urine colony counts, PT is not required for colony counts. If the laboratory performs identification of the bacterial growth, PT is required for the identification. If the laboratory performs the colony count only and refers the isolate for identification, an appropriate result for the PT challenge would be to report detection or growth of bacteria. In response to the suggestions for revisions to the language for this option in each of the subspecialties, after considering the suggestions from commenters, for clarification in this final rule we have changed the language at § 493.911(a)(1)(iv)(A) to ''detection of the presence or absence of bacteria without identification.'' We changed the language at § 493.913(a)(1)(ii)(A) to ''detection of the presence or absence of mycobacteria without identification, ''and at § 493.915(a)(1)(ii)(A) to ''detection of the presence or absence of fungi and aerobic actinomycetes without identification.'' In parasitology, we added ''without identification'' to the end of the phrase currently at §§ 493.917(a)(1)(ii)(A) and 493.917(b)(1) to be consistent with the other microbiology subspecialties. In these subspecialties, we also revised the performance criteria at §§ 493.911(b)(1), 493.911(b)(7)(i), 913(b)(1), 493.913(b)(5)(i), 493.915(b)(5)(i), and 493.917(b)(5)(i) to correspond to these changes. For example, in bacteriology this change now specifies that the performance criterion is the correct detection of the presence or absence of bacteria without identification. This may be achieved when performing a culture and looking for bacterial growth or when using another test method that detects the presence of bacteria without any type of identification being performed.

Comment: Two commenters recommended clarification of the proposed categories of direct antigen and toxin detection, with specific questions about the applicability of this category and which antigens or toxins are required in the subspecialties of bacteriology (§ 493.911), mycobacteriology (§ 493.913), and mycology (§ 493.915). One commenter questioned whether the intent of the proposal was to require PT for only *Clostridium difficile* toxin or also for other toxins in bacteriology. The same commenter requested clarification on which direct antigen tests are proposed to be required in mycology. Another commenter questioned whether antigen

detection was intended to be required for mycobacteriology, as it was not proposed and no programs currently offer this PT.

Response: The requirement for PT for laboratories that perform direct antigen testing has been part of the CLIA regulations in the subspecialties of bacteriology and virology since PT was first required in 1994 and it was included as one of the required categories of microbiology PT in the proposed rule. As with other microbiology PT, the microorganisms for which it is required are not specified in the regulations. Rather, the regulations require that PT programs determine the reportable bacteria or viruses to be detected using direct antigen techniques. In this rule, required PT for direct antigen detection is included in bacteriology at § 493.911(a)(1)(ii); mycology at § 493.915(a)(1)(i); parasitology at § 493.917(a)(1)(i); and virology at § 493.919(a)(1)(i). Required PT for toxin detection is included in bacteriology at § 493.911(a)(1)(iii). As in the previous rule, the microorganisms for which direct antigen or toxin detection are required are not specified in the regulations. Rather, in all subspecialties for which this category is required, the regulations state the PT program determines the organisms to be reported by direct antigen or toxin detection. PT for direct antigen or toxin detection may be part of a combination module or offered as an individual five-challenge module in each subspecialty. If a laboratory performs direct antigen or toxin testing for which PT is not available, they are required to verify the accuracy of those procedures at least twice per year, as described at § 493.1236(c)(1).

Comment: A few commenters addressed the proposed requirements for microbiology stains, with agreement that Gram stain PT should require bacterial morphology as well as gram-reaction. Commenters requested for clarification regarding the level of detail required for bacterial morphology as part of PT and whether Gram stain PT would be required when a Gram stain is performed as part of organism identification. Commenters also questioned the proposed inclusion of Gram stains and acid-fast stains in bacteriology and mycobacteriology, but lack of requirements for stain challenges in other microbiology subspecialties.

Response: In this rule, we are finalizing the proposed requirement at § 493.911(b)(1) that includes bacterial morphology when performing Gram stain PT. This may apply to either a Gram stain required as an individual challenge or as part of bacterial identification. PT program instructions specify which tests are to be performed on each sample, thus identifying which samples require Gram stains. Morphology should include the basic shape and arrangement of bacteria. However, as stated at § 493.911(b)(1), the PT program determines the reportable staining and morphological characteristics to be interpreted by Gram stains. In response to the commenters who questioned whether PT was proposed for stains in mycology and virology, at this time, PT programs do not offer challenges for stains in these subspecialties. Thus, they were not proposed. In parasitology, although specific stains were not proposed as a required PT category, the sample types required at § 493.917(a)(2) include PVA (polyvinyl alcohol) fixed specimens and blood smears, both of which are used in parasite identification. Because a variety of stains are used by laboratories to facilitate identification of intestinal, blood, and tissue parasites, and in some cases, parasites can be identified directly in wet mounts without using a stain, no stains were included for this microbiology subspecialty. Each laboratory participating in PT for parasite identification should follow the staining procedures they use for patient specimens.

Comment: Commenters supported the removal of specific lists of microorganisms from the microbiology subspecialty requirements and replacement with general groups of organisms to be included over time. In addition, commenters requested clarification of the required groups in bacteriology, mycology, and virology. In bacteriology, one commenter suggested expansion of the groups to include Gram-negative cocci or coccobacilli, and another requested clarification of whether the groups of cocci include coccobacilli or diplococci. A third commenter suggested bacterial strains included in PT should be those routinely encountered in specimens. In mycology, two commenters expressed concern about inclusion of dimorphic fungi as a required category, noting that the majority require handling in a biosafety level 3 laboratory and are unable to be shipped. Comments pertaining to groups of organisms for virology recommended viral groups that must be included, and one organization questioned whether a PT program needed to offer all viruses and all specimen sources to be approved for virology PT. Specifically, the commenter questioned whether a program could offer PT challenges for susceptibility or resistance testing based on a single specimen source, such as urine. Another commenter requested for clarification regarding appropriate specimen sources to be included in virology modules and questioned whether combinations of viruses needed to be incorporated in a single PT sample.

Response: The PT requirements for the microbiology subspecialties specify that the organisms included are those that are commonly occurring in patient specimens or are important emerging pathogens. The groups identified for each of the five subspecialties are general groups to be included over time and annually, if appropriate for the sample sources. They are not intended to be the only groups that could potentially be included. In bacteriology, Gram-positive or Gram-negative coccobacilli or diplococci could be included as challenges in addition to, or as more specific subgroups of the individual morphologies listed for bacteriology at § 493.911(a)(3). No changes are being made in this final rule to the bacteriology groups that were proposed. As stated by the commenters for mycology, dimorphic fungi were proposed at § 493.915(a)(3)(ii)(C) as a group of organisms to be included in mycology over time and more specifically, required on an annual basis. We recognize the commenters concerns with the proposed inclusion of this group of fungi, some of which must be manipulated at a biosafety level 3. In response to these concerns, we have removed the dimorphic fungi from the groups of annually required organisms in mycology. However, over time, we encourage PT programs to include a variety of organisms in each subspecialty, as appropriate, to test a laboratory's ability to detect and identify the spectrum of organisms that might be found in patient specimens. In mycology, this may occasionally include dimorphic fungi, such as *Sporothrix schenckii,* that can be handled under biosafety level 2 conditions. In response to the questions about the PT requirements for virology at § 493.919(a)(3), the proposed rule did not specify that all viruses or specimen sources needed to be included for a PT program to be approved. However, it was proposed that if appropriate for sample sources offered, the types of viruses included annually must be representative of the groups of medically important viruses listed. Generally, with this rule, PT programs must continue to offer the same types of virology challenges and modules that have been offered in the past. Lastly, PT

samples containing combinations of viruses were not proposed and are not required in this final rule.

Comment: Several commenters indicated that the proposed requirement in all microbiology subspecialties for laboratories to detect and identify organisms to highest level performed on patient specimens was unclear. One commenter recommended changing the description of the category for identification of bacteria to ''the highest level that the laboratory reports results on patient specimens.'' Two commenters suggested identification needed to be clarified as to whether the intent was presumptive or definitive identification and others questioned how this requirement should be applied with respect to identification at the genus or species level. The commenters stated more specific and better-defined criteria are needed, as well as the incorporation of language to allow for abbreviated reporting frequently used in reporting mixed cultures. They also questioned whether this information would need to be transmitted from PT programs to CMS and State agencies and one noted it would take time to implement this requirement. Another commenter stated it is the responsibility of inspectors to review patient reporting practices and not that of PT programs.

Response: We agree that the language proposed in all subspecialties for identification of microorganisms to the highest level that it performs procedures on patient specimens may be unclear, and we agree that the revised description provided by the commenter earlier more clearly specifies that this requirement refers to how a laboratory reports results on patient specimens. As a result, we have incorporated the change suggested by the commenter and made conforming changes in this rule for all subspecialties at §§ 493.911(b)(2), 493.913(b)(2), 493.915(b)(2), 493.917(b)(2), and 493.919(b)(2). We expect that this will clarify that if a laboratory reports patient results to the genus level, that is the expectation for PT. Similarly, if a laboratory reports patient results to the species level, that would be the expectation for reporting patient results. In response to the question about incorporation of language to allow for reporting abbreviated results, if this is the practice for reporting results to the highest level on patient specimens, it may be an acceptable PT practice as well. In all subspecialties, PT programs determine the organisms that must be reported as part of their identification. We believe the delayed implementation of specific portions of this final rule will allow PT programs to incorporate updates needed for reporting results to CMS. We agree with the commenters who stated that it is the responsibility of laboratory inspectors to review patient reporting practices and not the responsibility of PT programs and this was part of a CLIAC recommendation made prior to the development of the proposed PT rule. It was not our intent that PT programs take on this responsibility and it was not included in the proposed rule.

Comment: Multiple commenters supported the proposed changes to decrease the required percentage of mixed culture challenges from at least 50 percent to at least 25 percent in bacteriology, mycobacteriology, and mycology. The change, if finalized, would specify that at least 25 percent of the PT samples must contain mixtures of the principal organisms and appropriate normal flora.

Response: We agree with the commenters and appreciate their support of these proposed changes. This is in alignment with a CLIAC recommendation stating such and was proposed at §§ 493.911(b)(1), 493.913(b)(1), 493.915(b)(1). We are finalizing these changes in this rule.

Comment: Some commenters recommended changes to the microbiology subspecialties for which susceptibility or resistance testing PT was proposed to be required. A commenter noted that it would be difficult to comply with the requirement for susceptibility or resistance testing in mycology since samples are limited, there are few FDA-cleared methods or breakpoints for fungi, and there is extensive variability in the testing. Another commenter recommended that susceptibility or resistance testing may not be added to required PT in mycology and may be removed in mycobacteriology since few laboratories perform this testing. A third commenter stated the value of requiring PT for *M. tuberculosis* susceptibility testing is limited since programs often send out the same strain that is susceptible to all drugs tested. With respect to virology, a commenter disagreed with requiring susceptibility or resistance testing in this subspecialty and proposed requiring PT for viral loads. Another commenter indicated that since only one PT program currently offers antiviral susceptibility testing, that does not meet the specified criterion of requiring that three programs offer PT for an analyte or test, and it may not be required in virology. Finally, a commenter questioned whether a PT program should be required to offer susceptibility or resistance testing PT in virology if they offered other virology PT.

Response: We agree with the commenters' reasons for suggesting that PT not be required for susceptibility or resistance testing in mycology and virology at this time. Therefore, we are removing the proposed requirements for inclusion of this category of required PT § 493.915(a)(1)(iii) for mycology and at § 493.919(a)(1)(iii) for virology in this final rule. If this testing becomes less variable and PT availability increases in these subspecialties in the future, we may propose to include it in rulemaking at that time. In the meantime, if a laboratory performs susceptibility or resistance testing on patient specimens in mycology or virology, they are required to verify the accuracy of those procedures at least twice per year, as described at § 493.1236(c)(1). Voluntary PT may be a way the laboratory chooses to meet this requirement. With respect to the requirement for susceptibility or resistance testing in mycobacteriology, we are aware that small numbers of laboratories perform this testing and subscribe to PT and that only one program currently offers susceptibility testing PT in mycobacteriology. We also recognize that PT programs are less likely to send out resistant strains of mycobacteria, especially *M. tuberculosis,* due to biosafety concerns when shipping or working with these organisms. For these reasons, in addition to the fact that mycobacteriology is unique in that only two PT events per year are required, we are removing the requirement at § 493.913(a)(1)(iii) for susceptibility or resistance testing in mycobacteriology in this final rule. As stated previously, if a laboratory performs susceptibility or resistance testing on patient specimens in mycobacteriology, they are required to verify the accuracy of those procedures at least twice per year, the same frequency as required PT in this subspecialty. Laboratories may choose to subscribe to voluntary PT as a way to meet the requirement or they may use another mechanism to meet the requirement that does not include shipping strains of organisms that require special precautions.

Comment: Commenters questioned or requested clarification of the proposed requirements specified for antimicrobial susceptibility or resistance testing, including clarification of the definition or intent of resistance testing, questioning whether it meant testing for resistance mechanisms or markers for specific organisms. One commenter stated clarification was needed as to whether susceptibility testing is optional if a laboratory performs

identification. Another commenter suggested the language for this category of PT in bacteriology be clarified to state ''antimicrobial susceptibility or resistance testing of select bacteria.''

Response: The category of antimicrobial susceptibility or resistance testing was included in the proposed rule in for the subspecialties of bacteriology at § 493.911(a)(1)(v); mycobacteriology at § 493.913(a)(1)(iii); mycology at § 493.915(a)(1)(iii); and virology at § 493.919(a)(1)(iii). Resistance testing was included in this proposed category as it was previously recommended by CLIAC to be required along with susceptibility testing. As discussed in the previous comment, the proposed requirement for susceptibility or resistance testing in mycobacteriology, mycology, and virology has been removed from this final rule. With respect to the proposed requirement for this category in bacteriology, we agree with the commenters that the interpretation of ''resistance testing'' may not be clear, and that in some cases, bacterial resistance may be determined as part of an organism identification. For these reasons, we have removed resistance testing from the required category proposed in bacteriology and in this final rule we are requiring antimicrobial susceptibility testing of select bacteria, as suggested by the commenter, at § 493.911(a)(1)(v), since antimicrobial susceptibility testing is not performed on every bacterium that is isolated in a culture and PT programs specify which challenges require that susceptibility testing be performed. This also addresses the comment suggesting a change in the description of this bacteriology category for clarification. If laboratories perform resistance testing separate from bacterial identification, they are required to verify the accuracy of those procedures at least twice per year, as previously stated, and may enroll in voluntary PT to do so. In response to the recommended clarification of whether susceptibility testing is optional when a laboratory performs identification, laboratories must follow PT program instructions when determining which tests to perform on a microbiology sample. The programs must clearly identify which samples require that susceptibility testing be performed on bacteria that are identified and those results reported for PT purposes.

Comment: Several commenters agreed with the proposed increase in the number of required susceptibility or resistance testing challenges from one to two per event in all microbiology subspecialties except parasitology, where PT for susceptibility testing is not required. They indicated that increasing the number of challenges and requiring one Gram-positive and one Gram-negative challenge per event in bacteriology would help identify issues with patient testing. Other commenters disagreed with this proposed change, expressing concerns that this requirement would provide too much information to laboratories about PT sample content and make the PT results more predictable. One commenter stated that including two susceptibility challenges per event lacked value and relevance. Others suggested that requiring a mixture of challenges throughout the year was preferred over the requirement to include one Gram-positive and one Gram-negative challenge per event.

Response: We agree with the commenters who supported the proposed change to increase the number of required susceptibility or resistance challenges to two per event and are finalizing that change in this rule at § 493.911(a)(4). This change was recommended by CLIAC, and we believe it will provide a better assessment of laboratory testing performance over time. We also agree with the commenters who suggested that we should not specify a predictable pattern of susceptibility testing challenges in bacteriology, requiring that each event must include one Gram-positive and one Gram-negative challenge. As a result, in this rule, we are revising the requirement to indicate that each year, a minimum of two samples per testing event of susceptibility testing challenges must include a mixture of Gram-positive and Gram-negative challenges.

Comment: A PT program commented on the proposed requirements to change scoring for the microbiology subspecialties by including separate category scores in addition to the overall subspecialty scores. The program inquired about the intent of this proposed change and suggested that it would increase the complexity of determining scores and it may be especially challenging to score laboratories that perform a mixture of detection and identification procedures. The commenter also noted the proposed scoring method would give PT programs discretion in the interpretation of the requirement which could result in laboratories choosing the program that uses the most advantageous method. The commenter advocated for simplifying the subspecialty scoring process rather than increasing complexity for efficiency and increasing the value to laboratories.

Response: The four categories of testing proposed for microbiology PT were recommended by CLIAC to replace the types of laboratory services that are part of the current regulations. The types of services guided the scoring of microbiology subspecialties since there are no specific analytes in this laboratory specialty. However, since only a single score is given for each subspecialty, many times representing a combination of results for different types of testing, it is not possible for laboratory surveyors to readily determine if a laboratory is having problems with one area of their microbiology testing. No changes were made to the scoring process for microbiology in the proposed rule other than aligning the requirements for evaluation of a laboratory's performance at §§ 493.911(b) through 493.919(b) to be consistent with the categories of testing and facilitate the identification of problems in any one of the categories.

Summary of Final Actions

- We are finalizing the proposed revisions at §§ 493.911 through 493.919 by removing the types of services listed for each microbiology subspecialty and inserting a more general list of organisms.
- We are finalizing the proposed revisions at §§ 493. 911(a), 493.913(a), and 493.915(a) that are related to growth or no growth and mixed culture requirements (50 percent to 25 percent).
- We are finalizing the proposed performance criteria revisions at §§ 493.911(b), 493.913(b), 493.915(b), 493.917(b), and 493.919(b).
- We are finalizing the proposed addition of ''without identification'' to the end of the phrase currently in the subspecialty of parasitology at § 493.917(a)(1)(ii)(A) to be consistent with the other subspecialties.
- We are finalizing the proposed revised requirement at §§ 493.911(b)(2), 493.913(b)(2), 493.915(b)(2), 493.917(b)(2), and 493.919(b)(2) to clarify and emphasize that laboratories should detect and identify organisms to the highest level that they report results on patient specimens.
- We will amend §§ 493.911(b)(1), 493.913(b)(1), 493.915(b)(1), 493.917(b)(1), 493.919(b)(1) to clarify that for the purpose of achieving consensus, PT programs must attempt to grade using both participant and referee laboratories before determining that the sample is ungradable.
- We are finalizing the proposed revisions to § 493.911(a) through (b) related to Gram stains, direct antigen detection, bacterial toxin detection, and performance and scoring related to

direct antigen and bacterial toxin detection for the subspecialty of bacteriology.

- We are finalizing the proposed addition to § 493.915(a) related to requiring direct antigen testing for the subspecialty of mycology.
- We are finalizing the proposed addition to § 493.917(a) related to requiring direct antigen testing for the subspecialty of parasitology.
- We are finalizing the proposed revision to § 493.919(a) related to requiring direct antigen testing for the subspecialty of virology.
- We are removing the reference to resistance testing in the subspecialty of bacteriology and have removed references to ''resistance testing'' in the requirement for antimicrobial susceptibility testing of select bacteria at § 493.911.
- We are not finalizing the proposed requirements for PT of antimicrobial susceptibility and resistance testing in the subspecialties of mycobacteriology, mycology, and virology and have removed the requirement at §§ 493.913, 493.915, and 493.919.

F. Proposed Changes to PT for Non-Microbiology Specialties and Subspecialties (§§ 493.921 Through 493.959)

1. Required Analytes

Comment: Several commenters agreed that the list of required analytes should be updated. Some commenters stated that the process for analyte inclusion and removal was thorough, understandable, and transparent. One commenter stated the inclusion threshold for new analytes that only included three PT programs, rather than four, could result in an unfair market advantage, raise PT costs for laboratories, or result in logistical difficulties in obtaining PT.

Response: In response to the comments, we reviewed our analyses and determined that there were no proposed analytes that would not have made the requirement for being offered by at least four PT programs, as was suggested by the commenter. We believe that the fact that there are already at least three programs available to choose from for each new analyte or test gives laboratories several options and should not result in increased costs or logistical difficulties in obtaining PT. All PT programs received notification of the proposed analytes or tests at the same time when the proposed rule was published. Whether a PT program elects to offer a particular analyte is a business decision of the PT program, and outside of our purview.

Comment: A small number of commenters mentioned concerns about the possibility that either inclusion of the PT analytes or the ALs we proposed would have a negative impact on access to testing. A few commenters suggested that for the ALs proposed for some analytes, some existing test systems would not meet the new requirements. For example, one manufacturer stated that the proposed ALs for creatine kinase isoenzymes may be challenging for some testing platforms to meet. A similar comment was made for proposed ALs for troponin I and hematocrit.

Response: During the phase in period, manufacturers will have time to improve test accuracy, and laboratories will have time to switch to higher accuracy test methods if those they use do not provide results that are able to meet the criteria for acceptable performance specified in the regulations. Clinicians and patients should be able to expect accurate testing, and assuring overall accuracy is the goal of performing PT. Therefore, these changes should drive the health care system toward more accurate methods. We have no reason to believe that access to testing will be impacted.

Comment: Several commenters supported the list of analytes that were proposed for addition and deletion, and commenters supported the process we used for determining the list of analytes for which PT is to be required. No commenters questioned any of the proposed new analytes. However, one commenter stated that a current analyte, T3 uptake, should be deleted because it lacked clinical utility. An accreditation organization and an individual commented that determination of creatine kinase (CK) MB fraction by electrophoresis should be discouraged, and therefore, it should be excluded from the required PT for creatine kinase isoenzymes. Rather, the commenters noted that PT should only be required for laboratories that use immunochemical methods when testing for this analyte. Some commenters recommended inclusion of analytes that we had considered but decided not to include. One commenter suggested that we require PT for several immunosuppressant drugs for which PT is not currently required.

Response: We had initially considered all the analytes that commenters recommended for either inclusion or deletion, but the suggested analytes did not meet one or more of our inclusion or deletion criteria. Both the inclusion and deletion processes, which were described in the proposed rule, were based upon per-analyte estimates of the availability and the number of programs already offering PT, the nationwide volume of patient testing, the impact on patient or public health of offering PT, and the cost and feasibility of PT implementation. We did not propose deletion of T3 uptake because test volumes were above the threshold for consideration. With respect to the suggestion to discourage laboratories from using electrophoretic methods to test for CK–MB isoenzymes, the method used is not a basis for requiring or not requiring PT for any test or analyte. Each laboratory needs to identify the method or test system used when submitting PT results for programs to properly grade the PT. To the extent that test results are used for clinical decision making, the test results should be accurate. The immunosuppressant drugs that were suggested were not done in sufficient volumes to meet the threshold for consideration in the proposed rule, so they were not proposed to be required.

Comment: For a few analytes that can be detected or quantified in more than one way, some commenters requested clarification concerning which analyte would require PT. For example, a commenter questioned if PT was proposed to be required whether LDL cholesterol was calculated or measured directly. Several commenters requested clarification concerning whether drugs were to be measured in total or free forms. One commenter mentioned a need to specify the sample type that should be tested if the analyte can be tested in more than one type of body fluid.

Response: For LDL cholesterol, which can be measured both directly and as an estimation based on other measured lipids, PT is only required for directly measured (not calculated) LDL cholesterol. For all drugs, we intend that the measured form must be total drug. For the specialty of chemistry, in subpart I the sample types for which PT is required are specified for each under each subspecialty, at § 493.931(b) for general chemistry, § 493.933(b) for endocrinology, and § 493.937(b) for toxicology. If a laboratory performs patient testing on other sample types than those listed, they are required to verify the accuracy of testing with those alternative sample types at least twice per year, as described at § 493.1236(c)(1). If available, voluntary PT may be a way the laboratory chooses to meet this requirement.

Comment: A few commenters requested clarification of what should be considered high sensitivity C-reactive protein, as opposed to traditional C-reactive protein, as included in the

proposed rule. A related comment suggested that we should require PT for all assays for C-reactive protein.

Response: Although traditional C-reactive protein has been used as a general marker of inflammation for many years, it did not meet the threshold for inclusion as a required PT analyte. In this rule we are finalizing the proposed PT requirement for high sensitivity C-reactive protein and we appreciate the need to define which test methods would be considered ''high sensitivity'' testing. High sensitivity C-reactive protein concerns testing related to cardiac ischemia, either for frank cardiac events or for risk stratification, which requires more sensitive test methods to detect lower concentrations. We are deferring to laboratories to know whether their assay is a high sensitivity method used to detect cardiac pathology, or the traditional, less sensitive C-reactive protein. PT programs must label their PT offerings accordingly.

Comment: One commenter suggested that we should specify the N-terminal region of pro-B-natriuretic peptide (BNP), which was included as a required analyte in the proposed rule because this is the epitope usually detected by antibodies used in most test methods.

Response: We agree with the commenter that the N-terminal region of pro-B-natriuretic peptide (BNP) is the part of the peptide that is usually measured, but we did not want to restrict the requirement for PT. Therefore, in this rule we are finalizing the name as proposed: proBNP.

2. Scoring and Acceptance Limits

Comment: With respect to scoring and ungradable samples, one commenter requested clarification about how performance on an analyte was determined for a PT event when one of the PT samples was not able to be graded. The commenter questioned what the denominator of graded samples would be. An accreditation organization agreed with our proposal to require PT programs to attempt to reach consensus using both laboratory and referee laboratories before deciding a sample is ungradable due to lack of consensus.

Response: If a sample for a particular PT event is ungradable, for example, because consensus could not be reached, it is still considered to be part of the denominator of five PT samples for that event, and in this case, the laboratory is given credit for passing the challenge. Therefore, if one of the remaining PT samples in the event is missed, the event score is 80 percent, and the event score is ''satisfactory'' for the majority of required PT.

Comment: Several commenters stated that the process used for simulating the impact of scoring PT using several alternative ALs to determine the optimal limit to require was unclear.

Response: As discussed in the proposed rule, we requested PT programs to examine the impact of various ALs on their aggregated sample failure rates, using the peer grouping approaches they had previously used. A number of the PT programs provided simulated results, applying various possible percentage-based ALs to actual results from previous PT events, and were able to help us select appropriate ALs. We selected ALs using a target miss rate (per sample) in the 1 to 2 percent range. Our intent was to assure that the ALs would work across the clinically important range and not inappropriately fail results that were accurate for clinical decision making. Therefore, we examined error rates at all concentrations that PT programs used throughout the 2 years of PT data they shared with us.

Comment: We received a number of comments related to the proposal to use percentage-based ALs whenever possible. While some commenters supported the proposed changes, others suggested changes to specific proposed ALs for both current and newly proposed analytes. Generally, these comments concerned whether the proposed limits would be workable across the clinically important measurement interval for all test methods and platforms. In almost all cases, the comments recommended less stringent ALs, either across the entire analytical measurement range or specifically at low concentrations, where test methods are generally less accurate. Commenters pointed out that unless there is allowance for low concentrations, PT programs would be discouraged from using PT samples with low concentrations, to the detriment of assuring accurate testing across the analytical range. Supporting this, some commenters stated that it is not clinically important to be as accurate as the percentage-based limits would require. Commenters suggested that we use a combination of a percentage and a concentration limit for certain analytes, such that PT samples with relatively low concentrations would be more fairly assessed. In some cases, commenters recommended a concentration limit that differed from a concentration limit we had proposed. A small number of commenters were generally concerned about moving from familiar 3 SD-limits to percentage based ALs for some currently required analytes.

Response: In response to commenters' concerns about the use of percentage limits when scoring PT analytes at low concentrations, in this final rule, we are including ''concentration limits'' such as are already used for glucose and some other analytes for many newly required analytes and some previously required analytes. When adding concentration limits and using combined ALs, programs are directed to score with whichever of the specifications is more tolerant, allowing for fairer and more realistic ALs that will allow PT programs to cover the clinically important range of results. We re-examined previously acquired simulation data from PT programs and have added concentration limits for 13 analytes. Specifically, we created concentration thresholds for alanine aminotransferase, aspartate aminotransferase, cholesterol (high density lipoprotein), CK–MB isoenzymes, glucose, carcinoembryonic antigen, human chorionic gonadotropin, vitamin B12, acetaminophen, carbamazepine, lithium, phenobarbital, and salicylate. Concerning the switch from current 3 SD limits to percentage-based limits, we believe that the new ALs will be workable, fair, and clinically relevant. As stated in the proposed rule, ALs based on analytical variability within a peer group, such as the use of 3 SD limits, are ill-suited to know whether testing results are sufficiently accurate for clinical purposes.

Comment: Two commenters noted that CLIA ALs have been used in ways other than their intended purpose of identifying laboratories with unacceptable performance. One commenter noted that ALs have been used as goals for ideal performance, for example, setting quality control acceptable limits. Another commenter pointed out that ALs have been used for verifying analytical performance, for example, accuracy.

Response: We agree with the comments and reemphasize that ALs must not be used as the criteria to establish performance goals in clinical laboratories. Goals for accuracy and precision must be based upon clinical needs and manufacturer's FDA-approved or -cleared labeling; PT performance is not the best assessment of these. Proficiency testing is intended to identify laboratories that are not performing with acceptable analytic accuracy; it is not intended, nor suited, to provide goals for analytical accuracy or clinical performance.

Comment: Many commenters stated the proposed AL for hemoglobin A1c (HbA1c) was too loose and not reflective of the testing accuracy of current test methods. Many individuals and organizations commented that the AL should be 6 percent, and several recommended lowering the limit to 5 percent. Several comments requested that CLIA ALs should not ''change'' from the current 6 percent, despite the fact that HbA1c is currently not a CLIA-required PT analyte, and therefore, no ALs are specified in the regulations. Many commenters expressed concerns that using a threshold higher than 6 percent would in some way subvert the substantial progress made by the National Glycohemoglobin Standardization Program (NGSP), working collaboratively with test method manufacturers, to improve accuracy of HbA1c testing. Commenters suggested that manufacturers would allow the accuracy of their test methods to deteriorate if CLIA added HbA1c with an AL as loose as 10 percent. A PT program proposed that we use an AL of 10 percent for non-commutable PT materials and a limit of 6 percent for commutable (accuracy-based) PT materials. Another PT program commented in favor of a 10 percent limit, noting that non-commutable PT materials may be less accurate with certain test methods and, moreover, PT is not intended to directly reflect accuracy needed for clinical testing.

Response: We appreciate the importance of HbA1c for diagnosis and monitoring patient management, and the need for testing accuracy that is sufficient to meet clinical needs, and we support the progress that continues to be made to improve the accuracy of HbA1c testing. As mentioned in the previous comment, CLIA PT ALs are intended to identify, and hopefully remediate, laboratories that are not providing results as accurate as their peers. CLIA PT ALs should not be used as accuracy goals by manufacturers or by standardization initiatives such as the NGSP. CLIA should not impose a requirement that limits access to critically important patient testing, especially if it is based on PT results that may not reflect the accuracy of patient testing.

One PT program has demonstrated progressive improvements in accuracy of testing by laboratories enrolled in their accuracy-based PT program, which uses commutable patient samples. We are aware that, over time, the program has incrementally tightened their ALs for the accuracy-based PT. This progress has been possible without CLIA requiring PT for HbA1c, and therefore, adding a PT requirement for HbA1c should not impede further progress in the future. Accreditation organizations have the flexibility to require their laboratories to meet a more stringent requirement than CLIA. They also have the option of using the CLIA limit and using a second, more stringent, AL for educational purposes. Either approach would allow these organizations to continue to tighten the limits for HbA1c for their accredited laboratories. We acknowledge the importance of standardization programs, like the NGSP, having the latitude to continuously adjust their accuracy goals to monitor and encourage improvements in the accuracy of HbA1c testing. We do not believe that a CLIA AL that is looser than the limit in use by the accuracy-based PT program would cause manufacturers to allow testing accuracy to deteriorate, as many commenters have suggested.

The AL adopted in CLIA regulations must not be too tight for laboratories that do not participate in an accuracy-based PT program that uses commutable PT materials. In simulation studies performed before issuing the proposed rule, laboratories using non-commutable PT samples had poorer performance, especially when scoring using any AL less than 10 percent. This might have occurred because laboratories not enrolled in accuracy-based PT use different test methods or because the PT they use is non-commutable. CLIA does not specify whether laboratories are required to participate in PT based on whether it is commutable or non-commutable. The same AL apply regardless of the PT samples' commutability.

After analyzing the comments received in response to the proposed rule, we requested the PT programs that offer HbA1c to simulate results that would be obtained if they used 5 percent, 6 percent, 8 percent, and 10 percent as the AL. We requested programs to indicate miss rates and unsatisfactory rates based upon different HbA1c concentrations in their materials, and to disclose performance based upon their testing platform or peer groups used. Based upon these more recent simulated results, we found that it will be possible to use a tighter AL than 10 percent. After this analysis, we are setting the AL for HbA1c at 8 percent in this final rule. The performance improvements we saw between the first and later simulations may reflect improvements in the accuracy of testing for HbA1c.

Comment: Commenters stated that rather than using the proposed AL of 20 percent for LDL cholesterol, we should require an AL of 12 percent, which is the accuracy target used by the National Cholesterol Education Program.

Response: Because the commenters suggested an AL tighter than was proposed, we requested PT programs to simulate the impact of using that limit. Based upon reanalysis of new data shared by PT programs, we confirmed that the proposed AL of 20 percent is appropriate for scoring PT for LDL cholesterol, and we are finalizing that limit in this rule.

Comment: With respect to PT for blood lead, we proposed a change from the current AL of ±4 mcg/dL or 10 percent (greater) to ±2 mcg/dL or 10 percent (greater). One commenter supported the proposed AL, consistent with efforts to improve the ability of laboratories to detect very low concentrations of blood lead in patient specimens. Conversely, another commenter stated that the reduction of the concentration AL from 4 mcg/dL to 2 mcg/dL would result in more instances of nonconsensus, which would result in more ungraded samples and events. Another commenter expressed concerns about the impact of the proposed limits on failures for certain testing platforms.

Response: We agree with the commenter who emphasized the public health importance of the need for accuracy at low concentrations of blood lead, to detect and prevent cases of childhood lead poisoning, and are finalizing the proposed AL for blood lead at 2 mcg/dL ±10 percent (greater) in this rule. We appreciate the commenters' concerns, however, one outcome of more stringent ALs may be that laboratories switch to test methods that are more accurate across the range of testing and better able to meet clinical needs. We believe that manufacturers of analytical platforms that may fail to achieve consensus, or otherwise perform poorly, will improve their accuracy during the phase-in period. To address concerns regarding unintended consequences that may increase health disparities, we will monitor changes in PT participation for all analytes after this rule becomes effective as this is required as part of PT oversight under CLIA. This includes the methods used for testing each PT analyte required by CLIA.

Comment: A few commenters provided suggestions related to the addition of troponin I and troponin T as required analytes in routine chemistry. One commenter was concerned that adding troponins to the required list for PT may potentially limit access to point-of-care cardiac triage testing of potential cardiac events in rural settings. The

same commenter also suggested that the ALs for troponin I and troponin T should be expanded to ±40 percent, with no suggested changes to the associated concentration limits. A couple of commenters suggested that the same, percentage-based AL would work for both generic and high sensitivity troponins. A small number of commenters suggested that we should require PT for high sensitivity troponin assays in addition to traditional troponin assays.

Response: Troponin I and troponin T are used to make decisions about the use of lifesaving, yet not risk-free, interventions, such as cardiac catheterization and therapeutic thrombolysis. Therefore, it is important that such testing be both accessible and accurate. We believe that requiring PT for the troponins is important and must not inhibit access to testing. We reviewed our simulation data to see if the same concentration limit would work for both troponin I and T. We determined that we must use the proposed, different ALs, and, therefore, are finalizing the AL for troponin I as ±0.9 ng/mL or 30 percent (greater) and for troponin T as ±0.2 ng/mL or 30 percent (greater). At the time we proposed these changes, troponin I and T were not frequently tested as ''high sensitivity'' analytes, that is, at very low limits of detection. Also, there were not enough PT program offerings to meet our threshold for inclusion for high sensitivity troponins. Therefore, we are not requiring PT for ''high sensitivity'' troponin I or T.

Comment: A few commenters stated that some proposed percentage-based ALs were too tight, regardless of whether a concentration threshold was included. Commenters stated that the proposed percentage ALs for immunoglobulin A (±15 percent), immunoglobulin E (±15 percent), amylase (±15 percent), and leukocyte count (±5 percent) were too tight. The commenters recommended ALs be set at ±20 percent for immunoglobulin A, ±25 percent for immunoglobulin E, and ±10 percent for leukocyte count. No recommendation was provided for amylase.

Response: We re-examined simulation data that had been submitted by PT programs and revised percentage limits as appropriate. Specifically, in this rule we are finalizing the AL for immunoglobulin A to ±20 percent, amylase to ±20 percent, and leukocyte count to ±10 percent. We determined that adding a concentration limit for these analytes was not necessary or adequate to make the AL workable at a lower concentration. For immunoglobulin E, we did not determine that it was necessary to increase the AL to ±25 percent; therefore, we are finalizing the AL for immunoglobulin E in this rule at ±20 percent.

Comment: Some commenters expressed concerns related to proposing ALs based on allowable total error derived from estimates of biological variability (BV). There was a comment that the use of BV data was in flux at this time. One commenter noted that estimates of BV that we used may be incorrectly wide due to errors in the way estimates were made, specifically that they may overestimate BV because the results are based upon analytical test methods that have inherent variability. One commenter stated that BV cannot be directly related to clinical outcomes. The same commenter stated that when setting ALs both BV and state-of-the art performance should be considered.

Response: We appreciate the concerns expressed and note that the ALs we proposed were not based strictly on estimates of BV. Moreover, we are aware that the field of estimating BV data has changed in the last few years. However, any impact of suboptimal estimations of BV on the ALs we proposed was likely negligible because we always tested potential ALs using simulations. ALs that were too tight to be workable were eliminated even if they were not as stringent as our estimates of BV might have suggested were necessary. In other words, consistent with one of the comments, we used state-of-the-art performance, demonstrated through simulations, to finalize the proposed ALs. In some cases, we showed through simulations that it was possible to use ALs that are tighter than the ''minimal'' threshold based upon estimates of BV and in these cases we used a somewhat tighter AL, but only if the data from PT programs supported the tighter limit. As a result, changes in the estimates of BV we used would not have affected our proposed ALs.

After re-examining the literature, we reconfirmed that BV is the only tenable approach to establishing new limits. We agree that clinical outcomes may not be reflected in BV data, but the preferred outcomes studies were not available to us.

Comment: Commenters generally favored the proposal to require separate PT for cell identification and differentials rather than including an option to participate in PT for one or the other. It was pointed out that the results can be used for different purposes in patient treatment. There were questions, however, questioning whether there should be separate scores for cell identification and differentials or if they should be averaged. One commenter recommended that the three standard deviation criteria for acceptable performance for differentials should be changed to a percentage-based criterion and another suggestion was made to include ±1.0 (whichever is greater) for low target values or absolute values (that is, basophils). An additional commenter requested clarification as to whether PT would be required for both manual and automated flow through differentials for laboratories that use platforms that can report flow through differentials.

Response: We appreciate the support from commenters who recognized the need to recognize cell identification and differentials as two separate analytes and are finalizing that change in this rule. As separate analytes they may be scored individually. We are finalizing the criteria for acceptable performance for both analytes in this rule. We are not changing the criterion for differentials to percentage-based because we have no BV data on which to base that change. As such, we are also not including the ±1.0 option for low target values. In response to the question regarding PT requirements for laboratories that perform both manual and automated flow through differentials, a laboratory should perform PT in the same manner as they perform testing on patient specimens. PT is required for the primary method of testing used for patient testing.

Comment: A few commenters supported the proposal to change the consensus requirement for cell identification from 90 percent to 80 percent. One commenter requested for clearer justification for the change.

Response: This change was proposed because it is not possible to score 90 percent on a 5-challenge PT panel. We are finalizing the change in this rule.

Comment: An accreditation organization made several suggestions about how standard deviations should be calculated when they are required as ALs for white blood cell differentials. For peer group sizes of 20 or more, they recommended that we continue to require elimination of outliers before calculation of the standard deviation. The commenter stated that when the peer group size is between 5 and 19 laboratories, robust methods as described in ISO 13528, ISO Guide 35, or ASTM E–691, should be used. They recommended that, alternatively, the standard deviation could be an average standard deviation determined from previous rounds of PT, calculated according to ISO 13528. They also noted that mention of 3 SD to set ALs should

be removed from parts of the regulation that no longer include 3 SD limits.

Response: As mentioned by the commenter, this final rule includes only one analyte with a three standard deviation limit. We agree that this recommendation would allow more accurate estimates of 3 SD ALs for relatively small peer group sizes. We also agree that robust statistical methods must be used to calculate the standard deviations when the peer group size is between 5 and 19 laboratories. However, we are not specifying the statistical approach that needs to be used. We appreciate the commenter's suggestion to remove reference to 3 SD ALs in relevant sections of this final rule and have done so in §§ 493.931(c)(2) and 493.933(c)(2).

Comment: A few commenters recommended that the international normalized ratio (INR) should be listed as a separate analyte in the specialty of hematology, the same way blood cell counts and white blood cell differentials are separate analytes, rather than including INR as a mechanism for reporting prothrombin time results, as was proposed. The commenters agreed that laboratories should report prothrombin time results in seconds, as an INR, or both as appropriate, in the same way that they report patient results. Commenters also stated that separating the prothrombin time and INR would allow for separate ALs for each of them.

Response: It is important for laboratories to report PT results the same way that they report patient results. If patient results are reported in seconds or as INR results, laboratories should report the same way to PT programs. If the laboratory reports patient results in both seconds and as an INR, they should report both to PT programs. The AL for prothrombin time at ±15 percent is applicable for both seconds and INR. When we referenced ''directly measured INR'' in the preamble to the proposed rule, we were referring to those devices that internally calculate and display the INR value rather than giving a value in seconds. The 15 percent AL for INR applies regardless of how it is derived.

Comment: Two commenters remarked on the proposed change to the criteria for acceptable performance of unexpected antibody detection in immunohematology from 80 percent to 100 percent accuracy. While one commenter agreed with this proposed change, the other disagreed. The opposition was concerned with the possibility that laboratories that use less sensitive, but safe, methods could be penalized, and it could limit patient access to care.

Response: We believe that the criteria for acceptable performance for unexpected antibodies should be 100 percent rather than 80 percent. We are finalizing this change because it is critical for laboratories to detect any unexpected antibody when crossmatching blood to protect the public health and not impact patient care. It is important that antibodies are detected to lessen the possibly of a transfusion reaction due to incompatible blood products.

Comment: Concerning appropriate units for reporting PT results or some other aspect of the AL, some commenters noted that we inadvertently deleted titers for some ALs. It was pointed out that for some analytes we incorrectly suggested that the AL should be qualitative. Some commenters noted inaccuracies in the units we used for quantitative analytes.

Response: We appreciate the commenters careful examination of the proposed limits and we made appropriate adjustments that are now reflected in the final rule. In response to comments about proposed units for reporting PT results, unintentional uses of incorrect units have been corrected in this final rule.

Summary of Final Actions

- We are finalizing the proposed revision at §§ 493.923(a), 493.927(a), 493.931(a), 493.933(a), 493.937(a) and 493.941(a) to remove the option that PT samples ''at HHS option, may be provided to HHS or its designee for on-site testing.''
- We are finalizing the proposed addition of 29 analytes and the deletion of five analytes. See section II of this final rule. Additional analytes can be found in section II.B.1. of this final rule, Table 1, and deleted analytes are listed in section II.B.6 of this final rule.
- We are amending §§ 493.923(b)(1), 493.927(c)(1), 493.931(c)(1), 493.933(c)(1), 493.937(c)(1), 493.941(c)(1), and 493.959(d)(1) to clarify that for the purpose of achieving consensus, PT programs must attempt to grade using both participant and referee laboratories before determining that the sample is ungradable.

- Section 493.927 (General Immunology)

++ We are correcting typographical or editorial errors in the proposed criteria for acceptable performance for alpha-1-antitrypsin, alpha-fetoprotein (tumor marker), complement C3, complement C4, antinuclear antibody, antistreptolysin O.

++ We are modifying the proposed AL for immunoglobulin A (IgA) of ±15 percent and finalizing the AL for IgA as ±20 percent based on public comments.

++ We are finalizing the proposed criteria for acceptable performance for antinuclear antibody, antistreptolysin O, rheumatoid factor, and rubella.

- Section 493.931 (Routine Chemistry)

++ We are finalizing the proposed ALs in the criteria for acceptable performance.

++ We are correcting the units for prostate specific antigen (total).

++ We are making a technical change to CK–MB isoenzymes to address measurement by electrophoresis or direct mass determination.

++ We are also modifying the proposed criteria for acceptable performance for hemoglobin A1c of ±10 percent and finalizing the AL for hemoglobin A1c to ±8 percent based on public comments.

- Section 493.933 (Endocrinology)

++ We are finalizing the proposed percentage based ALs in the criteria for acceptable performance.

- Section 493.937 (Toxicology)

++ We are finalizing the proposed concentration limits and percentage based ALs in the criteria for acceptable performance.

++ We are finalizing the proposed requirement that PT programs must provide samples that cover the full range of samples that could occur in patient specimens.

++ We are correcting the units for phenytoin and vancomycin.

- Section 493.941 (Hematology)

- We are finalizing the proposed AL for leukocyte count.

++ We are finalizing the proposed revision to units of reporting for prothrombin time to include seconds and INR (international normalized ratio) and that laboratories must report prothrombin time in the same was as they report patient results.

++ We are finalizing the proposed requirement that laboratories performing both cell counts and differentials must enroll and participate in PT for both.

++ We are finalizing the proposed change to the criteria for acceptable performance for ''cell identification'' from 90 percent to 80 percent.

- Section 493.959 (Immunohematology)

++ We are finalizing the proposed change to the criteria for acceptable performance for unexpected antibody detection from 80 percent to 100 percent.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

The requirements and burden will be submitted to OMB under (OMB control number 0938–New).

A. Clarification for Reporting of Microbiology Organism Identification

We proposed to clarify a requirement at §§ 493.801(b), 493.911(b), 493.913(b), 493.915(b), 493.917(b), and 493.919(b), to emphasize the point that, as currently required, laboratories must report PT results for microbiology organism identification to the highest level that they report results on patient specimens. In accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2), we believe the reporting of microbiology organism identification is a usual and customary practice when reporting PT results to PT programs. We are able to determine how many laboratories provide services in microbiology; however, we are unable to determine if the laboratories are enrolled in the appropriate PT outside of the survey process, or if the microbiology PT samples for which the laboratory is enrolled are required under subpart I. There are no data systems that capture this information. We estimate the number of laboratories that are not currently reporting microbiology organisms to the highest level that they report results on patient specimens to be about 10 percent of 34,113 laboratories which is 341 laboratories. We estimate it would take 20 minutes for a laboratory to fill this information on the PT submission form. Each laboratory would report this information 3 times per year and would take approximately 1 hour. The total annual burden is 341 hours (341 laboratories × 1 hour). A Clinical Laboratory Technologists/Technicians (29–2010) would perform this task at an hourly wage of $27.36 as published in 2021 by the Bureau of Labor Statistics.[11] The wage rate would be $54.72 to include overhead and fringe benefits. The total cost would be $18,660 (341 hours × $54.72).

B. Optional On-Site Visits to PT Programs

At § 493.901(e), we proposed to add the requirement that HHS may require on-site visits for all initial PT program applications for HHS approval and periodically for previously HHS-approved PT programs either during the reapproval process or as necessary to review and verify the policies and procedures represented in its application and other information, including, but not limited to, review and examination of documents and interviews of staff. There is no collection of information requirements associated with this proposed requirement because the documentation is already being collected and maintained by the PT program as normal course of business and is a usual and customary practice in accordance with implementing regulations of the PRA at 5 CFR 1320.3(b)(2).

C. PT Program Reapproval

At § 493.901(f), we proposed to specify that we may require a PT program to reapply for approval using the process for initial applications if widespread or systemic problems are encountered during the reapproval process. If a PT program would need to reapply for approval using the initial application process, we would estimate that the cost would be 10 hours for document collection. The total burden is 90 hours (9 PT programs × 10 hour). However, this would not be an annual burden, rather it would only occur under the circumstances outlined above, and we believe that these would only occur rarely. An Office/Administrative Support Worker (43–9199) would perform this task at an hourly wage of $20.47 as published in 2021 by the Bureau of Labor Statistics.[12] The wage rate would be $40.94 to include overhead and fringe benefits. The total cost would be $3,685 (90 hours × $40.94).

D. Withdrawal of Approval of a PT Program

At § 493.905, we proposed to add that HHS may withdraw the approval of a PT program at any point in the calendar year if the PT program provides false or misleading information that is necessary to meet a requirement for program approval or if the PT program has failed to correct issues identified by HHS related to PT program requirements. We also proposed to add a requirement that the PT program may request reconsideration. We believe this is excepted because of it being an administrative action per 5 CFR 1320.4(a)(2).

E. Submission of PT Data by Laboratories

At § 493.901(c)(6), we proposed to add the requirement that PT programs limit the participants' online submission of PT data to one submission or that a method be provided to track changes made to electronically reported results. As discussed in section II.C. of this final rule, based on public comments from PT programs and laboratories that this requirement would be burdensome and expensive, we are not finalizing this proposal.

Table 2 reflects the total burden and associated costs for the provisions included in this final rule.

[11] *https://www.bls.gov/oes/tables.htm.*

[12] *https://www.bls.gov/oes/tables.htm.*

TABLE 2: Summary of All Burden in This Final Rule

Information Collection Requests	Burden Hours Increase/Decrease (+/-)*	Cost (+/-)*
A. Clarification for Reporting of Microbiology Organism Identification	+341	+18,660
B. Optional On-Site Visits to PT Programs	+0	+0
C. PT Program Reapproval	+90	+3,685
D. Withdrawal of Approval of a PT Program	+0	+0
TOTAL	**+431**	**+22,345**

V. Regulatory Impact Analysis

A. Statement of Need

Proficiency testing (PT) has long been recognized as a critical component of a quality management system. It was first required at a national level for some clinical laboratories under CLIA '67. When CLIA '88 was enacted, and its implementing regulations were finalized in 1992, all clinical laboratories that perform nonwaived testing became subject to the CLIA PT requirements. Since that time, there have been many changes in the practice of laboratory medicine and improvements in the analytical accuracy of test methods, such that HHS decided to assess the need to revise the PT regulations to ensure the accuracy and reliability of testing currently being used for clinical decision-making and improved patient outcomes. For example, a number of analytes and tests now used for making clinical decisions were not recognized or commonly used at the time the CLIA PT requirements were published on February 28, 1992 at 42 CFR part 493 (57 FR 7002). Improvements in analytical accuracy required revisions to the criteria for acceptable performance to reflect the current practices and better assess clinical laboratory performance. We based our decision to update the regulations and incorporate the changes being finalized in this rule in part, as discussed above, upon advice from the Clinical Laboratory Improvement Advisory Committee (CLIAC), a Federal advisory committee charged with providing recommendations to HHS on revisions needed to CLIA. The members of CLIAC are knowledgeable about laboratory medicine and quality.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) having an annual effect on the economy of $100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. A regulatory impact analysis (RIA) is required for economically significant regulatory actions that are likely to impose costs or benefits of $100 million or more in any given year. We prepared the RIA and found that this PT final rule does not meet the threshold of section 3(f)(1) of the Executive Order for a significant regulatory action. In addition, our upper limit of estimated impact is under the threshold of $165 million for the year of 2022 under the Unfunded Mandates Reform Act (UMRA). Nevertheless, we have voluntarily performed an RIA, as would be required for an economically significant regulation.

This rule revises the CLIA PT requirements and affects approximately 35,967 clinical laboratories subject to participation in PT, resulting in some cost implications (Table 5). In addition, as a result of this final rule, the eight existing CLIA-approved PT programs will incur some costs as they modify their programs to meet the specified requirements. It will also have an effect on CLIA-exempt States regarding State PT requirements.

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we assume that the great majority of clinical laboratories and PT programs are small entities, either by being nonprofit organizations or by meeting the Small Business Administration definition of a small business (having revenues of less than $8.0 million to $41.5 million in any 1 year). For purposes of the RFA, we believe that approximately 82 percent of clinical laboratories qualify as small entities based on their nonprofit status as reported in the American Hospital Association Fast Fact Sheet, updated January 2021 [13] and 100 percent of PT programs are nonprofit organizations. Individuals and States are not included in the definition of a small entity. As its measure of significant economic impact on a substantial number of small entities, HHS uses a change in revenue of more than 3 to 5 percent. We do not believe that this threshold will be reached by the requirements in this final rule. Therefore, the Secretary has certified that this final rule will not have a significant economic impact on a substantial number of small entities. We have included several provisions in this rule to address the requirements of the RFA and provide regulatory relief or minimize burden for small entities such

[13] *https://www.aha.org/statistics/fast-facts-us-hospitals.*

as laboratories and PT programs. The first is incorporating a phase-in period for implementation of this rule. This phase-in will provide time for laboratories to identify PT programs offering the newly required PT and subscribe to PT for any of the analytes or tests that they offer. It will also provide the time needed by PT programs to add new analytes and tests to their programs, which requires the identification of new sources of PT materials and revision of administrative processes to accommodate the revised requirements. Other changes that will decrease burden, which are incorporated in this rule as a result of public comments from laboratories and PT programs, were several proposed revisions to microbiology PT. These proposed changes included adding PT requirements for susceptibility or resistance testing in the subspecialties of mycology and virology and adding a PT requirement for resistance testing in bacteriology. Because public comments indicated these requirements would be difficult to comply with due to limited materials and variability in the testing, we are not finalizing those changes in this rule, which mitigates burden that would have been placed on both laboratories and PT programs. In addition, because of similar public comments that questioned the value of currently required PT for susceptibility testing in mycobacteriology, we are removing this requirement in this final rule. These changes will provide regulatory flexibility and reduce burden to small entities.

In addition, section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We do not expect this final rule will have a significant impact on small rural hospitals and we are unable to estimate the number of laboratories that support small rural hospitals. Such hospitals often provide limited laboratory services and may refer testing for the newly required analytes to larger hospitals. For the small rural hospitals with laboratories that perform testing for the new analytes, we expect they are already performing PT for other analytes and minimal effort will be required since they should already have PT policies and procedures in place. Therefore, the Secretary has certified that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the UMRA also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any one year of $100 million in 1995 dollars, updated annually for inflation. In 2022, that threshold is approximately $158 million. This rule will not impose an unfunded mandate on States, tribal governments, or the private sector of more than $165 million annually and thus does not meet the UMRA threshold.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. The changes in this rule will not have a substantial direct effect on State and local governments, preempt State law, or otherwise have a Federalism implication and there is no change in the distribution of power and responsibilities among the various levels of government. This rule will not impose substantial direct compliance costs on State and local governments that are not required by statute. A significant number of laboratories affected by this rule are not operated by State or local governments. Therefore, promulgation of this rule will not cause substantial additional costs to State and local governments.

C. Anticipated Effects

This final rule will impact approximately 35,967 clinical laboratories (total of Certificate of Compliance and Certificate of Accreditation laboratories, as of January 2020) required to participate in PT under the CLIA regulations implemented by the February 28, 1992 final rule, eight current CLIA-approved PT programs, and to a lesser extent, in vitro diagnostics (IVD) manufacturers, healthcare providers, laboratory surveyors, and patients. Although complete data are not available to calculate all estimated costs and benefits that will result from the changes made in this rule, we are providing an analysis of the potential impact based on available information and certain assumptions. Implementation of these requirements will result in changes that will have both quantifiable and non-quantifiable impacts on laboratories, PT programs, and others mentioned above. In estimating the quantifiable impacts, we separated the laboratory specialties into two broad categories that include: (1) PT changes to the microbiology specialty; and (2) PT changes to non-microbiology specialties. This was done because the PT requirements differ for microbiology than for other laboratory specialties and laboratories that are certified to perform microbiology testing may be impacted differently than those that perform non-microbiology clinical testing. In each microbiology subspecialty, PT participation is required based on the types of services offered by a laboratory, and an overall score is given per that subspecialty, whereas in the other specialties and subspecialties, PT participation is required and scores are given based on specific required analytes listed in the regulations.

1. Quantifiable Costs for Laboratories

CDC receives catalogs from all CLIA-approved PT programs annually. We estimated material costs for purchasing PT materials based on the range of 2020 catalog prices from the eight CLIA-approved PT programs. In estimating the labor costs for performing PT for all laboratory specialties that will be affected by this regulatory change, we assumed the average national clinical laboratory fee schedule [14] as an estimate of the cost the laboratory incurs when testing each sample (or challenge). This amount represents the average reimbursement to laboratories performing patient testing for that analyte or test. We also assume the cost for testing patient samples is the same as the cost for testing PT samples.

We calculated that, on average, the cost impact would be between $695 and $2,511 per laboratory, with laboratories testing fewer analytes bearing a smaller burden.

a. Costs of PT Changes to the Microbiology Specialty

Changes to the microbiology specialty include changes in each of the subspecialties (bacteriology, mycobacteriology, mycology, parasitology, and virology) that will replace the types of services offered and the examples of organisms to be included over time with a list of categories of tests and groups of microorganisms for which PT is required. In addition, this rule finalizes other changes in the CLIA regulations, Subpart I for each individual subspecialty. These changes will have a cost impact on laboratories. As stated in

[14] CMS Clinical Laboratory Fee Schedule Files: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Clinical-Laboratory-Fee-Schedule-Files.*

CLIA at § 493.801(a)(2)(ii) and § 493.1236(c)(1), for tests or procedures performed by the laboratory that are not listed in Subpart I, Proficiency Testing Programs for Nonwaived Testing, a laboratory must verify the accuracy of that test or procedure at least twice annually. Although we do not have a way to estimate how many microbiology laboratories voluntarily enroll in PT to meet this requirement, we assume the added burden of performing the newly required PT would be minimal for those already performing voluntary PT. For the 5,341 affected microbiology laboratories, the estimated cost of the quantifiable changes to required PT for each microbiology subspecialty follows.

To estimate the costs that will be incurred by laboratories to purchase PT materials to meet the revised requirements for the microbiology specialty, we compiled a range of PT material cost estimates per each challenge using 2020 catalog pricing for each PT program. For this analysis we refer to the PT catalog offerings as ''modules.'' In microbiology, PT programs offer different types of modules. Individual modules such as stain(s), antigen detection, or toxin detection are intended for reporting a result for a single type of test. Many microbiology modules include challenges that address different types of testing. These modules, such as urine culture, may include individual PT challenges for Gram stain, bacterial identification, and antimicrobial susceptibility testing. In many cases, estimating the challenge cost was difficult because PT programs' pricing varies and in some cases the PT challenge cost per microbiology test depends upon whether the test is offered as an individual module or as part of a collection of multiple types of PT challenges in a module. In addition, to accurately estimate the challenge cost, we had to account for differences in the frequency at which the PT programs currently offer their modules and challenges. For example, one PT program may offer an antigen detection module at a frequency of two events per year, and three samples per event (six total samples per year), while another offers a similar module at three events per year, and five samples per event (15 total samples per year). Based upon the module type and frequency, we estimated the total low and high challenge cost for PT material using the range of 2020 catalog prices from the eight CLIA-approved PT programs for microbiology. Details are explained under each subsection. We acknowledge that these estimated ranges may be higher than the actual costs of requiring additional PT since laboratories may already voluntarily purchase PT to meet the biannual CLIA requirement for verifying the accuracy of testing. However, we do not have a way of estimating the number of laboratories or the cost of this voluntary participation.

In estimating the number of microbiology laboratories that will be impacted by each of the regulatory changes, we determined the numbers of Certificate of Compliance (CoC) and Certificate of Accreditation (CoA) laboratories for each microbiology subspecialty using the CMS Quality Improvement and Evaluation System (QIES) database. To categorize the laboratories as described below, the QIES database was used to determine the accreditation organization for each CoA laboratory.

We designated two laboratory categories when estimating the impact of the final PT rule in microbiology:

- Laboratories participating in a PT program for already required microbiology PT (Category M1).
- Laboratories not participating in a PT program for newly required microbiology PT (Category M2).

Category M1: Laboratories Already Participating in Required Microbiology PT

For changes or additions to required microbiology PT, we used data from the PT program event summaries provided to CDC by the PT programs to estimate the total number of laboratories performing the already required PT. We then used that number to estimate how many laboratories would be affected by proposed changes or additions to the required PT.

Category M2: Laboratories Not Participating in a PT Program for Newly Required Microbiology PT

We used Certificate of Accreditation data to estimate the number of laboratories that are subject to the microbiology PT requirements in this rule and are not already participating in a PT program. Of the seven CLIA-approved accreditation organizations, data were provided by COLA showing how many of the 6,999 COLA-accredited laboratories offer testing for the microbiology tests that are being added to the list for required PT. We used these data to estimate the percentage of COLA-accredited laboratories that provide testing for these microbiology tests. We assumed that COLA-accredited laboratories are similar to Certificate of Compliance laboratories and laboratories accredited by deemed status organizations other than the College of American Pathologists (CAP) (who did not provide data) with regard to test volumes and the microbiology testing they provide. Therefore, we assumed that the percentage of COLA-accredited laboratories that perform a specific microbiology test could be used to approximate the total number of laboratories that perform the test. For the newly required microbiology PT, the number of CAP-accredited laboratories was considered negligible because they are already required to purchase PT for all testing performed and were not included in the total. We analyzed each proposed change for the microbiology specialty for each category and added our estimates to obtain the total projected impact on all affected laboratories.

(1) Costs of the PT Changes in the Bacteriology Subspecialty

In the bacteriology subspecialty, the changes being finalized in this rule that may have a cost impact include the determination of bacterial morphology as part of the Gram stain module, the addition of bacterial toxin detection as required PT, and the addition of a second antimicrobial susceptibility testing challenge per year. Gram stain reaction is currently required in the PT regulations and all PT programs that offer a Gram stain PT module also offer the determination of bacterial morphology as part of the same module. We know the numbers of total laboratories enrolled in the PT program modules that require Gram stain reporting from the PT program event summaries. To determine the number of laboratories that will be impacted by this change, we calculated the number currently enrolled in Gram stain PT. Since this change will require that these laboratories report bacterial morphology in addition to Gram stain reaction on each challenge, we estimate the cost impact would be minimal. We estimated the range of costs by using the number of category M1 laboratories that perform Gram stain; the estimate of the cost the laboratory incurs when testing each challenge, using the average national CMS clinical laboratory fee schedule; the low price and high price per challenge for PT (based on PT program catalog variations); and the number of challenges required per year using one challenge for the low estimate (Table 3) and 15 challenges for the high estimate (Table 4).

To evaluate the impact of requiring PT for bacterial toxin detection, we determined the total number of category M2 laboratories for bacteriology. Laboratories performing voluntary PT

for bacterial toxin detection are already meeting the new PT requirements. Since CAP-accredited laboratories are already required to perform PT if they perform bacterial toxin detection, we assumed they are already meeting the new PT requirements and did not include them in our estimate. The range of estimated costs was determined by using the number of category M2 impacted laboratories that perform bacterial toxin detection; the estimate of the cost the laboratory incurs when testing each challenge, using the average national CMS clinical laboratory fee schedule; the low price and high price per challenge for PT (based on PT program catalog variations); and the number of challenges required per year using one challenge for the low estimate (Table 1) and 15 challenges for the high estimate (Table 3).

Currently, one sample or challenge per testing event is required for antimicrobial susceptibility testing in bacteriology. To evaluate the impact of increasing the required antimicrobial susceptibility testing from one challenge per year to two challenges per year, we calculated the total number of category M1 laboratories already participating in PT for antimicrobial susceptibility testing. The range of estimated costs was determined by using the number of category M1 laboratories that currently perform antimicrobial susceptibility testing; the estimate of the cost the laboratory incurs when testing each challenge, using the average national CMS clinical laboratory fee schedule; the low price and high price per challenge for PT (based on PT program catalog variations); and the number of challenges required per year using one challenge for the low estimate (Table 3). Considering all of the potential cost impacts, the range of estimated impact for the proposed bacteriology subspecialty changes for the first year is $169,128 to $1,058,207.

(2) Costs of the PT Changes in the Mycobacteriology Subspecialty

Changes to add a second antimycobacterial susceptibility or resistance testing challenge per event were proposed for the mycobacteriology subspecialty. However, as discussed in section III.E. of this final rule, due to public comments, those changes are not being finalized. In addition, due to the public comments received, the requirement for susceptibility testing in mycobacteriology is being removed altogether in this rule. Although there may be a cost savings for the small number of laboratories that perform antimycobacterial susceptibility testing, we are assuming that the majority of these laboratories will continue to subscribe to PT for this test to meet the requirement at §§ 493.801(a)(2)(ii) and 493.1236(c)(1) to verify the accuracy of testing twice per year. As such, we are not anticipating a significant cost savings by removing this requirement and are not able to estimate the impact.

(3) Costs of the PT Changes in the Mycology Subspecialty

In the mycology subspecialty, the changes being finalized in this rule that may have a cost impact include the addition of required PT for direct fungal antigen detection and detection of the presence or absence of fungi and aerobic actinomycetes without identification. To evaluate the impact of the required PT for direct fungal antigen detection, we determined the total number of category M2 laboratories for mycology. Laboratories performing voluntary PT for direct fungal antigen detection are already meeting the new PT requirements. Since CAP-accredited laboratories are already required to perform PT if they perform direct fungal antigen detection, we assumed they are already meeting the new PT requirements and did not include them in our estimate. The range of estimated costs was determined by using the number of category M2 impacted laboratories that perform direct fungal antigen detection; the estimate of the cost the laboratory incurs when testing each challenge, using the average national CMS clinical laboratory fee schedule; the low price and high price per challenge for PT (based on PT program catalog variations); and the number of challenges required per year using one challenge for the low estimate (Table 3) and 15 challenges for the high estimate (Table 4).

The newly required detection of the presence or absence of fungi and aerobic actinomycetes without identification impacts laboratories that are currently performing dermatophyte identification using dermatophyte test medium to determine the presence or absence of dermatophytes in a patient specimen. We calculated the impact using the same methodology as was performed to determine the impact of the proposal to include direct fungal antigen detection (Tables 1 and 2). Considering the cost impact of this rule in the mycology subspecialty, the range estimated for the first year is $3,288 to $61,940.

(4) Costs of the PT Changes in the Parasitology Subspecialty

In the parasitology subspecialty, the change being finalized in this rule that may have a cost impact is the addition of required PT for direct parasite antigen detection. To evaluate the potential impact of this addition, we determined the total number of category M2 laboratories for parasitology. Laboratories performing voluntary PT for direct parasite antigen detection are already meeting the new PT requirement. Since CAP-accredited laboratories are already required to perform PT if they perform direct parasite antigen detection, we assumed they are already meeting the new PT requirement and did not include them in our estimate. The range of estimated costs was determined by using the number of category M2 impacted laboratories that perform direct parasite antigen detection; the estimate of the cost the laboratory incurs when testing each challenge, using the average national CMS clinical laboratory fee schedule; the low price and high price per challenge for PT (based on PT program catalog variations); and the number of challenges required per year using one challenge for the low estimate (Table 3) and 15 challenges for the high estimate (Table 4). Considering the potential cost impact of this rule in the parasitology subspecialty, the range estimated for the first year is $8,098 to $458,136.

(5) Costs of the PT Changes in the Virology Subspecialty

In the virology subspecialty, the proposed change that would have had a cost impact was the addition of two antiviral susceptibility or resistance testing challenges per year. However, as a result of the public comments received, that change is not being finalized in this rule. Therefore, we do not estimate a cost impact resulting from this rule in the subspecialty of virology.

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TABLE 3: Low Estimate for Microbiology PT Regulatory Changes

Regulatory Change	Total Number of Affected M1 Laboratories	Total Number of Affected M2 Laboratories	Labor[1]	Supply/Material Cost[2]	TOTAL Low Estimate for One Challenge	Total Low Estimate for Microbiology Regulatory Changes
Gram Stain including Morphology	31	0	$4.27	$4.53	$272.80	$180,513.47
Bacterial Toxin Detection	0	546	$16.00	$12.80	$15,724.80	
Antimicrobial susceptibility testing	4,299	0	$23.62	$12.00	$153,130.38	
Direct fungal antigen detection	0	37	$12.61	$16.80	$1,088.17	
Detection of the presence of absence of fungi and aerobic actinomycetes without identification	0	92	$7.71	$16.20	$2,199.72	
Direct parasite antigen detection	0	336	$12.90	$11.20	$8,097.60	

[1]Average national CMS clinical laboratory fee schedule (https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Clinical-Laboratory-Fee-Schedule-Files).
[2]Low 2020 PT catalog price per challenge.

TABLE 4: High Estimate for Microbiology PT Regulatory Changes

Regulatory Change	Total Number of Affected M1 Laboratories	Total Number of Affected M2 Laboratories	Labor[1]	Supply/Material Cost[2]	TOTAL High Estimate /for one challenge	TOTAL High Estimate/for 15 challenges	Total High Estimate for Microbiology Regulatory Changes
Gram Stain including Morphology	31	0	$4.27	$15.40	$609.77	$9,146.55	$1,340,032.50
Bacterial Toxin Detection	0	546	$16.00	$83.00	$54,054.00	$810,810.00	
Antimicrobial susceptibility testing	4,299	0	$23.62	$31.80	$238,250.58	N/A	
Direct fungal antigen detection	0	37	$12.61	$33.40	$1,702.37	$25,535.55	
Detection of the presence or absence of fungi and aerobic actinomycetes without identification	0	92	$7.71	$18.67	$2,426.96	$36,404.40	
Direct parasite antigen detection	0	336	$12.90	$78.00	$30,542.40	$458,136.00	

[1] Average national CMS clinical laboratory fee schedule (https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Clinical-Laboratory-Fee-Schedule-Files).
[2]High 2020 PT catalog price per challenge.

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b. Costs of PT Changes to the Non-Microbiology Specialties/Subspecialties

The changes being finalized in this rule in specialties and subspecialties other than microbiology include adding 30 new analytes at the frequency of three events per year and five challenges per event. According to CLIA, laboratories with Certificates of Compliance and Certificates of Accreditation are required to perform PT. There are 35,967 clinical laboratories that will be affected (18,938 Certificate of Compliance and 17,029 Certificate of Accreditation laboratories). The changes to required PT will be a new burden for some laboratories, but many laboratories are already paying for PT of these analytes. As previously mentioned, in CLIA §§ 493.801(a)(2)(ii) and 493.1236(c)(1), for tests or procedures performed by the laboratory that are not listed in the CLIA regulations Subpart I, the laboratory must verify the accuracy of that test or procedure at least twice annually. Since laboratories may voluntarily enroll in PT as one way to meet this requirement, we assume the added burden would be minimal. We have evidence from laboratories that responded to our national PT survey that of those who were not already required by the CAP to perform PT on more than the CLIA-required analytes, 39 percent purchased PT for 1 to 5 analytes, 17 percent for 6 to 10 analytes, 10 percent for 11 to 20 analytes, and 10 percent for more than 20 analytes. We estimated the costs for newly required analytes by grouping all affected laboratories into four categories: (1) CAP enrolled in CAP PT program, (2) CAP enrolled in 7 non-CAP PT Program, (3) Non-CAP not enrolled in 7 non-CAP PT program, and (4) Non-CAP enrolled in 7 non-CAP PT program), calculating the number of laboratories in each category and calculating the costs using the analyte price, test reimbursement rate and labor cost to update PT policies and procedures. We also tightened ALs and added concentration limits for several currently required analytes, which may have an impact on laboratories, but the cost impact is not included in our estimate. In addition, with this rule, we are finalizing the removal of five required analytes (ethosuximide, LDH isoenzymes, primidone, procainamide/NAPA, and quinidine) that are infrequently performed. As such, we do not anticipate this being a substantial cost savings since laboratories may continue to use PT voluntarily as a way of meeting the biannual accuracy verification requirement.

Three issues had to be considered to estimate the costs for PT materials for new analytes: PT programs may offer analytes as an individual analyte or as part of a module that combines multiple analytes; some of the new analytes may already be offered but at a frequency other than the CLIA-required frequency ($3 \times 5 = 15$ samples per year); and the extent to which laboratories already use PT varies that is, laboratories accredited by the CAP are required to enroll in PT for each test they perform. For all these reasons, laboratories enrolled in different PT programs will be impacted differently. Based on this observation and our inability to make estimates at the level of individual laboratories, we accounted for each of these variations when calculating the costs incurred.

To account for the different prices each PT program charges for different analytes, as an individual analyte or as part of a module, we used a range of estimates based upon the PT programs' unit costs for PT currently offered. We used two approaches to estimate the cost of individual PT analytes. If the analyte was offered individually by the PT program, we used that price. However, if the analyte was not offered individually, we divided the panel price by the total number of analytes in the panel to determine the cost per analyte, which is used as individual analyte price. For the lower cost estimate, we selected the lowest individual analyte price among all PT providers. For the higher cost estimate, we used the highest individual analyte price. In some cases, PT programs offer PT for the new analytes at different frequencies, that is, different numbers of events per year and different numbers of challenges per event. Therefore, to accurately estimate future costs, we had to calculate the increased frequency for each analyte in order to achieve three events/year with five challenges per event.

Implementation of this final rule will have different impacts on different laboratories mainly because laboratories either have a Certificate of Compliance or a Certificate of Accreditation and may be accredited by different accreditation organizations and purchase PT from different PT programs. Our analysis starts with CAP-accredited laboratories as CAP is not only a large accreditation organization but also the largest PT program. In estimating the number of affected laboratories as a result of this final rule, we acknowledged that any CAP-accredited laboratory that offers patient testing for one of the CAP PT program analytes must enroll in the relevant program for that analyte. However, CAP-accredited laboratories are permitted to enroll in PT from other CAP-approved PT programs. Laboratories not accredited by the CAP may purchase PT materials from any CLIA-approved PT program, including the CAP PT program. Therefore, we have designated four categories to estimate the cost impact of this rule.

Category 1: Laboratories Accredited by the CAP That Purchase Material From the CAP PT Program

The CAP provided us with the number of CAP-accredited laboratories that are enrolled in their PT program for each new analyte.

The cost increase was calculated on a per analyte basis by multiplying the cost per sample (PT material + CMS reimbursement amount) by the increase in frequency of samples and the number of laboratories that purchase PT from the CAP PT program. We estimate the costs for laboratories accredited by CAP that purchase material from the CAP PT program to be $4,498,535.

Category 2: CAP-Accredited Laboratories That Purchase PT Materials From Other PT Programs

For the analytes we are adding in this rule, CAP-accredited laboratories are required to enroll in a CLIA-approved PT program. Ordinarily CAP-accredited laboratories enroll in the CAP PT program but are permitted to enroll in PT from other CAP-approved PT programs. Using the data the CAP provided, we calculated the total number of CAP-accredited laboratories enrolled in one of the other PT programs provided through PT Program A, PT Program D, PT Program E, or PT Program G.

The cost increase in this category was calculated on a per analyte basis. We were able to obtain the enrollment distribution of the CAP-accredited laboratories in each of the non-CAP PT programs. The cost increase was calculated on a per analyte basis by multiplying the cost per sample (PT material + CMS reimbursement amount) by the increase in frequency of samples and the number of laboratories that purchase PT from the non-CAP PT program. We estimate the costs for CAP-accredited laboratories that purchase PT materials from other PT programs will range from $0 to $1,304,343.

Category 3: Laboratories Not Accredited by CAP That Are Not Already Enrolled in Other PT Programs

To derive the minimum and maximum number of laboratories not already enrolled in a PT program that may provide testing for the newly required analytes, we began by

estimating that there are 22,119 laboratories that perform nonwaived testing and are not accredited by the CAP in the US. To facilitate the calculations, we presumed that laboratories not accredited by CAP will not purchase CAP PT. From the QIES database, we derived the number of laboratories not accredited by CAP that provide testing in each specialty and reasoned that this was the maximum number of laboratories not accredited by the CAP that might provide testing for each analyte.

COLA provided us with the percentages of the approximately 6,999 COLA-accredited laboratories that perform testing for each new analyte. We determined that COLA-accredited laboratories are similar to CoC laboratories in terms of their annual test volumes. Therefore, we assumed that the percentage of COLA-accredited laboratories that test each new analyte could be used to estimate the minimum number of CoC and CoA (other than CAP- or COLA-accredited) laboratories that test each analyte.

We used the percentage of CAP-accredited laboratories that participate in PT for each new analyte to estimate the maximum number of CoC and CoA (other than CAP and COLA) laboratories that test each analyte. This percentage was much higher for many of the analytes when compared to the laboratories accredited by organizations other than the CAP. Since CAP-accredited laboratories are often either hospital-based or commercial laboratories that already participate in PT for the additional analytes, approximations for high estimates may substantially overestimate the number of laboratories impacted.

Using the above information, we calculated low and high estimates for the total number of CoC and non-CAP-accredited CoA laboratories that may provide testing for each new analyte.

For each new analyte, we calculated the number of CAP-accredited laboratories that buy from non-CAP PT programs by subtracting the CAP-accredited laboratories enrolled in CAP PT from the total number of CAP-accredited laboratories.

We derived a low estimate of the total number of laboratories not accredited by CAP and not enrolled in one of the non-CAP PT programs for each analyte. Negative estimates were taken as ''0.'' This represents our low estimate of the number of laboratories that will need to purchase PT for each analyte.

To obtain the high estimate for the number of laboratories not accredited by CAP and not enrolled in one of the non-CAP PT programs, we took the high estimate of CoC laboratories and CoA laboratories not accredited by the CAP and subtracted the number of this subset of CoA laboratories already known to be enrolled in PT. For the high estimate of the number of laboratories not accredited by CAP and not enrolled in one of the non-CAP PT programs, we also used an additional criterion of the number of laboratories in the respective specialty from QIES to cap the estimate at the number of laboratories in the specialty. If this number was less than the high estimate of CoC laboratories and CoA laboratories accredited by a program other than CAP, then the high estimate was calculated by subtracting the number of laboratories not accredited by CAP and not enrolled in one of the non-CAP PT programs from the total number of laboratories in the specialty.

The cost increase in this category was calculated on a per analyte basis. The minimum cost per sample that was the lowest across all seven non-CAP PT programs and the maximum cost per sample that was the highest across all seven non-CAP PT programs were used for these calculations. The minimum cost increase was calculated by multiplying the minimum cost per sample, including the CMS reimbursement amount, by the number of laboratories that are not purchasing PT from any PT program. The same calculation was made using the maximum cost per sample for the maximum cost increase. We estimate the costs for laboratories not accredited by CAP and not already enrolled in other PT programs will range from $7,047,880 to $58,710,510.

Category 4: Laboratories Not Accredited by the CAP and Enrolled in PT Programs Other Than the CAP PT Program

We obtained the number of laboratories enrolled in PT programs other than the CAP PT program from the PT event summaries from each PT program. The cost increase in this category was calculated on a per analyte basis. The estimated cost increases were calculated for each of the non-CAP PT programs for which information was available. The minimum increase was calculated for each of the PT programs by multiplying the cost per sample, including the CMS reimbursement amount, by the increase in frequency of samples and the number of laboratories that purchase PT from that individual program. To determine the maximum increase, the same calculation was made using the highest cost per analyte, including the CMS reimbursement amount. We estimate the costs for laboratories not accredited by CAP and already enrolled in non-CAP PT programs will be $1,051,614.

c. Costs for Laboratories, Deemed Accreditation Organizations, Exempt States, and PT Programs To Update Policies and Procedures

We expect that the 35,967 CoC and CoA laboratories will incur costs for the time needed to review the revised PT regulations and update their policies, procedures, and information technology (IT) systems, as needed, to be in compliance with the updated regulations. We assume a one-time burden of 4 to 8 hours per laboratory will be needed for this. A general management level employee (13–1111) would perform this task at an hourly wage of $46.91 per hour as published in 2020 by the Bureau of Labor Statistics (*https://www.bls.gov/oes/current/oes_nat.htm*). The wage rate would be $93.82 to include overhead and fringe benefits. Therefore, we estimate the one-time costs for CoC and CoA laboratories will range from $13,497,696 to $26,995,392 ($93.82 × 35,967 × 4 or 8 hours). Similarly, seven approved accreditation organizations and two exempt States will need to review the regulations and may need to revise their survey policies and procedures to be consistent with the updated requirements. We estimate a one-time burden of 10 to 15 hours to review the revised regulations and to develop policies and procedures needed to reflect the new PT requirements. We assume the person performing this review will be a business management level employee (11–1021) paid $60.45 per hour as published in 2020 by the Bureau of Labor Statistics (*https://www.bls.gov/oes/current/oes_nat.htm*). The wage rate would be $120.90 to include overhead and fringe benefits. Therefore, we estimate the one-time costs for accreditation organizations and exempt States to update their policies and procedures will range from $10,881 to $16,322. For PT programs, we estimate a one-time burden of 30 to 35 hours for them to review the updated regulations, revise their policies and procedures, and add new analytes or microbiology tests that they choose to offer. We assume the person performing this job will be a business management level employee paid $60.45 per hour as published in 2020 by the Bureau of Labor Statistics (*https://www.bls.gov/oes/current/oes_nat.htm*). The wage rate would be $120.90 to include overhead and fringe benefits. Therefore, we estimate the one-time costs for PT programs will range from $36,270 to $42,315.

d. Results

We estimate that the overall impact of adding requirements for the new analytes in the specialties and subspecialties other than microbiology will range from approximately $13 to $66 million for the first year (Table 5). Because of the larger number of non-CAP accredited laboratories, and the fact that they tend not to enroll in non-required PT as frequently as CAP-accredited laboratories do, we estimate that non-CAP accredited laboratories that are not enrolled in any PT program will have an impact between $7 and $59 million for the first year. We also estimate that laboratories not accredited by CAP that are enrolled in PT programs other than CAP will have a relatively minor impact, $1 million for the first year (Table 5).

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TABLE 5: Low and High Estimates for Non-microbiology PT Regulations Changes

Category	Low Estimate	High Estimate
1. Laboratories accredited by CAP that purchase material from the CAP PT program	$4,498,535.16	$4,498,535.16
2. Laboratories accredited by CAP that purchase PT materials from other PT programs	$0.00	$1,304,342.82
3. Laboratories not accredited by CAP that are not already enrolled in other PT programs	$7,047,879.53	$58,710,509.52
4. Laboratories not accredited by CAP that are enrolled in other PT programs	$1,051,614.08	$1,051,614.08
Total increased cost	$12,598,028.77	$65,565,001.58

Table 6 shows the total estimated range of annual cost for the changes (including both microbiology and non-microbiology) in undiscounted 2020 dollars and discounted at 3 percent and 7 percent to translate expected costs in any given future years into present value terms. The base year is 2020 for the calculations displayed in Table 6 and we assume costs in future years to be the same as costs in the base year.

TABLE 6: Total Estimated Annual Costs of PT Regulations Changes (All specialties in both microbiology and non-microbiology)

	Undiscounted (2020 $)			Discounted at 3 percent			Discounted at 7 percent		
	Primary	Low[#]	High[&]	Primary	Low	High	Primary	Low	High
2020	$60,141,226	$26,323,389	$93,959,062	$56,688,874	$24,812,319	$88,565,429	$52,529,677	$22,991,868	$82,067,485
2021	$60,141,226	$26,323,389	$93,959,062	$55,037,742	$24,089,630	$85,985,853	$49,093,156	$21,487,727	$76,698,584
2022	$60,141,226	$26,323,389	$93,959,062	$53,434,701	$23,387,991	$83,481,411	$45,881,454	$20,081,988	$71,680,920
2023	$60,141,226	$26,323,389	$93,959,062	$51,878,350	$22,706,787	$81,049,914	$42,879,863	$18,768,213	$66,991,514
2024	$60,141,226	$26,323,389	$93,959,062	$50,367,330	$22,045,424	$78,689,237	$40,074,639	$17,540,386	$62,608,892

[#] Total low cost is the sum of Table 3 (microbiology), Table 4 (non-microbiology).

[&] Total high cost is the sum of Table 3 (microbiology), Table 4 (non-microbiology).

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d. Non-Quantifiable Costs

A number of non-quantifiable cost impacts will also result for PT programs and laboratories when this rule becomes effective.

As with any required PT, implementation of this final regulation does not require approved PT programs to offer additional analytes. Several programs already offer the analytes or tests that will be required, and, in these cases, we expect there to be a minimal cost impact on the PT programs. We expect there will initially be some increased expenditures for PT programs to implement the changes, even if they are only scaling up currently offered PT. We have included an estimate of those costs in this RIA. At the same time, PT programs will also increase revenue received if they increase the PT analytes or tests they offer. We have no way to estimate how many programs may choose to offer additional PT analytes or tests, but we assume that most will implement the changes included in the final rule. For some programs, this will mean offering an analyte or test for the first time, while for others it will mean increasing the yearly number of events and/or challenges per event. The costs will be relatively less for the programs that are already offering the PT analytes or tests, including those currently offering challenges at less than the PT frequency required under CLIA. There are also differences in what the PT programs charge laboratories for PT. In part, these differences depend upon the total number of samples distributed per year and how the PT is packaged; some PT is sold as modules that group several related analytes together. Because CLIA-approved PT programs are required to maintain non-profit status, any increased revenue that results from an expanded PT menu will not be turned into profit. We have attempted to account for the quantifiable impacts in our estimates for laboratories.

When this rule becomes effective, some PT programs may cease offering the analytes that are no longer required, others may continue to offer them at a frequency less than that required under CLIA, and still others may continue to offer them at the PT frequency required under CLIA. For these reasons we are unable to estimate the cost impact to PT programs for this change.

Although we cannot precisely predict how the changes may qualitatively affect clinical laboratories, we do not expect there to be major changes in how they function. We have quantified the costs we expect laboratories to incur but there may be costs associated with other administrative functions related to PT ordering, result reporting, and record keeping that we are not able to estimate. For those laboratories that currently purchase PT for the five analytes for which PT is no longer required, we cannot estimate the lowered expenditure for laboratories that stop buying PT materials and must begin doing something else to verify accuracy. Based on our focus groups and surveys, we know there are a variety of things laboratories may do to externally verify accuracy, ranging from splitting samples with other laboratories to purchasing PT materials voluntarily. Also, we do not know the extent to which split samples are tested, or how many patient samples might be tested in this way; there is no stated minimum number of specimens that must be tested semi-annually to verify accuracy. Therefore, we have not attempted to estimate the costs for alternative approaches that may be adopted to verify accuracy for the deleted analytes. Regardless of how laboratories might be impacted, we expect that they will not spend more than what they currently spend on PT for the analytes deleted, but we cannot estimate this. By not attempting to estimate the number of laboratories that may stop buying PT material for the deleted analytes, we may be slightly overestimating the net impact.

e. Benefits

While we cannot quantify the benefits that implementation of this final rule revising the PT requirements will bring, we believe that the changes will improve the accuracy and reliability of testing and allow for quicker identification of unacceptable practice in laboratories, especially those laboratories that have not previously participated in PT. Remediation after identification of problems should also occur more quickly and clinical test results of marginal or inferior quality are less likely to be used as analytical systems will improve. All of these things will serve to minimize the potential adverse impact to patients and will benefit physicians and healthcare providers while not impacting access to testing.

PT performance partially reflects daily clinical laboratory performance. Updating ALs will benefit laboratories by helping to ensure the accuracy and reliability of testing and providing a mechanism for laboratories to be held accountable for clinically appropriate patient test results, which directly affects the public's health. Both clinical laboratories and patients can benefit from continued monitoring of PT to help assess the success of intervention efforts to improve the overall quality of clinical laboratory testing.

Another benefit that may result from adding new PT analytes and tests and updating the limits for acceptable PT performance under CLIA includes the generation of additional information on test performance and sources of errors that PT programs can share with laboratories. Such information can also be used as a source of training and can help to maintain the competency of testing personnel (Garcia, et al, 2014).

Last, while we do not anticipate that the changes in this final rule will result in any costs on the IVD industry, we expect the IVD industry to potentially benefit by the changes made in this rule, from having the ability to track PT results for the added analytes to enable better and faster detection of problems with product manufacturing, including reagent problems. We are aware that some IVD manufacturers enroll in PT and are able to track the performance of the peer groups using their instruments in summary reports issued by the PT programs.

Ultimately, we believe that laboratories, healthcare providers, patients, and the IVD industry will benefit from improved analytical performance [5] that is expected to occur when this final rule becomes effective with this new rule.

D. Alternatives Considered

A number of alternatives were considered in finalizing the changes in this rule. We considered the possibility of changing either the required frequency of PT events per year or changing the number of required PT challenges per event. Responses from our national survey did not support changing either parameter nor did CLIAC recommend any changes to the required PT frequency or number of challenges per event. Similarly, public comments received in response to the proposed rule did not suggest changes to required PT frequency or number of challenges per event. We did not perceive a benefit from either reducing or increasing the number of events per year. Reducing the number of events to two per year and keeping all other factors the same would cost less, but it would delay the potential time it takes to identify a poor performing laboratory as ''unsuccessful'' to at least 12 months, instead of the current 8 months. Increasing the number of events might help to identify a laboratory with testing issues slightly earlier, but increasing the number of events would increase costs. In this final rule, we will continue to require five challenges per event, with a successful event score defined under

CLIA '88 as a minimum of four out of five challenges (80 percent) falling within the criteria for acceptable performance.

For the microbiology specialty, we considered the possibility of including required PT analytes in each subspecialty at a frequency of three events per year with five challenges per event. We determined that the increase in required PT would result in an additional cost impact of more than five million dollars to laboratories who would be required to perform susceptibility testing for 15 challenges per year. For the non-microbiology specialties and subspecialties, we could have opted not to add any new PT analytes but testing of the analytes we are now adding in this rule is widespread and is important in clinical decision-making and public health testing. We also considered adding all analytes for which there was at least one existing PT program, but this alternative would have been excessively burdensome as it would mean adding hundreds of new required analytes which may not be necessary to identify problematic laboratory performance. We could have left the ALs as they were established in CLIA '88, but we rejected this approach as outdated given advancements in technology. We considered the option of enforcing the definition of peer group established in CLIA '88, but we decided this would be too expensive and ultimately unworkable because it would require PT programs to perform commutability testing using analyzers from multiple peer groups every time a new batch of PT materials was created.

E. Accounting Statement and Table

We have prepared the following accounting statement showing the classification of expenditures associated with the provisions of this rule.

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TABLE 7: Accounting Statement

Category	Primary Estimate	Minimum Estimate	Maximum Estimate	Source Citation (RIA, preamble, etc.)
BENEFITS				
Monetized benefits	NA	NA	NA	NA
Annualized qualified, but Unmonetized, benefits	More effective detection of laboratories that provide inaccurate laboratory test results. Increased confidence in laboratory test results.	NA	NA	Preamble and Impact Analysis
(Unqualified benefits)	NA	NA	NA	NA
COSTS				
Annualized monetized costs	$60,141,226	$26,323,389	$93,959,062	Impact analysis
Annualized qualified, but Unmonetized, benefits	NA	NA	NA	NA
Qualitative (unquantified) costs	NA	NA	NA	NA
TRANSFERS				
Annualized monetized transfers: "on budget"	NA	NA	NA	NA
From whom to whom?	NA	NA	NA	NA
Annualized monetized transfers: "off-budget"	NA	NA	NA	NA
From whom to whom?	NA	NA	NA	NA
Category	Effects			Source Citation (RIA, preamble, etc.)
Effects on State, local, and/or tribal governments	NA	NA	NA	NA
Effects on small businesses	NA	NA	NA	NA
Effects on wages	NA	NA	NA	NA
Effects on growth	NA	NA	NA	NA

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F. Conclusion

We estimate that the total cost for laboratories to participate in PT for the analytes and tests in this rule will be between $26 and $94 million in 2020 dollars. Although the effect of the changes will increase costs, implementation of these changes in this final rule will increase the confidence of laboratory professionals and the end-users of test results, including physicians and other healthcare providers, patients, and the public, in the reliability and accuracy of test results.

We have determined that this rule will not have a significant economic impact on a substantial number of small entities or a significant impact in the operations of a substantial number of small rural hospitals and for these reasons, we are not preparing analyses for either the RFA or section 1102(b) of the Act. However, we described actions being taken in finalizing this rule to reduce burden and minimize the impact on small entities such as laboratories and PT programs.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

VI. Analysis of and Responses to Public Comments on the Paperwork Reduction and Regulatory Impact Analysis

We have provided an analysis of the potential impact of this final rule, based upon available information and certain assumptions. We have prepared the Paperwork Reduction Act and the Regulatory Impact Analysis representing the costs and benefits of the final rule based on analysis of identified variables and data sources needed for this change. We requested that commenters provide any additional data that would assist us in the analysis of the potential impact of this regulation on CLIA-certified laboratories, but we did not receive any additional data.

Therefore, based on our analysis and assessment of the overall annual costs to the laboratories affected by this final rule, we are finalizing the provisions in this rule. The comments and our responses are set forth below:

Comment: As part of regulatory impact analysis for the proposed rule, we described the benefits of PT and the need to update the regulations. Commenters representing accreditation organizations and laboratory professional organizations were supportive of the proposed changes, especially the expansion of the list of required PT analytes. The commenters noted that PT is a valuable quality indicator and measure of laboratory performance and they emphasized that the accuracy and reliability of laboratory testing is critical to patient safety and the delivery of quality healthcare services. A few commenters stated that PT is burdensome and expensive, one of them adding that the benefits of PT in reducing testing errors has not been documented through studies or other evidence.

Response: We appreciate the comments that expressed support for the changes in the proposed rule and recognized the value of PT as a measure of laboratory quality and a mechanism to detect and prevent errors that can affect patient safety. However, we agree with the commenters who stated that it is difficult to quantify the value of PT and we recognize the financial and other resource costs associated with performing PT. Based on the positive comments received and previously published studies (7–10), we believe that PT is a useful adjunct to identify poor-performing laboratories and to help laboratories ensure the quality of their testing which directly affects patients, and ultimately the public's health.

Comment: We received comments from accreditation organizations, professional organizations, businesses, and individuals concerning our estimate of the impact of the proposed rule. Several commenters stated that we had underestimated the overall impact, including the impact on individual laboratories and accreditation organizations, especially the administrative burden of new PT. While one commenter stated our methodology was correct, others disagreed, and one commenter stated that we failed to consider bigger changes to the way PT is conducted which could reduce costs. A few commenters suggested that we conduct a more comprehensive impact analysis.

Response: We acknowledge that our analysis was limited by the availability of data and our ability to estimate all aspects of the proposed changes. In the proposed rule, we solicited comments and data to facilitate the determination of quantifiable estimates of the impact in the final rule. We did not receive any suggestions of alternative methods or data on which to base our estimates. Therefore, in this final rule we have used similar methodology to that used in the proposed rule with exceptions as follows. We added a range of estimates to cover the one-time costs that would be expected for CoC and CoA laboratories subject to PT to review the updated regulations; modify policies, procedures, and IT systems as needed; and enroll in appropriate PT to be in compliance with the revised requirements. We also modified the impact analysis to include estimation of the one-time costs for the seven deemed accreditation organizations and two exempt States to review the updated regulations and revise their survey policies and procedures to be consistent with the new PT requirements. Lastly, we added similar one-time estimates for PT programs to review the updated regulations, modify policies and procedures, and determine if they will choose to offer the new analytes or microbiology PT. We recognize that there will be ongoing costs for laboratories, deemed accreditation organizations, exempt States, and PT programs based on the revised list of required analytes and changes to microbiology PT. However, we are unable to project these costs since, although we do not know the number, some laboratories are already participating in PT for the new analytes and microbiology tests as a way of meeting the requirement to verify the accuracy of testing twice per year. For these laboratories, the ongoing additional costs may be minimal. Similarly, the accreditation organizations and exempt States may already be reviewing voluntary PT data for some of the newly required analytes and tests. With respect to ongoing costs for PT programs, we are also unable to estimate the costs. As previously described in this rule regarding the criteria used to select new analytes and microbiology PT, we are aware that at least three programs already offer PT for these analytes and tests, and we are unsure how many additional programs will choose to offer them since they are not required by CLIA to do so. For those that already offer the additional PT, we expect the ongoing costs to be minimal.

Comment: Several commenters recommended that the effects of the recent Protecting Access to Medicare Act of 2014 (PAMA) regulations should be considered as part of the regulatory impact analysis in light of PAMA's impact on laboratory testing reimbursement under Medicare.

Response: We recognize the impact of PAMA on Medicare payment for laboratory testing. However, PAMA was implemented in 2018 and those changes were independent of the CLIA PT changes that are now being finalized. We do not have data that would allow us to determine the cumulative effects of the two rules that were implemented at two separate points in time. We did use the CMS CLFS for 2020, which included post-PAMA payment rates, as

one part of our estimate of the costs of performing PT, as no other data sources were suggested by commenters.

Comment: A commenter noted that the RIA had not accounted for the costs of disallowing the use of for-profit entities by PT programs for conducting any part of their business and suggested that the final rule should include this economic assessment.

Response: The proposed rule did not specify that for-profit entities were disallowed for use by PT programs for conducting any part of their business. In this final rule, we are clarifying that the provision being finalized at § 493.901(c)(8), previously proposed at § 493.901(c)(9), requires that technical and scientific responsibilities, such as grading PT, must be carried out by nonprofit organizations, Federal or State agencies, or entities acting as a designated Federal or State agency. This is an inherent function of an approved PT program and should not result in additional costs for the programs. Contractors used to perform tasks such as manufacturing or transportation of samples are not required to be non-profit entities.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on June 21, 2022.

Rochelle P. Walensky, MD, MPH, Director of the Centers for Disease Control and Prevention, approved this document on June 17, 2022.

List of Subjects in 42 CFR Part 493

Administrative practice and procedure, Grant programs-health, Health facilities, Laboratories, Medicaid, Medicare, Penalties, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR part 493 as set forth below:

PART 493—LABORATORY REQUIREMENTS

■ 1. The authority citation for part 493 continues to read as follows:

Authority: 42 U.S.C. 263a, 1302, 1395x(e), the sentence following 1395x(s)(11) through 1395x(s)(16).

■ 2. Amend § 493.2 by—

■ a. Adding the definitions of ''Acceptance limit'' and ''Peer group'' in alphabetical order; and

■ b. Revising the definition of ''Target value''.

The additions and revision read as follows:

§ 493.2 Definitions.

* * * * *

Acceptance limit means the symmetrical tolerance (plus and minus) around the target value.

* * * * *

Peer group means a group of laboratories whose testing process utilizes similar instruments, methodologies, and/or reagent systems and is not to be assigned using the reagent lot number level.

* * * * *

Target value for quantitative tests means:

(1) If the peer group consists of 10 participants or greater:

(i) The mean of all participant responses after removal of outliers (that is, those responses greater than three standard deviations from the original mean, as applicable);

(ii) The mean established by a definitive method or reference methods; or

(iii) If a definitive method or reference methods are not available, the mean of a peer group; or

(2) If the peer group consists of fewer than 10 participants, the mean of all participant responses after removal of outliers (as defined in paragraph (1) of this definition) unless acceptable scientific reasons are available to indicate that such an evaluation is not appropriate.

* * * * *

■ 3. Amend § 493.20 by revising paragraph (c) to read as follows:

§ 493.20 Laboratories performing tests of moderate complexity.

* * * * *

(c) If the laboratory also performs waived tests, compliance with § 493.801(a) and (b)(7) and subparts J, K, and M of this part is not applicable to the waived tests. However, the laboratory must comply with the requirements in §§ 493.15(e), 493.801(b)(1) through (6), 493.1771, 493.1773, and 493.1775

■ 4. Amend § 493.25 by revising paragraph (d) to read as follows:

§ 493.25 Laboratories performing tests of high complexity.

* * * * *

(d) If the laboratory also performs waived tests, compliance with §§ 493.801(a) and 493.801(b)(7) and subparts J, K, and M of this part are not applicable to the waived tests. However, the laboratory must comply with the requirements in §§ 493.15(e), 493.801(b)(1) through (6), 493.1771, 493.1773, and 493.1775.

■ 5. Amend § 493.801 by—

■ a. Redesignating paragraphs (b)(3) through (6) as paragraphs (b)(4) through (7), respectively; and

■ b. Adding new paragraph (b)(3).

The addition reads as follows:

§ 493.801 Condition: Enrollment and testing of samples.

* * * * *

(b) * * *

(3) The laboratory must report PT results for microbiology organism identification to the highest level that it reports results on patient specimens.

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■ 6. Amend § 493.861 by revising paragraph (a) to read as follows:

§ 493.861 Standard; Unexpected antibody detection.

(a) Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance.

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■ 7. Amend § 493.901 by—

■ a. Redesignating paragraphs (a), (b), (c), and (d) as paragraphs (b), (c), (d), and (e), respectively;

■ b. Adding new paragraph (a);

■ c. In newly redesignated paragraph (c)(7) by removing '';'' and adding in its place ''; and'';

■ d. Adding new paragraph (c)(8);

■ e. Revising newly redesignated paragraph (e); and

■ f. Adding new paragraph (f).

The additions and revisions read as follows:

§ 493.901 Approval of proficiency testing programs.

* * * * *

(a) Require a minimum of 10 laboratory participants for each specialty, subspecialty, and analyte or test for which the proficiency testing program is seeking reapproval;

* * * * *

(c) * * *

(8) A contractor performing technical and scientific responsibilities as described in this section and § 493.903 (including, but not limited to, processes for selecting appropriate target values to be included in challenges as part of the annual PT program or grading PT results, determining target values, reporting scores to CMS, and determining organisms included in microbiology PT samples) must be a private nonprofit organization or a Federal or State agency, or an entity acting as a designated agent for the Federal or State agency.

* * * * *

(e) HHS may require on-site visits for all initial proficiency testing program applications for CMS approval and

periodically or when problems are encountered for previously HHS-approved proficiency testing programs either during the reapproval process or as necessary to review and verify the policies and procedures represented in its application and other information, including, but not limited to, review and examination of documents and interviews of staff.

(f) HHS may require a proficiency testing program to reapply for approval using the process for initial applications if significant problems are encountered during the reapproval process.

■ 8. Amend § 493.903 by—

■ a. In paragraph (a)(1) by removing the period and adding '';'';

■ b. In paragraph (a)(2) by removing '';'' and adding in its place ''; and''; and

■ c. By adding new paragraph (a)(3).

The addition reads as follows:

§ 493.903 Administrative responsibilities.

* * * * *

(a) * * *

(3) Not change submitted laboratory data and results for any proficiency testing event;

* * * * *

■ 9. Section 493.905 is revised to read as follows:

§ 493.905 Nonapproved proficiency testing programs.

(a) *Effect on approval status.* If a proficiency testing program is determined by HHS to fail to meet any criteria contained in §§ 493.901 through 493.959 for approval of the proficiency testing program, CMS will notify the program of its withdrawal of approval. Approval of the PT program remains in effect for 60 days from the date of notification. The proficiency testing program must notify all of its participating laboratories of the withdrawal of approval within 30 days from the date of notification. CMS may disapprove any proficiency testing program that provides false or misleading information with respect to any information that is necessary to meet any criteria contained in §§ 493.901 through 493.959 for approval of the proficiency testing program.

(b) *Request for reconsideration.* Any proficiency testing program that is dissatisfied with a determination to disapprove the program may request that CMS reconsider the determination, in accordance with subpart D of part 488.

■ 10. Section 493.911 is revised to read as follows:

§ 493.911 Bacteriology.

(a) *Program content and frequency of challenge.* To be approved for proficiency testing for bacteriology, the annual program must provide a minimum of five samples per testing event. There must be at least three testing events provided to the laboratory at approximately equal intervals per year. The samples may be provided to the laboratory through mailed shipments. The specific organisms included in the samples may vary from year to year.

(1) The annual program must include, as applicable, samples for:

(i) Gram stain including bacterial morphology;

(ii) Direct bacterial antigen detection;

(iii) Bacterial toxin detection; and,

(iv) Detection and identification of bacteria which includes one of the following:

(A) Detection of the presence or absence of bacteria without identification; or

(B) Identification of bacteria; and

(v) Antimicrobial susceptibility testing of select bacteria.

(2) An approved program must furnish HHS and its agents with a description of samples that it plans to include in its annual program no later than 6 months before each calendar year. The program must include bacteria commonly occurring in patient specimens and other important emerging pathogens. The program determines the reportable isolates and correct responses for antimicrobial susceptibility testing for any designated isolate. At least 25 percent of the samples must be mixtures of the principal organism and appropriate normal flora. Mixed cultures are samples that require reporting of one or more principal pathogens. Mixed cultures are not ''negative'' samples such as when two commensal organisms are provided in a PT sample with the intended response of ''negative'' or ''no pathogen present.'' The program must include the following two types of samples to meet the 25 percent mixed culture criterion:

(i) Samples that require laboratories to report only organisms that the testing laboratory considers to be a principal pathogen that is clearly responsible for a described illness (excluding immuno-compromised patients). The program determines the reportable isolates, including antimicrobial susceptibility for any designated isolate; and

(ii) Samples that require laboratories to report all organisms present. Samples must contain multiple organisms frequently found in specimens where multiple isolates are clearly significant or where specimens are derived from immuno-compromised patients. The program determines the reportable isolates.

(3) The content of an approved program must vary over time, as appropriate. The types of bacteria included annually must be representative of the following major groups of medically important aerobic and anaerobic bacteria, if appropriate for the sample sources:

(i) Gram-negative bacilli.

(ii) Gram-positive bacilli.

(iii) Gram-negative cocci.

(iv) Gram-positive cocci.

(4) For antimicrobial susceptibility testing, the program must provide at least two samples per testing event. The program must annually provide samples that include Gram-positive organisms and samples that include Gram-negative organisms that have a predetermined pattern of susceptibility or resistance to the common antimicrobial agents.

(b) *Evaluation of a laboratory's performance.* HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (b)(1) through (9) of this section.

(1) The program determines the reportable bacterial staining and morphological characteristics to be interpreted by Gram stain. The program determines the bacteria to be reported by direct bacterial antigen detection, bacterial toxin detection, detection of the presence or absence of bacteria without identification, identification of bacteria, and antimicrobial susceptibility testing. To determine the accuracy of each of the laboratory's responses, the program must compare each response with the response which reflects agreement of either 80 percent or more of 10 or more referee laboratories or 80 percent or more of all participating laboratories. Both methods must be attempted before the program can choose to not grade a PT sample.

(2) A laboratory must identify the organisms to highest level that the laboratory reports results on patient specimens.

(3) A laboratory's performance will be evaluated on the basis of the average of its scores for paragraph (b)(4) through (8) of this section as determined in paragraph (b)(9) of this section.

(4) The performance criteria for Gram stain including bacterial morphology is staining reaction, that is, Gram positive or Gram negative and morphological description for each sample. The score is the number of correct responses for Gram stain reaction plus the number of correct responses for morphological description divided by 2 then divided by the number of samples to be tested, multiplied by 100.

(5) The performance criterion for direct bacterial antigen detection is the presence or absence of the bacterial antigen. The score is the number of correct responses divided by the number of samples to be tested, multiplied by 100.

(6) The performance criterion for bacterial toxin detection is the presence or absence of the bacterial toxin. The score is the number of correct responses divided by the number of samples to be tested multiplied by 100.

(7) The performance criterion for the detection and identification of bacteria includes one of the following:

(i) The performance criterion for the detection of the presence or absence of bacteria without identification is the correct detection of the presence or absence of bacteria without identification. The score is the number of correct responses divided by the number of samples to be tested multiplied by 100.

(ii) The performance criterion for the identification of bacteria is the total number of correct responses for bacterial identification submitted by the laboratory divided by the number of organisms present plus the number of incorrect organisms reported by the laboratory multiplied by 100 to establish a score for each sample in each testing event. Since laboratories may incorrectly report the presence of organisms in addition to the correctly identified principal organism(s), the scoring system must provide a means of deducting credit for additional erroneous organisms that are reported. For example, if a sample contained one principal organism and the laboratory reported it correctly but reported the presence of an additional organism, which was not considered reportable, the sample grade would be $1/(1+1) \times 100 = 50$ percent.

(8) For antimicrobial susceptibility testing, a laboratory must indicate which drugs are routinely included in its test panel when testing patient samples. A laboratory's performance will be evaluated for only those antimicrobials for which susceptibility testing is routinely performed on patient specimens. A correct response for each antimicrobial will be determined as described in paragraph (b)(1) of this section. Scoring for each sample is based on the number of correct susceptibility responses reported by the laboratory divided by the actual number of correct susceptibility responses determined by the program, multiplied by 100. For example, if a laboratory offers susceptibility testing using three antimicrobial agents, and the laboratory reports correct responses for two of the three antimicrobial agents, the laboratory's grade would be $2/3 \times 100 = 67$ percent.

(9) The score for a testing event in bacteriology is the average of the scores determined under paragraphs (b)(4) through (8) of this section based on the type of service offered by the laboratory.

■ 11. Section 493.913 is revised to read as follows:

§ 493.913 Mycobacteriology.

(a) *Program content and frequency of challenge.* To be approved for proficiency testing for mycobacteriology, the annual program must provide a minimum of five samples per testing event. There must be at least two testing events provided to the laboratory at approximately equal intervals per year. The samples may be provided through mailed shipments. The specific organisms included in the samples may vary from year to year.

(1) The annual program must include, as applicable, samples for:

(i) Acid-fast stain; and

(ii) Detection and identification of mycobacteria which includes one of the following:

(A) Detection of the presence or absence of mycobacteria without identification; or

(B) Identification of mycobacteria.

(2) An approved program must furnish HHS and its agents with a description of the samples it plans to include in its annual program no later than 6 months before each calendar year. At least 25 percent of the samples must be mixtures of the principal mycobacteria and appropriate normal flora. The program must include mycobacteria commonly occurring in patient specimens and other important emerging mycobacteria. The program determines the reportable isolates and correct responses.

(3) The content of an approved program may vary over time, as appropriate. The mycobacteria included annually must contain species representative of the following major groups of medically important mycobacteria, if appropriate for the sample sources:

(i) *Mycobacterium tuberculosis* complex; and

(ii) *Mycobacterium* other than tuberculosis (MOTT).

(4) The program must provide at least five samples per testing event that include challenges that contain acid-fast organisms and challenges that do not contain acid-fast organisms.

(b) *Evaluation of a laboratory's performance.* HHS approves only those programs that assess the accuracy of a laboratory's response in accordance with paragraphs (b)(1) through (6) of this section.

(1) The program determines the reportable mycobacteria to be detected by acid-fast stain. The program determines the mycobacteria to be reported by detection of the presence or absence of mycobacteria without identification, and identification of mycobacteria. To determine the accuracy of each of the laboratory's responses, the program must compare each response with the response that reflects agreement of either 80 percent or more of 10 or more referee laboratories or 80 percent or more of all participating laboratories. Both methods must be attempted before the program can choose to not grade a PT sample.

(2) A laboratory must detect and identify the organisms to the highest level that the laboratory reports results on patient specimens.

(3) A laboratory's performance will be evaluated on the basis of the average of its scores for paragraph (b)(4) through (5) of this section as determined in paragraph (b)(6) of this section.

(4) The performance criterion for acid-fast stains is positive or negative or the presence or absence of acid-fast organisms. The score is the number of correct responses divided by the number of samples to be tested, multiplied by 100.

(5) The performance criterion for the detection and identification of mycobacteria includes one of the following:

(i) The performance criterion for the detection of the presence or absence of mycobacteria without identification is the correct detection of the presence or absence of mycobacteria without identification. The score is the number of correct responses divided by the number of samples to be tested multiplied by 100.

(ii) The performance criterion for the identification of mycobacteria is the total number of correct responses for mycobacterial identification submitted by the laboratory divided by the number of organisms present plus the number of incorrect organisms reported by the laboratory multiplied by 100 to establish a score for each sample in each testing event. Since laboratories may incorrectly report the presence of mycobacteria in addition to the correctly identified principal organism(s), the scoring system must provide a means of deducting credit for additional erroneous organisms reported. For example, if a sample contained one principal organism and the laboratory reported it correctly but reported the presence of an additional organism, which was not considered

reportable, the sample grade would be 1/(1+1) × 100 = 50 percent.

(6) The score for a testing event in mycobacteriology is the average of the scores determined under paragraphs (b)(4) through (5) of this section based on the type of service offered by the laboratory.

■ 12. Section 493.915 is revised to read as follows:

§ 493.915 Mycology.

(a) *Program content and frequency of challenge.* To be approved for proficiency testing for mycology, the annual program must provide a minimum of five samples per testing event. There must be at least three testing events provided to the laboratory at approximately equal intervals per year. The samples may be provided through mailed shipments. The specific organisms included in the samples may vary from year to year.

(1) The annual program must include, as applicable, samples for:

(i) Direct fungal antigen detection; and

(ii) Detection and identification of fungi and aerobic actinomycetes which includes one of the following:

(A) Detection of the presence or absence of fungi and aerobic actinomycetes without identification; or

(B) Identification of fungi and aerobic actinomycetes.

(2) An approved program must furnish HHS and its agents with a description of the samples it plans to include in its annual program no later than 6 months before each calendar year. At least 25 percent of the samples must be mixtures of the principal organism and appropriate normal background flora. The program must include fungi and aerobic actinomycetes commonly occurring in patient specimens and other important emerging fungi. The program determines the reportable isolates and correct responses.

(3) The content of an approved program must vary over time, as appropriate. The fungi included annually must contain species representative of the following major groups of medically important fungi and aerobic actinomycetes, if appropriate for the sample sources:

(i) Yeast or yeast-like organisms;

(ii) Molds that include;

(A) Dematiaceous fungi;

(B) Dermatophytes;

(C) Hyaline hyphomycetes;

(D) Mucormycetes; and

(iii) Aerobic actinomycetes.

(b) *Evaluation of a laboratory's performance.* HHS approves only those programs that assess the accuracy of a laboratory's response, in accordance with paragraphs (b)(1) through (6) of this section.

(1) The program determines the reportable fungi to be reported by direct fungal antigen detection, detection of the presence or absence of fungi and aerobic actinomycetes without identification, and identification of fungi and aerobic actinomycetes. To determine the accuracy of a laboratory's responses, the program must compare each response with the response reflects agreement of either 80 percent or more of 10 or more referee laboratories or 80 percent or more of all participating laboratories. Both methods must be attempted before the program can choose to not grade a PT sample.

(2) A laboratory must detect and identify the organisms to highest level that the laboratory reports results on patient specimens.

(3) A laboratory's performance will be evaluated on the basis of the average of its scores for paragraphs (b)(4) through (5) of this section as determined in paragraph (b)(6) of this section.

(4) The performance criterion for direct fungal antigen detection is the presence or absence of the fungal antigen. The score is the number of correct responses divided by the number of samples to be tested, multiplied by 100.

(5) The performance criterion for the detection and identification of fungi and aerobic actinomycetes includes one of the following:

(i) The performance criterion for the detection of the presence or absence of fungi and aerobic actinomycetes without identification is the correct detection of the presence or absence of fungi and aerobic actinomycetes without identification. The score is the number of correct responses divided by the number of samples to be tested multiplied by 100.

(ii) The performance criterion for the identification of fungi and aerobic actinomycetes is the total number of correct responses for fungal and aerobic actinomycetes identification submitted by the laboratory divided by the number of organisms present plus the number of incorrect organisms reported by the laboratory multiplied by 100 to establish a score for each sample in each testing event. Since laboratories may incorrectly report the presence of fungi and aerobic actinomycetes in addition to the correctly identified principal organism(s), the scoring system must provide a means of deducting credit for additional erroneous organisms that are reported. For example, if a sample contained one principal organism and the laboratory reported it correctly but reported the presence of an additional organism, which was not considered reportable, the sample grade would be 1/(1+1) × 100 = 50 percent.

(6) The score for a testing event is the average of the sample scores as determined under paragraphs (b)(4) through (5) of this section.

■ 13. Section 493.917 is revised to read as follows:

§ 493.917 Parasitology.

(a) *Program content and frequency of challenge.* To be approved for proficiency testing for parasitology, the annual program must provide a minimum of five samples per testing event. There must be at least three testing events provided to the laboratory at approximately equal intervals per year. The samples may be provided through mailed shipments. The specific organisms included in the samples may vary from year to year.

(1) The annual program must include, as applicable, samples for:

(i) Direct parasite antigen detection; and

(ii) Detection and identification of parasites which includes one of the following:

(A) Detection of the presence or absence of parasites without identification; or

(B) Identification of parasites.

(2) An approved program must furnish HHS and its agents with a description of the samples it plans to include in its annual program no later than 6 months before each calendar year. Samples must include both formalinized specimens and PVA (polyvinyl alcohol) fixed specimens as well as blood smears, as appropriate for a particular parasite and stage of the parasite. The majority of samples must contain protozoa or helminths or a combination of parasites. Some samples must be devoid of parasites.

(3) The content of an approved program must vary over time, as appropriate. The types of parasites included annually must be representative of the following major groups of medically important parasites, if appropriate for the sample sources:

(i) Intestinal parasites; and

(ii) Blood and tissue parasites.

(4) The program must provide at least five samples per testing event that include challenges that contain parasites and challenges that are devoid of parasites.

(b) *Evaluation of a laboratory's performance.* HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (b)(1) through (6) of this section.

(1) The program determines the reportable parasites to be detected by direct parasite antigen detection, detection of the presence or absence of parasites without identification, and identification of parasites. It may elect to establish a minimum number of parasites to be identified in samples before they are reported. Parasites found in rare numbers by referee laboratories are not considered in a laboratory's performance; such findings are neutral. To determine the accuracy of a laboratory's response, the program must compare each response with the response which reflects agreement of either 80 percent or more of 10 or more referee laboratories or 80 percent or more of all participating laboratories. Both methods must be attempted before the program can choose to not grade a PT sample.

(2) A laboratory must detect and identify or concentrate and identify the parasites to the highest level that the laboratory reports results on patient specimens.

(3) A laboratory's performance will be evaluated on the basis of the average of its scores for paragraphs (b)(4) through (5) of this section as determined in paragraph (b)(6) of this section.

(4) The performance criterion for direct parasite antigen detection is the presence or absence of the parasite antigen. The score is the number of correct responses divided by the number of samples to be tested, multiplied by 100.

(5) The performance criterion for the detection and identification of parasites includes one of the following:

(i) The performance criterion for the detection of the presence or absence of parasites without identification is the correct detection of the presence or absence of parasites without identification. The score is the number of correct responses divided by the number of samples to be tested, multiplied by 100.

(ii) The performance criterion for the identification of parasites is the total number of correct responses for parasite identification submitted by the laboratory divided by the number of parasites present plus the number of incorrect parasites reported by the laboratory multiplied by 100 to establish a score for each sample in each testing event. Since laboratories may incorrectly report the presence of parasites in addition to the correctly identified principal organism(s), the scoring system must provide a means of deducting credit for additional erroneous organisms that are reported and not found in rare numbers by the program's referencing process. For example, if a sample contained one principal organism and the laboratory reported it correctly but reported the presence of an additional organism, which was not considered reportable, the sample grade would be $1/(1+1) \times 100 = 50$ percent.

(6) The score for a testing event is the average of the sample scores as determined under paragraphs (b)(4) through (5) of this section.

■ 14. Section 493.919 is revised to read as follows:

§ 493.919 Virology.

(a) *Program content and frequency of challenge.* To be approved for proficiency testing for virology, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The samples may be provided to the laboratory through mailed shipments. The specific organisms included in the samples may vary from year to year.

(1) The annual program must include, as applicable, samples for:

(i) Viral antigen detection; and

(ii) Detection and identification of viruses.

(2) An approved program must furnish HHS and its agents with a description of the samples it plans to include in its annual program no later than 6 months before each calendar year. The program must include other important emerging viruses and viruses commonly occurring in patient specimens.

(3) The content of an approved program must vary over time, as appropriate. If appropriate for the sample sources, the types of viruses included annually must be representative of the following major groups of medically important viruses:

(i) Respiratory viruses;

(ii) Herpes viruses;

(iii) Enterovirus; and

(iv) Intestinal viruses.

(b) *Evaluation of laboratory's performance.* HHS approves only those programs that assess the accuracy of a laboratory's response in accordance with paragraphs (b)(1) through (6) of this section.

(1) The program determines the viruses to be reported by direct viral antigen detection, and detection and identification of viruses. To determine the accuracy of a laboratory's response, the program must compare each response with the response which reflects agreement of either 80 percent or more of 10 or more referee laboratories or 80 percent or more of all participating laboratories. Both methods must be attempted before the program can choose to not grade a PT sample.

(2) A laboratory must detect and identify the viruses to the highest level that the laboratory reports results on patient specimens.

(3) A laboratory's performance will be evaluated on the basis of the average of its scores for paragraphs (b)(4) through (5) of this section as determined in paragraph (b)(6) of this section.

(4) The performance criterion viral antigen detection is the presence or absence of the viral antigen. The score is the number of correct responses divided by the number of samples to be tested, multiplied by 100.

(5) The performance criterion for the detection and identification of viruses is the total number of correct responses for viral detection and identification submitted by the laboratory divided by the number of viruses present plus the number of incorrect virus reported by the laboratory multiplied by 100 to establish a score for each sample in each testing event. Since laboratories may incorrectly report the presence of viruses in addition to the correctly identified principal organism(s), the scoring system must provide a means of deducting credit for additional erroneous organisms that are reported. For example, if a sample contained one principal organism and the laboratory reported it correctly but reported the presence of an additional organism, which was not considered reportable, the sample grade would be $1/(1+1) \times 100 = 50$ percent.

(6) The score for a testing event is the average of the sample scores as determined under paragraphs (b)(4) and (5) of this section.

■ 15. Amend § 493.923 by revising paragraphs (a) and (b)(1) to read as follows:

§ 493.923 Syphilis serology.

(a) *Program content and frequency of challenge.* To be approved for proficiency testing for syphilis serology, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The samples may be provided through mailed shipments. An annual program must include samples that cover the full range of reactivity from highly reactive to non-reactive.

(b) * * *

(1) To determine the accuracy of a laboratory's response for qualitative and quantitative syphilis tests, the program must compare the laboratory's response with the response that reflects agreement of either 80 percent or more of 10 or more referee laboratories or 80

percent or more of all participating laboratories. Both methods must be attempted before the program can choose to not grade a PT sample.

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■ 16. Amend § 493.927 by revising paragraphs (a), (b), (c)(1), and (2) to read as follows:

§ 493.927 General immunology.

(a) *Program content and frequency of challenge.* To be approved for proficiency testing for immunology, the annual program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The annual program must provide samples that cover the full range of reactivity from highly reactive to nonreactive. The samples may be provided through mailed shipments.

(b) *Challenges per testing event.* The minimum number of challenges per testing event the program must provide for each analyte or test procedure is five. Analytes or tests for which laboratory performance is to be evaluated include:

TABLE 1 TO PARAGRAPH (b)—ANALYTE OR TEST PROCEDURE

Alpha-I antitrypsin.
Alpha-fetoprotein (tumor marker).
Antinuclear antibody.
Antistreptolysin O (ASO).
Anti-human immunodeficiency virus (HIV).
Complement C3.
Complement C4.
C-reactive protein (high sensitivity).
HBsAg.
Anti-HBc.
HBeAg.
Anti-HBs.
Anti-HCV.
IgA.
IgG.
IgE.
IgM.
Infectious mononucleosis.
Rheumatoid factor.
Rubella.

(c) * * *

(1) To determine the accuracy of a laboratory's response for quantitative and qualitative immunology tests or analytes, the program must compare the laboratory's response for each analyte with the response that reflects agreement of either 80 percent or more of 10 or more referee laboratories or 80 percent or more of all participating laboratories. The proficiency testing program must indicate the minimum concentration that will be considered as indicating a positive response. Both methods must be attempted before the program can choose to not grade a PT sample.

(2) For quantitative immunology analytes or tests, the program must determine the correct response for each analyte by the distance of the response from the target value. After the target value has been established for each response, the appropriateness of the response must be determined by using either fixed criteria or the number of standard deviations (SDs) the response differs from the target value.

TABLE 2 TO PARAGRAPH (c)(2)—CRITERIA FOR ACCEPTABLE PERFORMANCE

The criteria for acceptable performance are— Analyte or test	Criteria for acceptable performance
Alpha-1 antitrypsin	Target value ± 20%.
Alpha-fetoprotein (tumor marker)	Target value ± 20%.
Antinuclear antibody (ANA)	Target value ±2 dilutions or positive or negative.
Antistreptolysin O	Target value ±2 dilutions or positive or negative.
Anti-Human Immunodeficiency virus (HIV)	Reactive (positive) or nonreactive (negative).
Complement C3	Target value ±15%.
Complement C4	Target value ±20% or ±5 mg/dL (greater).
C-reactive protein (HS)	Target value ±30% or ±1 mg/L (greater).
HBsAg	Reactive (positive) or nonreactive (negative).
Anti-HBc	Reactive (positive) or nonreactive (negative).
HBeAg	Reactive (positive) or nonreactive (negative).
Anti-HBs	Reactive (positive) or nonreactive (negative).
Anti-HCV	Reactive (positive) or nonreactive (negative).
IgA	Target value ±20%.
IgE	Target value ±20%.
IgG	Target value ±20%.
IgM	Target value ±20%.
Infectious mononucleosis	Target value ±2 dilutions or positive or negative.
Rheumatoid factor	Target value ±2 dilutions or positive or negative.
Rubella	Target value ±2 dilutions or positive or negative or immune or nonimmune.

* * * * *

■ 17. Amend § 493.931 by revising paragraphs (a), (b), (c)(1) and (2) to read as follows:

§ 493.931 Routine chemistry.

(a) *Program content and frequency of challenge.* To be approved for proficiency testing for routine chemistry, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The annual program must provide samples that cover the clinically relevant range of values that would be expected in patient specimens. The specimens may be provided through mailed shipments.

(b) *Challenges per testing event.* The minimum number of challenges per testing event a program must provide for each analyte or test procedure listed below is five serum, plasma or blood samples.

TABLE 1 TO PARAGRAPH (b)—ANALYTE OR TEST PROCEDURE

Alanine aminotransferase (ALT/SGPT).
Albumin.
Alkaline phosphatase.
Amylase.
Aspartate aminotransferase (AST/SGOT).
Bilirubin, total.
Blood gas (pH, pO2, and pCO2).
B-natriuretic peptide (BNP).
proBNP.
Calcium, total.
Carbon dioxide.
Chloride.
Cholesterol, total.
Cholesterol, high density lipoprotein.
Cholesterol, low density lipoprotein, (direct measurement).
Creatine kinase (CK).
CK–MB isoenzymes.
Creatinine.
Ferritin.
Gamma glutamyl transferase.
Glucose (Excluding measurements on devices cleared by FDA for home use).
Hemoglobin A1c.
Iron, total.
Lactate dehydrogenase (LDH).
Magnesium.
Phosphorus.
Potassium.
Prostate specific antigen (PSA), total.
Sodium.
Total iron binding capacity (TIBC) (direct measurement).
Total Protein.
Triglycerides.
Troponin I.
Troponin T.
Urea Nitrogen.
Uric Acid.

(c) * * *

(1) To determine the accuracy of a laboratory's response for qualitative and quantitative chemistry tests or analytes, the program must compare the laboratory's response for each analyte with the response that reflects agreement of either 80 percent or more of 10 or more referee laboratories or 80 percent or more of all participating laboratories. Both methods must be attempted before the program can choose to not grade a PT sample.

(2) For quantitative chemistry tests or analytes, the program must determine the correct response for each analyte by the distance of the response from the target value. After the target value has been established for each response, the appropriateness of the response must be determined by using either fixed criteria based on the percentage difference from the target value or the number of standard deviations (SD) the response differs from the target value.

TABLE 2 TO PARAGRAPH (c)(2)—CRITERIA FOR ACCEPTABLE PERFORMANCE

The criteria for acceptable performance are— Analyte or test	Criteria for acceptable performance
Alanine aminotransferase (ALT/SGPT)	Target value ±15% or ±6 U/L (greater).
Albumin	Target value ±8%.
Alkaline phosphatase	Target value ±20%.
Amylase	Target value ±20%.
Aspartate aminotransferase (AST/SGOT)	Target value ±15% or ±6 U/L (greater).
Bilirubin, total	Target value ±20% or ±0.4 mg/dL (greater).
Blood gas pCO2	Target value ±8% or ±5 mm Hg (greater).
Blood gas pO2	Target value ±15% or ±15 mmHg (greater).

TABLE 2 TO PARAGRAPH (C)(2)—CRITERIA FOR ACCEPTABLE PERFORMANCE—Continued

The criteria for acceptable performance are— Analyte or test	Criteria for acceptable performance
Blood gas pH	Target value ±0.04.
B-natriuretic peptide (BNP)	Target value ±30%.
Pro B-natriuretic peptide (proBNP)	Target value ±30%.
Calcium, total	Target value ±1.0 mg/dL.
Carbon dioxide	Target value ±20%.
Chloride	Target value ±5%.
Cholesterol, total	Target value ±10%.
Cholesterol, high density lipoprotein (HDL)	Target value ±20% or ±6 mg/dL (greater).
Cholesterol, low density lipoprotein (LDL), direct measurement.	Target value ±20%.
Creatine kinase (CK)	Target value ±20%.
CK–MB isoenzymes	Target value ± 25% or ±3 ng/mL (greater) or MB elevated (presence or absence).
Creatinine	Target value ±10% or ±0.2 mg/dL (greater).
Ferritin	Target value ±20%.
Gamma glutamyl transferase	Target value ±15% or ±5 U/L (greater).
Glucose (excluding measurements devices cleared by FDA for home use.).	Target value ±8% or ±6 mg/dL (greater).
Hemoglobin A1c	Target value ±8%.
Iron, total	Target value ±15%.
Lactate dehydrogenase (LDH)	Target value ±15%.
Magnesium	Target value ±15%.
Phosphorus	Target value ± 10% or ±0.3 mg/dL (greater).
Potassium	Target value ±0.3 mmol/L.
Prostate Specific Antigen, total	Target value ±20% or ±0.2 ng/mL (greater).
Sodium	Target value ±4 mmol/L.
Total Iron Binding Capacity (TIBC). (direct measurement)	Target value ±20%.
Total Protein	Target value ±8%.
Triglycerides	Target value ±15%.
Troponin I	Target value ± 30% or ±0.9 ng/mL (greater).
Troponin T	Target value ±30% or ±0.2 ng/mL (greater).
Urea nitrogen	Target value ±9% or ±2 mg/dL (greater).
Uric acid	Target value ±10%.

* * * * *

■ 18. Amend § 493.933 by revising paragraphs (a), (b), (c)(1), and (2) to read as follows:

§ 493.933 Endocrinology.

(a) *Program content and frequency of challenge.* To be approved for proficiency testing for endocrinology, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The annual program must provide samples that cover the clinically relevant range of values that would be expected in patient specimens. The samples may be provided through mailed shipments.

(b) *Challenges per testing event.* The minimum number of challenges per testing event a program must provide for each analyte or test procedure is five serum, plasma, blood, or urine samples.

TABLE 1 TO PARAGRAPH (b)—ANALYTE OR TEST

Cancer antigen (CA) 125.
Carcinoembryonic antigen (CEA).
Cortisol.
Estradiol.
Folate, serum.
Follicle stimulating hormone.
Free thyroxine.
Human chorionic gonadotropin (HCG) (excluding urine pregnancy tests done by visual color comparison categorized as waived tests).
Luteinizing hormone.
Parathyroid hormone.
Progesterone.
Prolactin.
Testosterone.
T3 Uptake.
Triiodothyronine.
Thyroid-stimulating hormone.
Thyroxine.
Vitamin B12.

(c) * * *

(1) To determine the accuracy of a laboratory's response for qualitative and quantitative endocrinology tests or analytes, a program must compare the laboratory's response for each analyte with the response that reflects agreement of either 80 percent or more of 10 or more referee laboratories or 80

percent or more of all participating laboratories. Both methods must be attempted before the program can choose to not grade a PT sample.

(2) For quantitative endocrinology tests or analytes, the program must determine the correct response for each analyte by the distance of the response from the target value. After the target value has been established for each response, the appropriateness of the response must be determined by using either fixed criteria based on the percentage difference from the target value or the number of standard deviations (SDs) the response differs from the target value.

TABLE 2 TO PARAGRAPH (C)(2)–CRITERIA FOR ACCEPTABLE PERFORMANCE

The criteria for acceptable performance are— Analyte or test	Criteria for acceptable performance
Cancer antigen (CA) 125	Target value ±20%.
Carcinoembryonic antigen (CEA)	Target value ±15% or ±1 ng/dL (greater).
Cortisol	Target value ±20%.
Estradiol	Target value ±30%.
Folate, serum	Target value ±30% or ±1 ng/mL (greater).
Follicle stimulating hormone	Target value ±18% or ±2 IU/L (greater).
Free thyroxine	Target value or ±15% or ±0.3 ng/dL (greater).
Human chorionic	Target value ±18% or ±3
gonadotropin (excluding urine pregnancy tests done by visual color comparison categorized as waived tests).	mIU/mL (greater) or positive or negative.
Luteinizing hormone	Target value ±20%.
Parathyroid hormone	Target value ±30%.
Progesterone	Target value ±25%.
Prolactin	Target value ±20%.
Testosterone	Target value ±30% or ±20 ng/dL (greater).
T3 uptake	Target value ±18%.
Triiodothyronine	Target value ±30%.
Thyroid-stimulating hormone	Target value ±20% or ±0.2 mIU/L (greater).
Thyroxine	Target value ±20% or ±1.0 mcg/dL (greater).
Vitamin B12	Target value ±25% or ±30 pg/mL (greater).

* * * * *

■ 19. Amend § 493.937 by revising paragraphs (a), (b), (c)(1), and (2) to read as follows:

§ 493.937 Toxicology.

(a) *Program content and frequency of challenge.* To be approved for proficiency testing for toxicology, the annual program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The annual program must provide samples that cover the full range of values that could occur in patient specimens and that cover the level of clinical significance for the particular drug. The samples may be provided through mailed shipments.

(b) *Challenges per testing event.* The minimum number of challenges per testing event a program must provide for each analyte or test procedure is five serum, plasma, or blood samples.

TABLE 1 TO PARAGRAPH (b)—ANALYTE OR TEST PROCEDURE

Acetaminophen, serum.
Alcohol (blood).
Blood lead.
Carbamazepine, total.
Digoxin, total.
Gentamicin.
Lithium.
Phenobarbital.
Phenytoin, total.
Salicylate.
Theophylline.
Tobramycin.
Valproic Acid, total.
Vancomycin.

(c) * * *

(1) To determine the accuracy of a laboratory's responses for quantitative toxicology tests or analytes, the program must compare the laboratory's response for each analyte with the response that reflects agreement of either 80 percent or more of 10 or more referee laboratories or 80 percent or more of all participating laboratories. Both methods must be attempted before the program can choose to not grade a PT sample.

(2) For quantitative toxicology tests or analytes, the program must determine the correct response for each analyte by the distance of the response from the target value. After the target value has been established for each response, the appropriateness of the response must be determined by using fixed criteria based on the percentage difference from the target value.

TABLE 2 TO PARAGRAPH (c)(2)—CRITERIA FOR ACCEPTABLE PERFORMANCE

The criteria for acceptable performance are— Analyte or test	Criteria for acceptable performance
Acetaminophen	Target value ±15% or ±3 mcg/mL (greater).
Alcohol, blood	Target Value ±20%.
Blood lead	Target Value ±10% or ±2 mcg/dL (greater).
Carbamazepine, total	Target Value ±20% or ±1.0 mcg/mL (greater).
Digoxin, total	Target Value ±15% or ± 0.2 ng/mL (greater).
Gentamicin	Target Value ±25%.
Lithium	Target Value ±15% or ±0.3 mmol/L (greater).
Phenobarbital	Target Value ±15% or ±2 mcg/mL (greater).
Phenytoin total	Target Value ±15% or ± 2 mcg/mL (greater).
Salicylate	Target Value ±15% or ±2 mcg/mL (greater).
Theophylline	Target Value ±20%.
Tobramycin	Target Value ±20%.
Valproic Acid, total	Target Value ±20%.
Vancomycin	Target Value ±15% or ±2 mcg/mL (greater).

* * * * *

■ 20. Amend § 493.941 by revising paragraphs (a), (b), (c)(1) and (2) to read as follows:

§ 493.941 Hematology (including routine hematology and coagulation).

(a) *Program content and frequency of challenge.* To be approved for proficiency testing for hematology, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The annual program must provide samples that cover the full range of values that would be expected in patient specimens. The samples may be provided through mailed shipments.

(b) *Challenges per testing event.* The minimum number of challenges per testing event a program must provide for each analyte or test procedure is five.

TABLE 1 TO PARAGRAPH (b)—ANALYTE OR TEST PROCEDURE

Cell identification.
White blood cell differential.
Erythrocyte count.
Hematocrit (excluding spun microhematocrit).
Hemoglobin.
Leukocyte count.
Platelet count.
Fibrinogen.
Partial thromboplastin time.
Prothrombin time (seconds or INR).

(c) * * *

(1) To determine the accuracy of a laboratory's responses for qualitative and quantitative hematology tests or analytes, the program must compare the laboratory's response for each analyte with the response that reflects agreement of either 80 percent or more of 10 or more referee laboratories or 80 percent or more of all participating laboratories. Both methods must be attempted before the program can choose to not grade a PT sample.

(2) For quantitative hematology tests or analytes, the program must determine the correct response for each analyte by the distance of the response from the target value. After the target value has been established for each response, the appropriateness of the response is determined using either fixed criteria based on the percentage difference from the target value or the number of standard deviations (SD) the response differs from the target value.

TABLE 2 TO PARAGRAPH (c)(2)—CRITERIA FOR ACCEPTABLE PERFORMANCE

The criteria for acceptable performance are: Analyte or test	Criteria for acceptable performance
Cell identification	80% or greater consensus on identification.
White blood cell differential	Target ±3SD based on the percentage of different types of white blood cells in the samples.
Erythrocyte count	Target ±4%.
Hematocrit (Excluding spun hematocrit)	Target ±4%.
Hemoglobin	Target ±4%.
Leukocyte count	Target ±10%.
Platelet count	Target ±25%.
Fibrinogen	Target ±20%.
Partial thromboplastin time	Target ±15%.

If a laboratory reports a prothrombin time in both INR and seconds, the INR should be reported to the PT provider program.

TABLE 2 TO PARAGRAPH (c)(2)—CRITERIA FOR ACCEPTABLE PERFORMANCE—Continued

The criteria for acceptable performance are: Analyte or test	Criteria for acceptable performance
Prothrombin time (seconds or INR)	Target ±15%.

* * * * *

■ 21. Amend § 493.959 by revising paragraphs (b), (d)(1) and (2) to read as follows:

§ 493.959 Immunohematology.

* * * * *

(b) *Program content and frequency of challenge.* To be approved for proficiency testing for immunohematology, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The annual program must provide samples that cover the full range of interpretation that would be expected in patient specimens. The samples may be provided through mailed shipments.

(d) * * *

(1) To determine the accuracy of a laboratory's response, a program must compare the laboratory's response for each analyte with the response that reflects agreement of either 100 percent of 10 or more referee laboratories or 95 percent or more of all participating laboratories except for antibody identification. To determine the accuracy of a laboratory's response for antibody identification, a program must compare the laboratory's response for each analyte with the response that reflects agreement of either 95 percent or more of 10 or more referee laboratories or 95 percent or more of all participating laboratories. Both methods must be attempted before the program can choose to not grade a PT sample.

(2) *Criteria for acceptable performance.* The criteria for acceptable performance are—

TABLE 2 TO PARAGRAPH (d)(2)—CRITERIA FOR ACCEPTABLE PERFORMANCE

Analyte or test	Criteria for acceptable performance
ABO group	100% accuracy.
D (Rho) typing	100% accuracy.
Unexpected antibody detection	100% accuracy.
Compatibility testing	100% accuracy.
Antibody identification	80%+ accuracy.

* * * * *

Dated: June 24, 2022.

Xavier Becerra,

Secretary, Department of Health and Human Services.

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